

### Specificație Tehnică Completată

**Model: Logiq Fortis HDU PN: H43302LA; Producător: GE Healthcare/ GE Ultrasound Korea in comun cu GE Medical Systems; Țara: Korea și Franța.**

Specificarea tehnică deplină solicitată, Standarde de referință	Specificarea tehnică deplină propusă, Standarde de referință
Anul de producere 2022 Aplicații clinice General, Ginecologic, Cardiologice, Vascular.	Anul de producere <b>2023</b> Aplicații clinice General, Ginecologic, Cardiologice, Vascular. <b>DA pagina 1-2 din LOGIQ Fortis R3.x HDU product specification sheet /Applications</b>
Porturi active pentru traductori Minim 4	Porturi active pentru traductori Minim 4 porturi active + 1 port-inactiv DA pagina 1 din LOGIQ Fortis R3.x HDU product specification sheet/ Console Design
Porturi pentru traductori CW Minim 1 opțiune disponibilă	Porturi pentru traductori CW Minim 1 opțiune disponibilă <b>DA este prezent pentru sondele specializate tip pencil/ creion( nimită de specialiști locali) tip doar CW sau Dopplerul orb pagina 142/3-44 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b>
Nivele de gri $\geq 256$	Nivele de gri - 256 <b>pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet /Scanning Parameters</b>
Gama dinamică maximă $\geq 350\text{dB}$	Gama dinamică maximă $\geq 350\text{dB}$ <b>DA Tehnologie mai avansată de tip infinită - pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet /Scanning Parameter/ Continuous dynamic receive aperture; Adjustable dynamic range, infinite upper level</b>
Preprocesare, Canale digitale $\geq 12$ mil sau tehnologie mai avansată	Preprocesare, Canale digitale tehnologie mai avansată <b>DA pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet Scanning Parameters &gt; cSound™ Imageformer: Infinite number of effective channels</b>
Adâncime de scanare maximă $\geq 50$ cm	Adâncime de scanare maximă <b>DA 1 - 100 cm pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet Scanning Parameters</b>
Traductoare acceptate de sistem: liniare matriciale,	Traductoare acceptate de sistem: liniare matriciale, <b>DA In acest sens atasez Logiq Fortis Probe Guide pagina 2 L2-9-D XDClear, ML6-15-D comunicare cu tehnologia XDClear este in Standart nu necesita o activare separata prin procurarea unui modul sau obtiuni de soft.</b>
convexe matriciale,	convexe matriciale, <b>DA In acest sens atasez Logiq Fortis Probe Guide pagina 2 C1-6-D, C2-9-D comunicare cu tehnologia XDClear este in Standart nu necesita o activare separata prin procurarea unui modul sau obtiuni de soft.</b>
sectoriale matriciale,	sectoriale matriciale, <b>DA In acest sens atasez Logiq Fortis Probe Guide pagina 3 M5Sc-D comunicare cu tehnologia XDClear este in Standart nu necesita o activare separata prin procurarea unui modul sau obtiuni de soft.</b>
volumetrică 4D,	volumetrică 4D, <b>DA In acest sens atasez Logiq Fortis Probe Guide pagina 3 RAB6-D.</b>
CW pencil,	CW pencil, <b>DA In acest sens atasez Logiq Fortis Probe Guide pagina 3 P2D si P6D.</b>


## Anexa 1

<p>Endocavitare 4D.</p> <p>Număr frecvențe emise de un traductor <math>\geq 8</math> a se indica transductorul care are aceste posibilități</p> <p><b>Postprocesare</b></p> <p>Imagine moduri</p> <p>B-mod/ 2D</p> <p>M-mod</p> <p>M-mod și 2-D</p> <p>Armonici Tisulare</p> <p>Armonici Tisulare diferențiale</p> <p>M-mod anatomic</p> <p>M-Mod color</p> <p>Doppler: Tip CW, PW, CFM, TVI;</p> <p>Măsurări automatizate</p>	<p>Endocavitare 4D. <b>DA</b> In acest sens atasez Logiq Fortis Probe Guide pagina 3 RIC5-9-D.</p> <p>Număr frecvențe emise de un traductor <math>\geq 8</math> a se indica transductorul care are aceste posibilități <b>DA</b> 6S-D, BE9CS-D, C1-6-D XDclear, C2-9-D XDclear, IC5-9-D, L2-9-D XDclear, L3-12-D, M5Sc-D XDclear, ML6-15-D, RIC5-9D, pagina 16-19 din LOGIQ Fortis R3.x HDU product specification sheet /Scanning Parameter</p> <p><b>Postprocesare</b></p> <p>Imagine moduri</p> <p>B-mod/ 2D <b>DA</b> pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet /Operating Modes</p> <p>M-mod <b>DA</b> din LOGIQ Fortis R3.x HDU product specification sheet /Operating Modes</p> <p>M-mod și 2-D <b>DA</b> pagina 4 din LOGIQ Fortis R3.x HDU product specification sheet /Simultaneous capability</p> <p>Armonici Tisulare <b>DA</b> pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet / Coded harmonic imaging</p> <p>Armonici Tisulare diferențiale <b>DA</b> pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet / Coded harmonic imaging - este același lucru ca Armonice Tisulare un beneficiu mare este prezenta regimului SRI și SRI HD care este activ împreună cu CHI dintr-o imagine de rezoluție superioară. <b>DA</b> pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet SRI și Advance SRI</p> <p>M-mod anatomic <b>DA</b> pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet /Operating Modes/ Anatomical M-Mode</p> <p>M-Mod color <b>DA</b> este același ca și în M-Mod în prima fază iar în Faza 2 este în comun lucru TVI ( Dopplerului Tisular) care până la urmă rezultă la aceși măsurători de Time, Distance, Depth, Heart rate, Slope; Rezultatele acestor combinate de măsurători în final dau Fracția de Ejecție. Pagina 11 din LOGIQ Fortis R3.x HDU product specification sheet</p> <p>Doppler: Tip CW, PW, CFM, TVI; <b>DA</b> CEW, PW, CFM pagina 2 din LOGIQ Fortis R3.x HDU product specification sheet</p> <p><b>TVI</b> pagina 3 LOGIQ Fortis R3.x HDU product specification sheet</p> <p>Măsurări automatizate <b>DA</b> pagina 3 din LOGIQ Fortis R3.x HDU product specification sheet Auto IMT- măsurarea automată a grosimii vasului, Pagina 7 LOGIQ Fortis R3.x HDU product specification sheet</p> <p><b>Auto Ejection Fraction</b> este în regim 2 automat detectează dimensiunea cavității care se scanează cu formarea imaginii în cine loop în regim sistolic și diastolic și după se calculează automat Fracția de Ejecție. Este un model care cuprinde și măsurarea automată și calculul automat</p>
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Anexa 1

<p>Calcul automate</p> <p>Power Doppler</p> <p>B - Flow sau analogic</p> <p>(disponibil minim pe sonda liniara si covexa)</p> <p>Duplex</p> <p>Triplex</p> <p>Elastografie Compresiva cu Analiza de tip Q-analiz</p> <p>(compatibila obligatoriu minim cu sonda liniară, convexă si endocavitară)</p> <p>Elastografie shear wave</p> <p>(compatibila obligatoriu minima cu sonada liniara, convexă și endocavitară)</p> <p>UGAP / masurarea atenuari ficatului in db/cm/MHz</p> <p>(compatibila obligatoriu minima cu sonada liniara și convexa)</p> <p>Formarea raportului automat pentru măsurările care vor fi făcute de către medic, cu printarea la un printer extern;</p>	<p>Calcul automate <b>DA pagina 14 din LOGIQ Fortis R3.x HDU product specification sheet / <i>real-time Doppler Auto Measurements / Calculations</i></b></p> <p>Power Doppler <b>DA pagina 8 din LOGIQ Fortis R3.x HDU product specification sheet / <i>Digital Power Doppler Imaging</i> - cu descriere completa</b></p> <p>B - Flow <b>DA pagina 3 din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p>(disponibil minim pe sonda liniara si covexa) <b>DA pagina 9 din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p><b>C1-6-D, C1-6VN-D, C2-7-D, C2-7VN-D, C2-9-D, C2-9VN-D, C3-10-D, L2-9-D, L2-9VN-D, L3-12-D, L6-24-DML6-15-D, M5Sc-D, L8-18i-D</b></p> <p>Duplex <b>DA pagina 4 din LOGIQ Fortis R3.x HDU product specification sheet/ <i>Simultaneous capability</i></b> <b>Ex: B/M mode; B-Flow/PW; B/PW etc.</b></p> <p>Triplex <b>DA pagina 5 din LOGIQ Fortis R3.x HDU product specification sheet/ <i>Simultaneous capability</i></b> <b>Ex: B or CrossXBeam + CFM or PDI/PWetc.</b></p> <p>Elastografie Compresiva cu Analiza de tip Q-analiz <b>DA pagina 1021 / 13-113 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 <i>Strain Elastography</i></b> <b>Pagina 1030 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 <i>Elastography Analysis Display Description</i></b></p> <p>(compatibila obligatoriu minim cu sonda liniară, convexă si endocavitară) <b>ML6-15-D, L2-9-D, L2-9VN-D, L3-12-D, IC5-9-D, C2-9-D, C2-9VN-D, C1-6-D, C1-6VN-D, L8-18i-D, BE9CS-D</b></p> <p><b>Pagina 11 din LOGIQ Fortis R3.x HDU product specification sheet/ <i>Strain elastography</i></b></p> <p>Elastografie shear wave (compatibila obligatoriu minima cu sonada liniara, convexă și endocavitară) <b>C1-6-D, C1-6VN-D, L2-9-D, L2-9VN-D, IC5-9-D, L8-18i-D, ML6-15-D, L3-12-D</b></p> <p><b>DA Pagina 11 din LOGIQ Fortis R3.x HDU product specification sheet/ <i>Shear Wave Elastography</i></b></p> <p>UGAP / masurarea atenuari ficatului in db/cm/MHz (compatibila obligatoriu minima cu sonada liniara și convexa) <b>DA Pagina 10 din LOGIQ Fortis Data Sheet/ UGAP Sondele convexe C1-6-D, C1-6VN-D, C2-9D, C2-9VN-D, si liniara cu revizia dea cest vva fi posibil pe sonda L2-9-D pe protocolul de abdomne Ficat. Cu o foaie dde prezentare a stadrteleor separta.</b></p> <p>Formarea raportului automat pentru măsurările care vor fi făcute de către medic, cu printarea la un printer extern; <b>DA pagina 3 din LOGIQ Fortis R3.x HDU product specification sheet / <i>On-board reporting - Editing a Report</i></b> <b>DA pagina 1317/13-409 si 1320/13-415 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 <i>Report Writer</i></b></p>
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## Anexa 1

Possibilitate printare rapoarte	Possibilitate printare rapoarte <b>DA</b> pagina 1317/13-409 si <b>1320/13-412</b> din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 <i>Report Writer</i>
Funcționalități: Ajustare frecventa	Funcționalități: Ajustare frecventa <b>DA</b> pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet <i>Ex: Digital B-Mode Adjustable /Frequency</i>
Diapazon dinamic reglabil sau tehnologie mai avansarta	Diapazon dinamic reglabil sau tehnologie mai avansarta <b>DA</b> pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet <i>Adjustable dynamic range, infinite upper level</i>
Focalizare pe imagine pe toată adincimea	Focalizare pe imagine pe toată adincimea <b>DA</b> pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet <i>Continuous dynamic receive focus</i>
Ajustare mape de culori ≥ 9	Ajustare mape de culori ≥ 9 <b>DA</b> Ref pagina 248/5-32 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 <b>Ca confirmarea a celor indicate in manualul de utilizare vezi imaginea de mai jos:</b>
	
Selectare automata a sondei la aplicarea presetului	Selectare automata a sondei la aplicarea presetului <b>DA</b> se seteaza in dependeta de necesitatile utilizatorului
Reglare GAIN	Reglare GAIN <b>DA</b> pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet <i>Ex: Digital B-Mode Adjustable /Gain</i>
Reglarea semnalului acustic	Reglarea semnalului acustic <b>DA</b> pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet <i>Ex: Digital B-Mode Adjustable /Acoustic power</i>
Măsurători în timp real și în freeze	Măsurători în timp real și în freeze <b>DA</b> pagina 6 din LOGIQ Fortis R3.x HDU product specification sheet <i>Measurements/calculations and annotations on CINE playback</i>

## Anexa 1

Regim Virtual Convex pentru raductoarele liniare	<b>DA pagina 6 din LOGIQ Fortis R3.x HDU product specification sheet /Measurements/Calculations</b> Regim Virtual Convex pentru raductoarele liniare <b>DA</b>
PAN/ZOOM imagine în timp real	<b>Pagina 12 din LOGIQ Fortis R3.x HDU product specification sheet / Available on all linear and sector probes</b> PAN/ZOOM imagine în timp real <b>DA pagina 12 din LOGIQ Fortis R3.x HDU product specification sheet/ Controls available on “freeze” or recall / Pan zoom</b>
Imagine înghețată	Imagine înghețată <b>DA Freeze pagina 148 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b>
Stocare imagini	Stocare imagini
Capacitate ≥ 1000 GB/ 1TB tip SSD;	Capacitate ≥ 1000 GB/ 1TB tip SSD; <b>DA pagina 1din LOGIQ Fortis R3.x HDU product specification sheet</b>
Memorie CINE ≥ 950MB;	Memorie CINE 1000 MB/1GB; <b>DA pagina 6 din LOGIQ Fortis R3.x HDU product specification sheet / CINE Memory</b>
CD/DVD	CD/DVD <b>DA pagina 6 din LOGIQ Fortis R3.x HDU product specification sheet /Image Storage</b>
USB 3.0, 2.0	USB 3.0, 2.0 <b>DA USB 3.0 pagina 19 din LOGIQ Fortis R3.x HDU product specification sheet/ External Inputs and outputs(not including on-board peripherals)</b> <b>Nota</b> standartul USB 3.0 cuprinde in sine si compatibilitatea cu tehnologia USB 2.0. <a href="https://www.usbmemorydirect.com/blog/usb-2-0-vs-3-0/">https://www.usbmemorydirect.com/blog/usb-2-0-vs-3-0/</a>
Pachete de analiză	Pachete de analiză
Vascular include minim:	Vascular include minim:
- Regimuri specializate de detectat microvascularizări	- Regimuri specializate de detectat microvascularizări <b>DA MVI cu RadiantFlow Ref. pagina 35 din LOGIQ Fortis™ Demo Disc Guide</b>
- B-Flow sau analogic	- B-Flow <b>DA pagina 3 din LOGIQ Fortis R3.x HDU product specification sheet</b>
- Intima Medie	- Intima Medie <b>DA Auto IMT Ref. pagina 3 din LOGIQ Fortis R3.x HDU product specification sheet</b>
Cardiac include minim:	Cardiac include minim:
- Include monitorul/modul ECG integrat cu cablu pentru pacuie tn	- Include monitorul/modul ECG integrat cu cablu pentru pacuie tn <b>DA Physiological input panel pagina 7 din LOGIQ Fortis R3.x HDU product specification sheet</b>
- Calculul Fractiei de Ejectei in regim automat ( Auto EF)	- Calculul Fractiei de Ejectei in regim automat ( Auto EF) <b>DA Auto EF pagina. 11 din LOGIQ Fortis R3.x HDU product specification sheet</b>
- Stress Eco	- Stress Eco <b>DA Stress echo pagina 11 din LOGIQ Fortis R3.x HDU product specification sheet</b>
- Strain Cardiac	- Strain Cardiac <b>DA Cardiac AFI/ 2D Strain... pagina 11 din LOGIQ Fortis R3.x HDU product specification sheet</b>
Abdomen	Abdomen <b>DA este prezent in protocolul Abdominal</b>
Abdomen obez	Abdomen obez <b>DA este prezent cu inscriptia Abdomen 2 este prezent in protocolul Abdominal</b>
Tiroida	Tiroida <b>DA este prezent in protocolul Small Parts</b>
Glanda mamară	Glanda mamară <b>DA este prezent in protocolul Breast</b>
Protocoale de lucru și calculi pentru vase	Protocoale de lucru și calculi pentru vase

## Anexa 1

<p>Carotida</p> <p>Vertebrale</p> <p>Arterial: Membre inferioare si superioare stâng/drept,</p> <p>Venos:</p> <p>Membre inferioare si superioare stâng/drept;</p> <p>Regim Automat de setare in regim B</p> <p>Regim Automat de setare a vitezei si a unghiului ferestrei in regim Doppler.</p> <p>DICOM 3.0</p> <p>APLICATII (OPTIONALE): DA</p> <p>Fuzionarea imaginii obținute cu imaginile CT, RMN și angiografice; DA – A se prezenta dovezi ca are posibilitatea de ubgradare;</p> <p>Posibilitatea de transmitere datelor la sisteme de post procesare; DA–A se prezenta dovezi că are posibilitatea de ubgradare.</p> <p>Soft specializat pentru lucru cu substanța de contrast optional; DA – a se prezenta dovezi ca are posibilitatea de ubgradare.</p> <p>Traductoare de tip:</p> <p>1) Liniar, cu valoare minimă nu mai mare de 2 Mhz, cu valoare maximă nu mai mică de 10 Mhz, cu FOV (field of View) câmpul de vedere minim 40 mm si maxim 60 mm Obligatoriu sa fie prezenta tehnologia single cristal/ XDclear/ Matrix sau analogic conform patentului care îl are producătorul.</p> <p>2) convex cu valoare minimă nu mai mare de 1 Mhz și valoare maximă nu mai mică de 5 Mhz, cu FOV (fild of View) câmpul de vedere minim 70° și maxim 90°// Obligatoriu să fie prezenta tehnologia single cristal/ XDclear/ Matrix conform patentului care îl are producătorul.</p> <p>3) Sectoriala, cardiac convex cu valoare minimă nu mai mare de 1 Mhz și valoare maximă nu mai mică de 5 Mhz, cu FOV (field of View)câmpul de vedere minim 110° si maxim 130°//</p>	<p>Carotida <b>DA este prezent in protocolul Peripheral Vascular</b></p> <p>Vertebrale <b>DA este prezent in protocolul Peripheral Vascular</b></p> <p>Arterial: Membre inferioare si superioare stâng/drept, <b>DA este prezent in protocolul Peripheral Vascular</b></p> <p>Venos:</p> <p>Membre inferioare si superioare stâng/drept; <b>DA este prezent in protocolul Peripheral Vascular</b></p> <p>Regim Automat de setare in regim B <b>DA Automatic Optimization pagina 9 din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p>Regim Automat de setare a vitezei si a unghiului ferestrei in regim Doppler. <b>pagina 9 Automatic Optimization din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p>DICOM 3.0 <b>DA</b></p> <p>APLICATII (OPTIONALE): <b>DA</b></p> <p>Fuzionarea imaginii obținute cu imaginile CT, RMN și angiografice; DA – A se prezenta dovezi ca are posibilitatea de ubgradare; <b>DA pagina 1171/13-263 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3 Optiunea Volume navigation pagina 10 din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p>Posibilitatea de transmitere datelor la sisteme de post procesare; DA–A se prezenta dovezi că are posibilitatea de ubgradare. <b>DA pagina 6 din LOGIQ Fortis R3.x HDU product specification sheet /Nu necesita Ubgradare este inclus in standart</b></p> <p><b>Pagina 1374/13-466 pina 1376/13-468 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b></p> <p>Soft specializat pentru lucru cu substanța de contrast optional; DA – a se prezenta dovezi ca are posibilitatea de ubgradare. <b>DA pagina 9 din LOGIQ Fortis R3.x HDU product specification sheet /Coded contrast imaging</b></p> <p>Traductoare de tip:</p> <p>1) Liniar, <b>L2-9-D XDclear</b> cu valoare minimă de <b>2 Mhz</b>, cu valoare maximă de <b>10 Mhz</b>, cu FOV (field of View) câmpul de vedere <b>44 mm</b>.</p> <p>Obligatoriu sa fie prezenta tehnologia single cristal/ <b>XDclear/ Matrix</b> sau analogic conform patentului care îl are producătorul. <b>Pagina 2 din Logiq Fortis Probe Guide</b></p> <p>2) Convex, <b>C1-6-D XDclear</b> cu valoare minimă de 1 Mhz și valoare maximă de <b>6 Mhz</b>, cu FOV (fild of View) câmpul de vedere <b>80°</b></p> <p>Obligatoriu să fie prezenta tehnologia single cristal/ <b>XDclear/ Matrix</b> conform patentului care îl are producătorul. <b>Pagina 2 din Logiq Fortis Probe Guide</b></p> <p>3) Sectoriala, cardiac convex <b>M5Sc-D</b> cu valoare minimă de 1 Mhz și valoare maximă de 5 Mhz, cu FOV (field of View)câmpul de vedere <b>120°//</b></p>
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## Anexa 1

<p>Obligatoriu să fie prezenta tehnologia single cristal/ XDclear/ Matrix conform patentului care îl are producătorul</p> <p>4) Microconvex, Endocavitar cu valoare minimă nu mai mare de 3 Mhz și valoare maximă nu mai mică de 9 Mhz, cu FOV (field of View)câmpul de vedere minim 135° si maxim 150°//</p> <p>Ultrasonograful livrat să fie setat pentru lucru cu traductoarele livrate; MONITOR FULL HD" ≥ 23"</p> <p>Panel de control touch ≥ 12";</p> <p>Butoane consola configurabile</p> <p>Tastatura digitala ;</p> <p>Braț flexibil DA</p> <p>Transfer și stocare date în format DICOM ; Posibilitatea efectuării Upgrade ; Accesorii: B/W imprimantă încorporată sau discretă</p>	<p>Obligatoriu să fie prezenta tehnologia single cristal/ XDclear/ Matrix conform patentului care îl are producătorul <b>Pagina 3 din Logiq Fortis Probe Guide</b></p> <p>4) Microconvex, Endocavitar <b>IC5-9-D</b> cu valoare minimă de <b>3 Mhz</b> și valoare maximă de <b>10 Mhz</b>, cu FOV (field of View)câmpul de vedere 180°// cuprinde valoarea de 150° ca standarta, 180° este valoarea <b>care se foloseste in conditi mai rare in caz ca este necesara in diagnosticul in o singura sectie pentru diagnosticul la pacienti complicati.</b></p> <p>Ultrasonograful livrat să fie setat pentru lucru cu traductoarele livrate; <b>MONITOR FULL HD" - 23,8"DA pagina 1 din LOGIQ Fortis R3.x HDU product specification sheet/ Resolution: 1920 X 1080</b></p> <p>Panel de control touch - <b>12,1"; DA pagina 1 din LOGIQ Fortis R3.x HDU product specification sheet</b></p> <p>Butoane consola configurabile <b>DA pagina 922/13-14 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b></p> <p>Tastatura digitala ; <b>DA pagina 151/3-53 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b></p> <p>Braț flexibil <b>DA pagina 161/3-63 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b></p> <p>Transfer și stocare date în format DICOM ; <b>DA</b> Posibilitatea efectuării Upgrade ; <b>DA</b> Accesorii: B/W imprimantă încorporată sau discretă <b>DA încorporat inclus pagina 897/12-67 din LOGIQ Fortis – Basic User Manual 5855997-1EN Rev. 3</b></p>
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# cSound Architecture

Ultrasound for today, platform for tomorrow

The breadth of clinical scenarios in general imaging ultrasound places significant demands on the ultrasound device. A patient who cannot hold her breath while a renal Doppler is performed. A patient whose tendon tear requires sub millimeter resolution. An obese patient needing a liver biopsy. A brain scan of a neonate in an incubator. A liver fibrosis assessment that depends on detecting a shear wave signal thinner than a human hair. In today's demanding clinical environment, the ultrasound machine is a partner in helping the clinician meet every challenge.

GE Healthcare has designed its advanced cSound™ Architecture to put the latest ultrasound technology in the hands of clinicians. It combines the power of XDclear™ probes with a new cSound Imageformer to enable confident diagnoses, provide comprehensive tools, and support concise workflow.

## cSound Imageformer

The cSound Imageformer is the data acquisition and processing engine of the new architecture. At its core are cutting-edge NVIDIA® GPUs, the same graphics processing technology that is advancing the driverless car industry and the next generation of video gaming. This technology gives GE ultrasound engineers access to 48 times the data throughput and 10 times the processing power of our previous systems.\* This opens up new opportunities, allowing the cSound Imageformer to collect and use more data to create every ultrasound image.





## Traditional Beamforming

To understand cSound Imageforming, it helps to review how traditional beamforming works. As shown in Figure 1, traditional beamforming is performed in customized hardware and only the resulting beam or vector data is provided to the flexible, software-based processor that creates the ultrasound images.

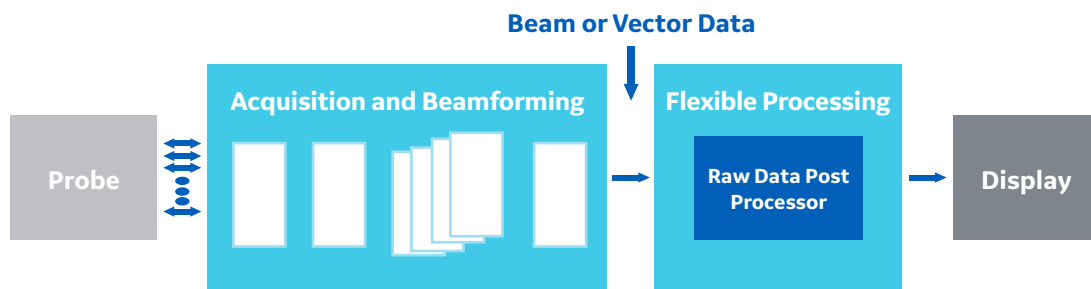
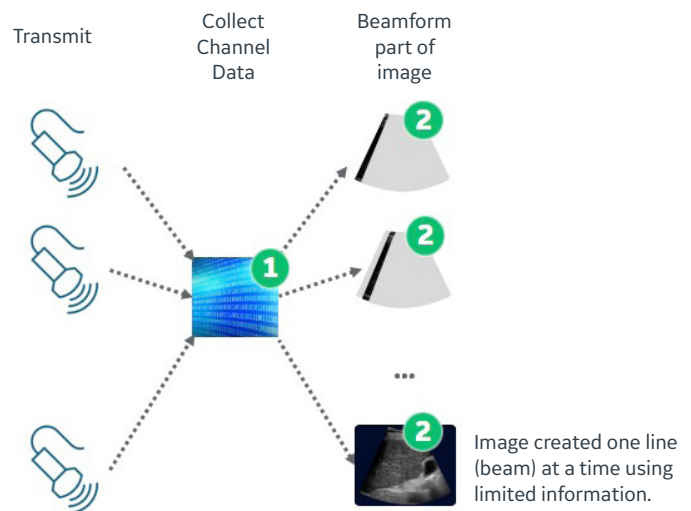


Figure 1. A traditional beamforming architecture.

## Traditional Beamforming Steps

1. A transmit event is performed. The return ultrasound data is dynamically received and collected in a single instance of channel memory.
2. The collected channel data is processed to create a particular portion of the image often referred to as one or more vectors or beams.  
*Note: If multiple focal depths are desired, steps 1 and 2 are also repeated with a transmit event focused at a different depth.*
3. Steps 1-2 are repeated for another portion of the image until the entire image has been created.

## Traditional Beamformer



The channel data processed in step 2 and then overwritten still has useful information. However, a traditional beamformer has no means to extract this additional value before the channel data associated with the next transmit event overwrites it.

## cSound Imageforming – Methodology

As shown in Figure 2, cSound Imageforming is performed using flexible, GPU-based processing. In contrast to traditional beamforming, the cSound Architecture moves raw channel data at high speeds from the acquisition system to components that perform flexible, software-based processing, including the cSound Imageformer. This channel data can be retained in memory even as channel data from subsequent transmit events is acquired and transferred to the cSound Imageformer.

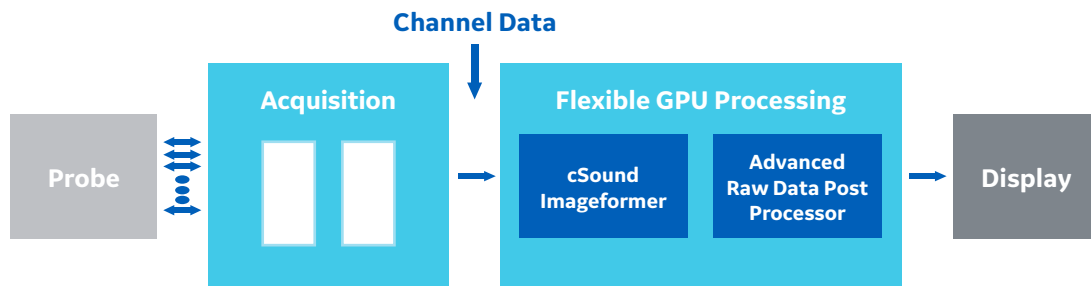
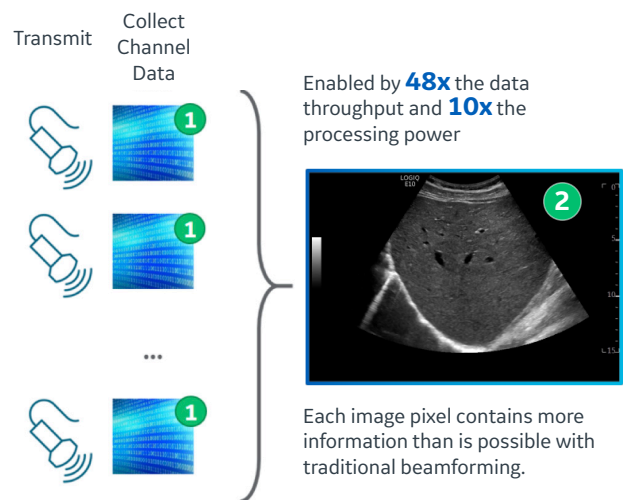


Figure 2. cSound Architecture.

### cSound Imageforming Phases

1. Acquisition – A series of transmit events are performed with the return ultrasound data being dynamically received and transferred to memory.
2. Reconstruction – The channel data from all of the transmits is combined to form the image.

### New cSound Imageformer



Similar to CT and MRI, cSound Imageforming has a distinct acquisition phase followed by a reconstruction phase. This requires the cSound Architecture to acquire, move and store large amounts of channel data and, once collected, the cSound Imageformer must be able to process the data at high speeds to enable real-time image reconstruction. The image formation process leverages channel data that would have been discarded in traditional beamforming. This additional data provides numerous samples for every point in the image. The image formation process combines these samples to achieve transmit focus for each point in the image, enhance contrast resolution and deliver fine spatial resolution.

## cSound Imageformer – Retrospective Transmit Focus

In traditional beamforming, each transmit event has a transmit focus that is created by adjusting the time delays of individual transducer elements. This generates a curved wave front that converges until reaching a particular depth (the focus depth) and then diverges as it continues to propagate beyond the focus depth. The focus is the location that is insonified from multiple directions.

For each transmit event, the cSound Imageformer collects and saves the receive ultrasound data for each element. This is referred to as channel data. *Even when a new transmit event occurs, the channel data associated with previous transmit events is retained and not overwritten.*

Individual transmit events are spatially and/or angularly offset from one another creating significant overlap. As a result, for any point in the image, there are multiple transmit events that have insonified the point, each from a different direction. Knowing the spatial locations of a particular point in the image relative to a given transmit event, the cSound Imageformer can retrospectively process the channel data of each intersecting transmit event, and then coherently

combine the results to achieve retrospective transmit focus at that point. It is worth noting that noise associated with each transmit beam is independent and therefore sums incoherently while the signal itself sums coherently. This increases the signal-to-noise ratio, further improving contrast resolution throughout the image.

This approach to focusing at each point in an image is possible for all types of transmit events providing there is overlap.

- **Converging waves** – Sound from multiple elements converges at a finite depth relative to the transducer face
- **Plane waves** – Sound from multiple elements is unfocused or essentially focused at an infinite depth
- **Diverging waves** – Sound from multiple elements diverges as if the focus was behind the transducer face

The cSound Imageformer is capable of all types of transmit events, giving engineers the flexibility to optimize the system uniquely depending on the needs of each clinical application.

## cSound Imageformer – Retrospective Transmit Focus, an Example

For illustrative purposes consider a simplified scenario, as shown in Figure 3.

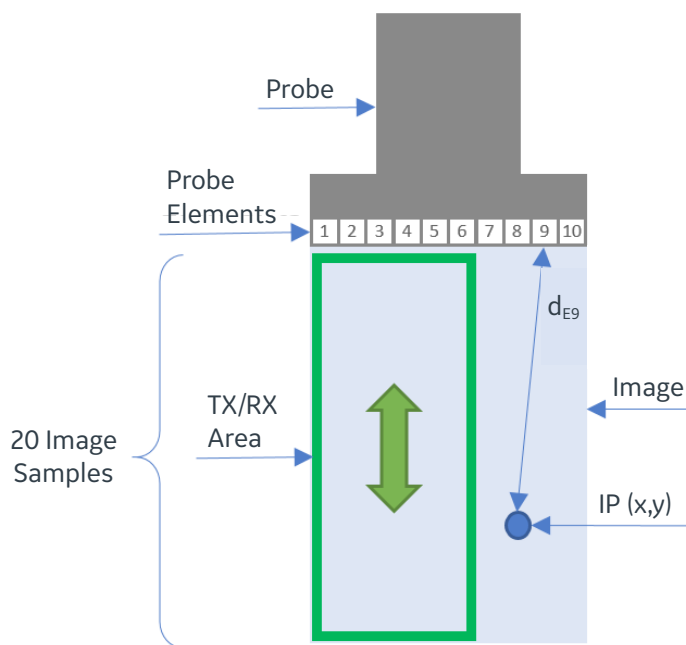


Figure 3. A simplified imaging scenario for illustrating retrospective transmit focus.

- Linear transducer with just 10 elements (E1 – E10)
- Each transmit event uses just six elements for transmitting and receiving. In this case, the first transmit event uses elements 1 through 6 (1-6) and then subsequent transmit events shift by a single element to use elements 2-7, 3-8, 4-9, and 5-10 for a total of 5 transmit events to create the image
- All transmit events are unfocused
- The receive signal is sampled so that 20 samples cover the depth of the image
- Each point in the image can be represented by IP (x,y) where x is the lateral direction and is restricted to the width of the image (which equals the width of the probe) and y is the axial direction and is restricted to the depth of the image
- The distance between IP (x,y) and a particular probe element is defined as  $d_{EN}$  where N is the element number 1-10

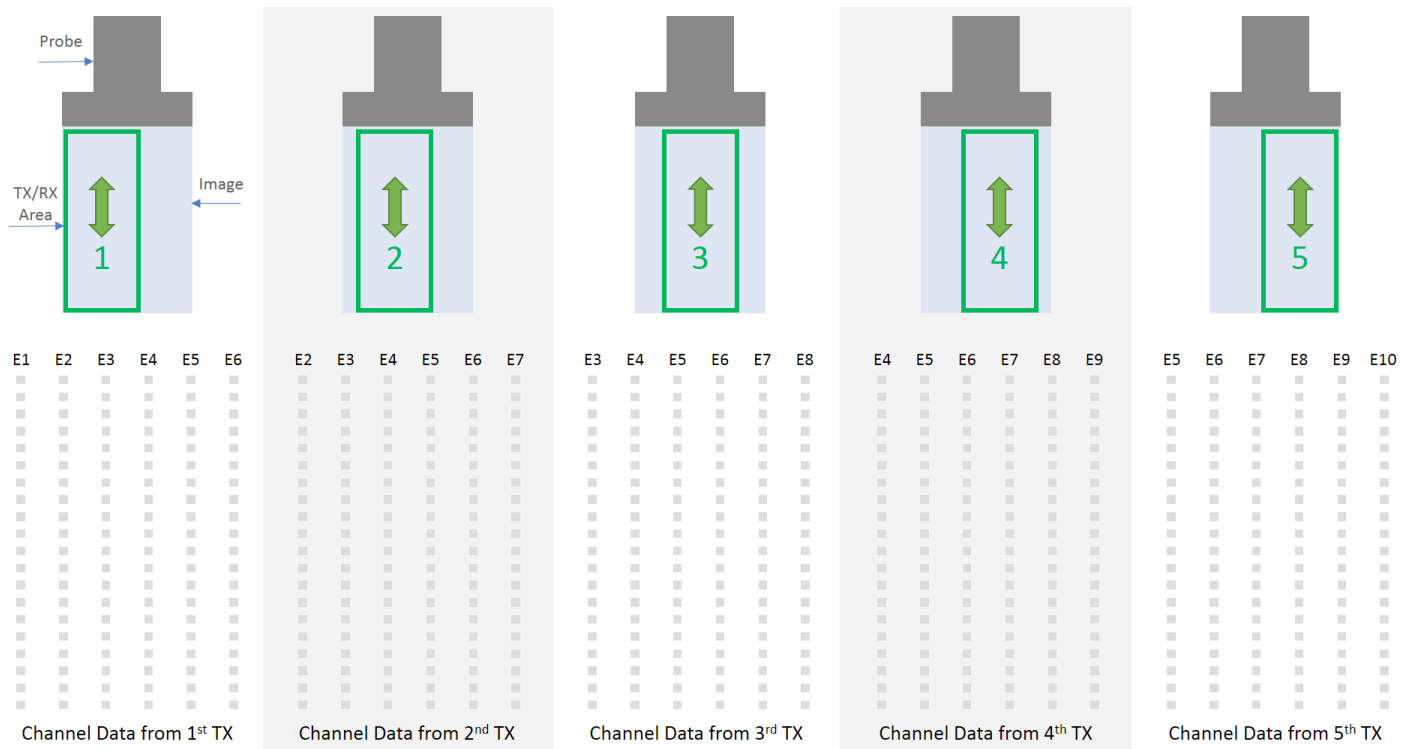


Figure 4. The first transmit (1) occurs and channel data is collected and stored. This is repeated for subsequent transmits (2 through 5) which are each offset from the previous.

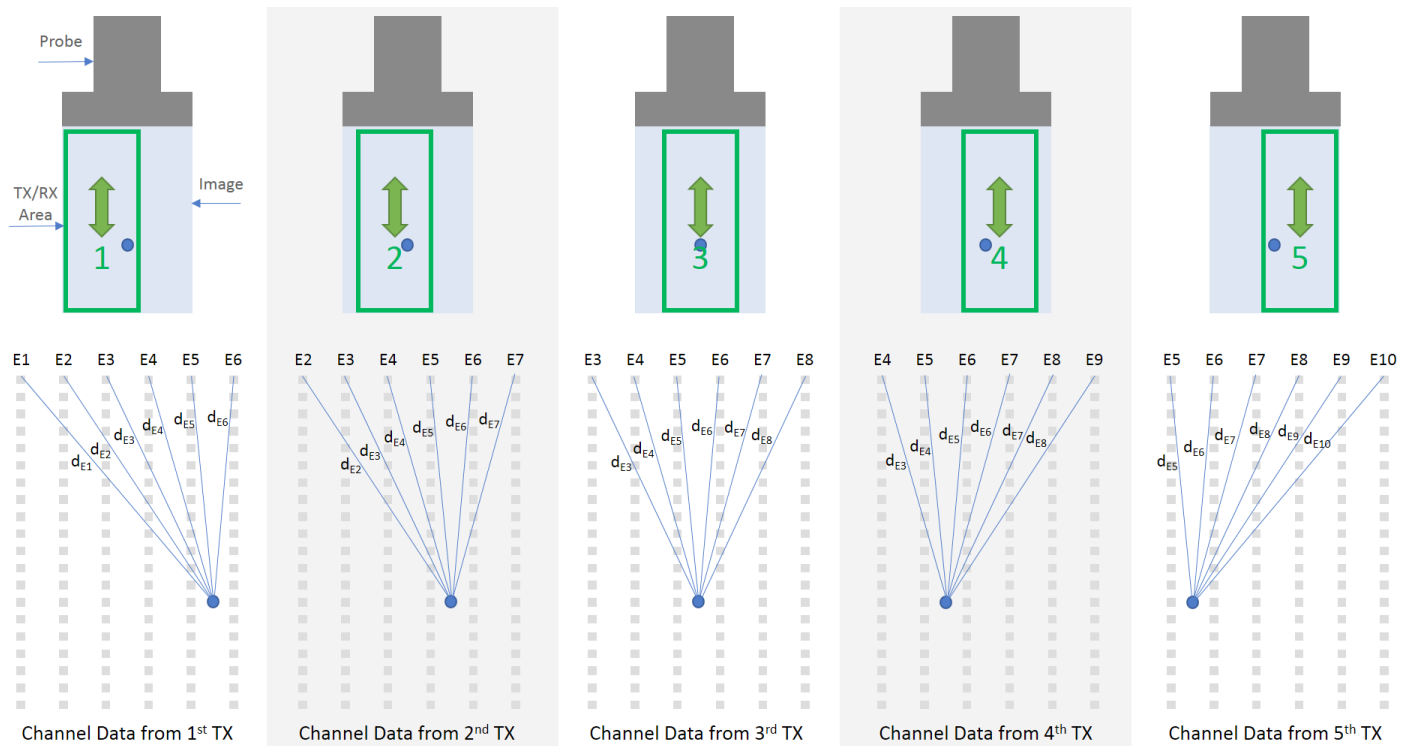


Figure 5. For each set of relevant channel data, the distance between the deep image point (represented by the circle) and each probe element is computed.

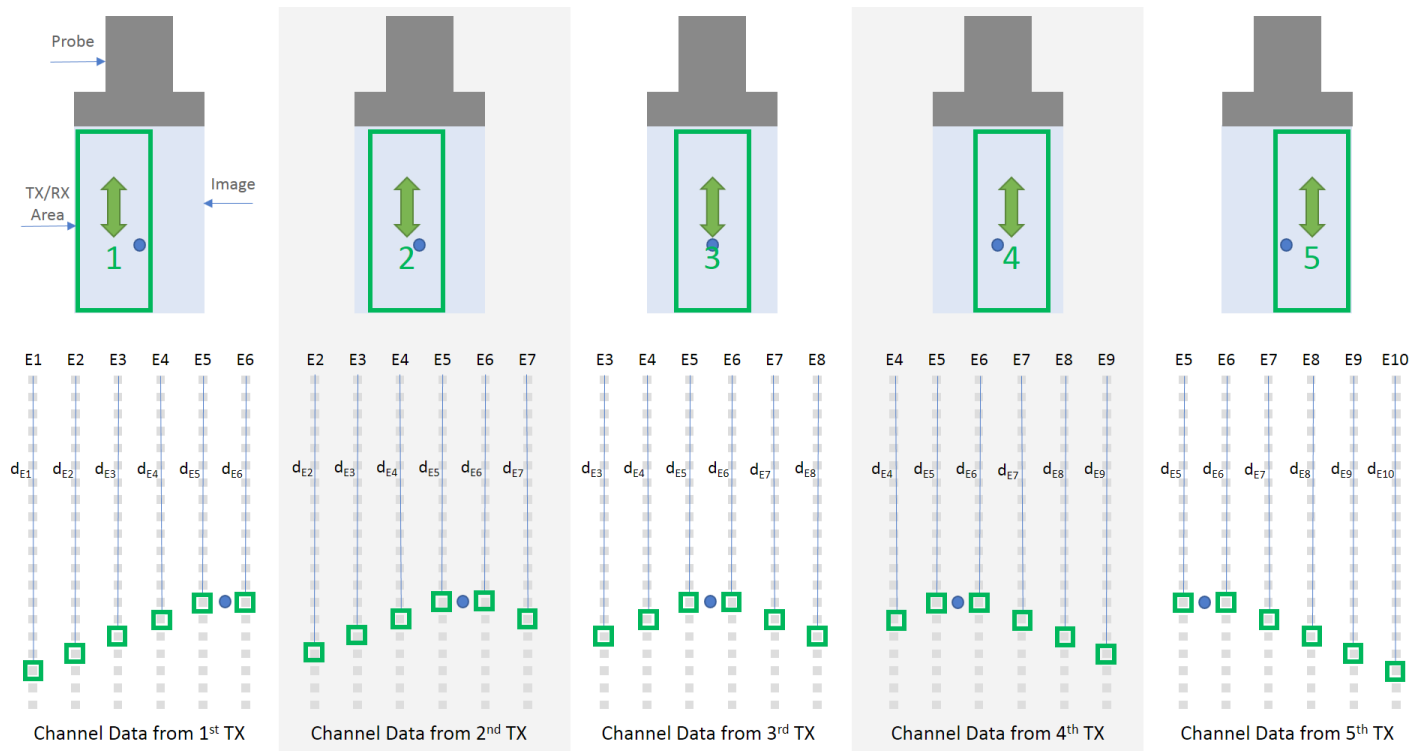


Figure 6. The computed distances between the image point and each element are used to access the channel data that focuses on the image point. The selected channel data from each transmit is coherently summed to determine the signal associated with the image point.

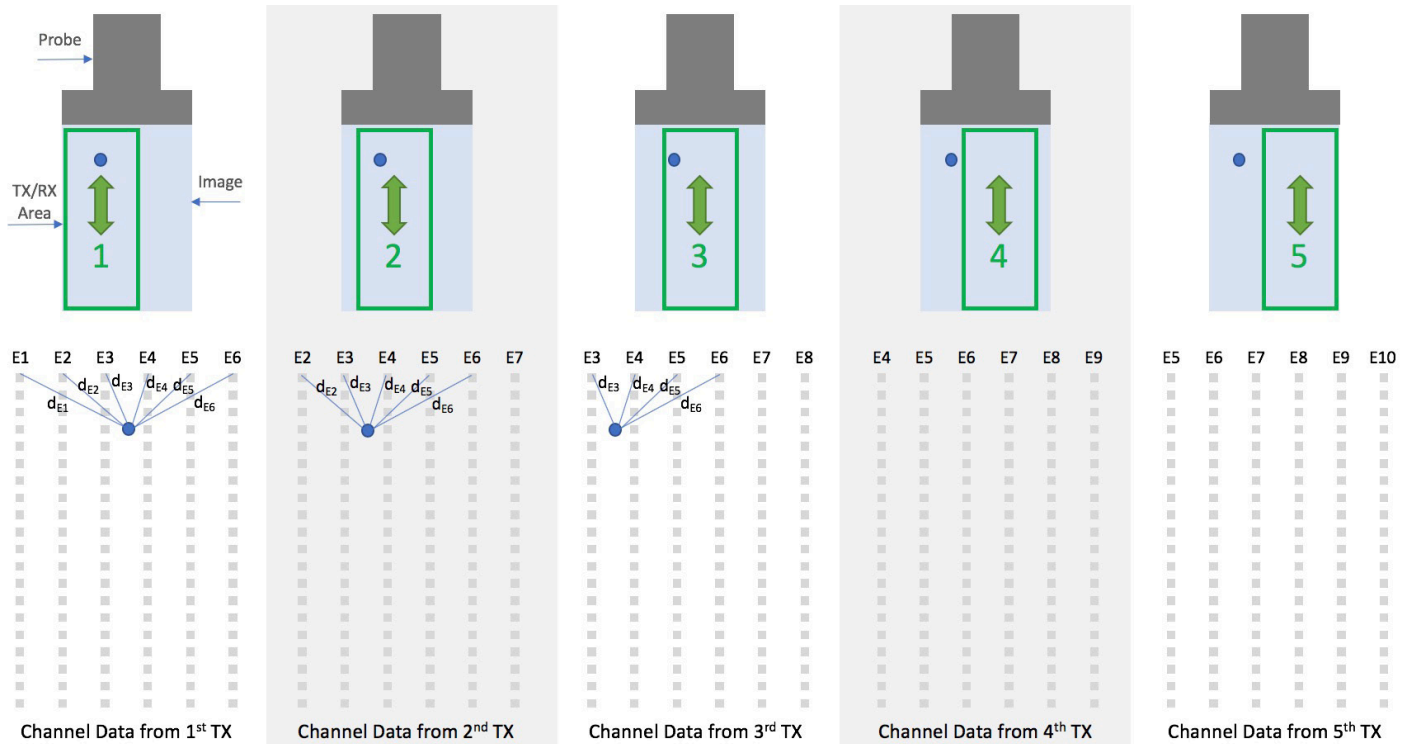


Figure 7. For each set of relevant channel data, the distance between the shallow image point (represented by the circle) and each probe element is computed. Note that transmits 4 and 5 do not overlap with the image point. Further note that some elements, such as E7 and E8 on transmit 3, are not included because of their steep angle relative to the image point.

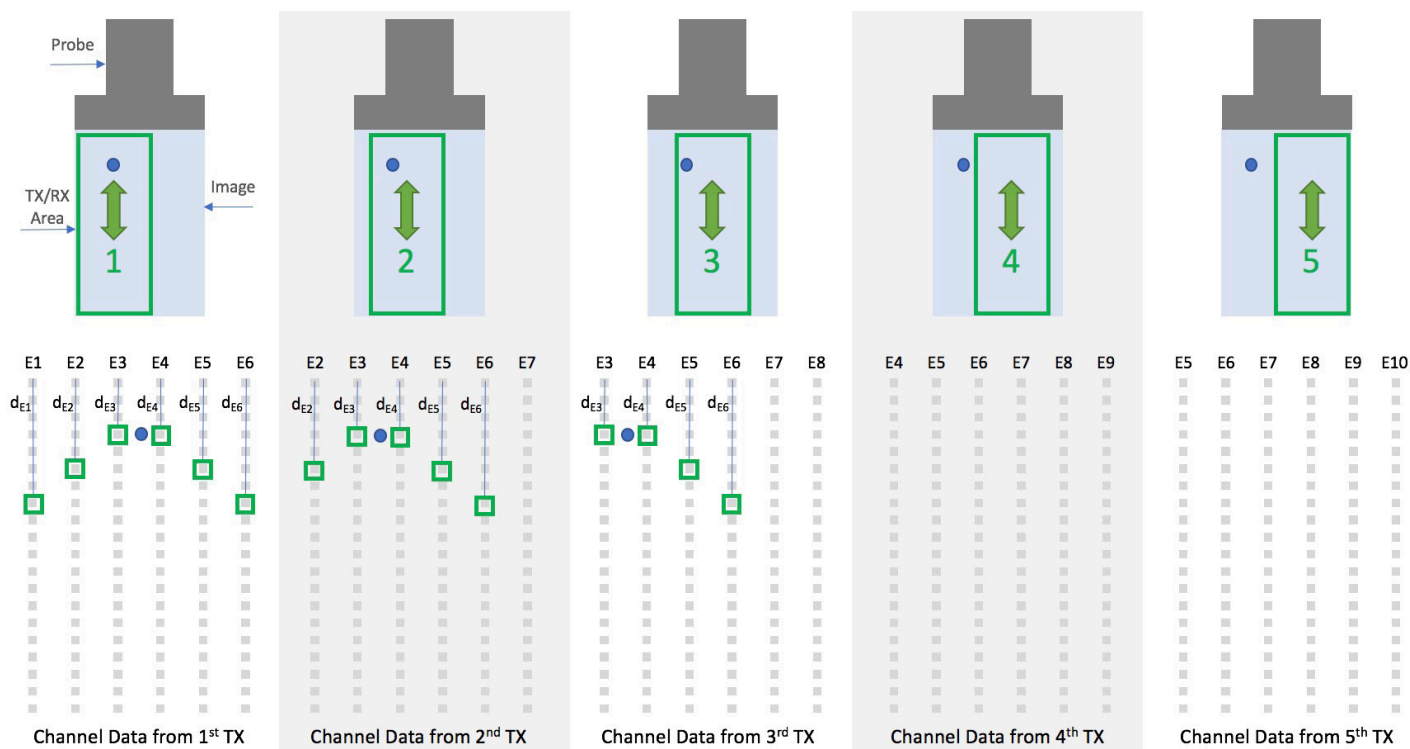


Figure 8. The computed distances between the image point and each element are used to access the channel data that focuses on the image point. The selected channel data from each transmit is coherently summed to determine the signal associated with the image point.

When extending this simplified scenario to the cSound Imageformer, there are additional complexities to consider. For example, the geometry of the transducer and the delay profile of the transmit event impact the computation of the image point to probe element distance and therefore the offset needed to reference the correct channel data. In another difference, the received elements are often larger than the number of transmit elements. Most notably, the sheer volume of data puts extensive demands on the system:

- The large quantity of collected channel data must be reliably and quickly streamed to the channel data memory before additional channel data is collected from the next transmit
- A massive amount of channel memory is required to store the channel data collected from many transmit events
- The retrospective processing of each relevant set of channel data for each point in the image requires intensive, ultra-high-speed, parallel computations to be performed to achieve real-time imaging at very high frame and volume rates

In a less powerful system, the real-time nature of imageforming could be achieved by restricting the amount of data collected by each transmit; speed would come at the expense of image quality. The cSound Architecture, in contrast, is able to keep up without restricting the data, even in radiology's most challenging applications. To put the cSound Architecture's performance in context, it can move the equivalent of multiple DVDs worth of data in one second.

## cSound Imageformer – Benefits

Imagine an ultrasound department where no image is acquired with the focal zone in the wrong position. With each point in the image in focus, the user doesn't need to select multiple focal zones or to move the focus position. Additionally, there are no trade-offs between near- and far-field image quality. Deep liver imaging provides detailed data from the capsule to the diaphragm. When biopsying a deep lesion, there is no compromise to needle visualization as it enters the image area. When surveying breast tissue, a clinician is able to see small lesions present from the skin line to the chest wall – all without the user having to make any adjustments.

While greater focal range in ultrasound has traditionally meant lower frame rates, cSound Imageforming actually increases frame rates. It requires a smaller collection of transmit events, a direct result of efficiently using the data collected from each individual transmit event. To understand this efficiency, consider that an ultrasound transmit event can be focused, but the sound energy still travels in many directions; it acts like a flashlight rather than a laser.

Though a flashlight generates maximum light energy in the center of its beam, there is still useful visual information in the light outside of the central beam. Similarly, there is much useful ultrasound image data in the sound that propagates outside the focused direction and the cSound Imageformer is designed to take full advantage of this data.

## cSound Imageformer – A Platform for Growth

cSound Imageforming runs on high performance NVIDIA GPUs, but the imageforming algorithms are software based. This affords significant flexibility; the algorithms can be adjusted for specific applications and evolve over time without impacting the underlying hardware architecture. In addition to forming the image, current algorithms can incorporate Adaptive Contrast Enhancement (ACE) and other GE proprietary techniques to boost the real image signal and suppress artifact. And with advances in GPU technology, there is potential to incorporate newer GPUs into the platform, enabling even more sophisticated algorithms.

## Advanced Raw Data Post Processor

The improved images resulting from the cSound Imageformer flow into the Advanced Raw Data Post Processor where additional enhancement is performed by spatial compounding, frame averaging, advanced speckle reduction imaging (Advanced SRI), and other functions. The post-processed image data is then mapped to gray scale levels and the scan is converted for display to the operator.

While speckle reduction imaging has been a feature of ultrasound systems for many years, Advanced SRI is GE's most sophisticated algorithm to date, and requires the expanded computational power of the cSound architecture to achieve real-time results. It employs proprietary processing steps at different resolutions of the raw image data to smooth speckle-based artifacts while simultaneously enhancing structures of all sizes within the image. The level of smoothing and enhancement is adjustable by the user.

The "Raw Data" aspect of the Advanced Raw Data Post Processor refers to the fact that image data is saved prior to the processing steps. This allows the user to continue to adjust the processing long after the images have been saved.

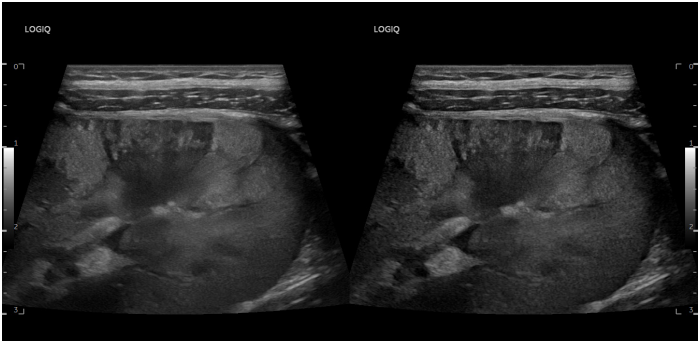
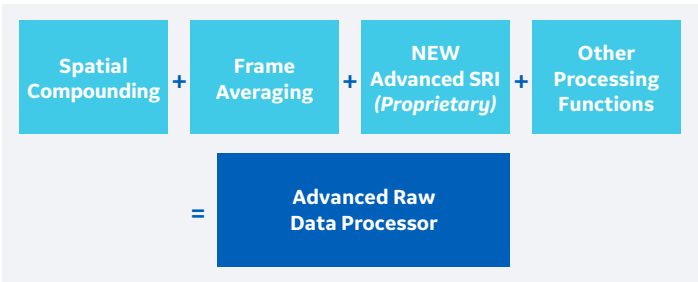


Figure 9. Advanced SRI (right) takes advantage of the increased computational power of the cSound Architecture to identify and enhance structures of all sizes while reducing speckle-based artifacts.





# XDclear Probes

While cSound Imageforming provides numerous benefits over traditional beamforming, the quality of the acoustic data coming into the system is still of utmost importance. In combination with the cSound Architecture’s state-of-the-art transmit and receive electronics, XDclear transducers help deliver a more powerful, pure, and efficient sound wave with wider bandwidth than traditional GE transducer technology. This results in impressive deep penetration and high resolution, enabling ultrasound to be used effectively on a broad range of patients.



Figure 10. XDclear probes: Derive their superior performance from three key technologies: Single Crystal, Cool Stack, and Acoustic Amplifier.

XDclear transducers are a proprietary combination of advanced materials and innovative design. The XDclear design incorporates an enhanced piezoelectric material, Single Crystal, to generate a high quality acoustic signal. The quality of that signal is preserved through an innovative Acoustic Amplifier design coupled with GE’s Cool Stack technology to help optimize energy management. The ability to effectively and efficiently combine these technologies is what makes XDclear extraordinary.

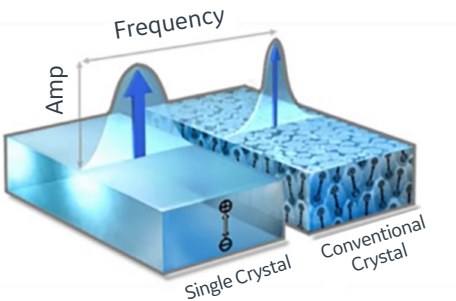


Figure 11. *Single Crystal*: Advanced piezoelectric material that delivers high quality acoustic signal with a wider bandwidth than conventional piezoelectric material.

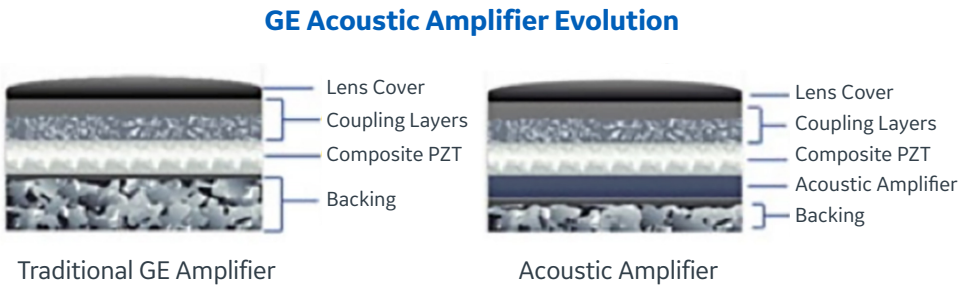


Figure 12. *Acoustic Amplifier*: Preserves the acoustic signal through an innovative design that captures and redirects the unused energy that passes through the crystal to enhance sensitivity, axial resolution, and penetration.



XDclear transducers enable deep penetration and resolution. One objective measure of transducer performance is bandwidth: the range of frequencies that the transducer can transmit and receive. Increased bandwidth allows a transducer to cover a broader frequency range, which makes it possible to achieve deep penetration and high resolution, as well as enhanced performance in harmonic imaging.

With sufficient bandwidth, one transducer can cover the range of acoustic frequencies that previously required separate transducers. XDclear transducers with Single Crystal materials have measurably enhanced bandwidth, achieving a -6 dB fractional bandwidth that can exceed 100 percent compared with 70 to 80 percent for traditional GE transducers. The result is a new level of penetration, resolution, and sensitivity in GE transducer performance.

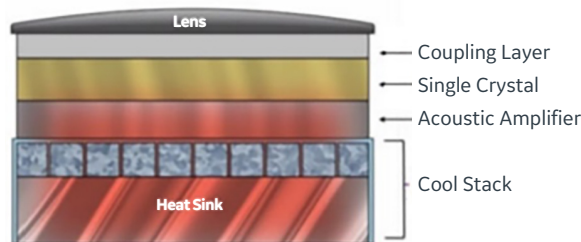


Figure 13. *Cool Stack*: Optimizes energy usage via patented technology integrated into the transducer's internal architecture; it relieves inherent heat generation that can otherwise reduce sensitivity and penetration.

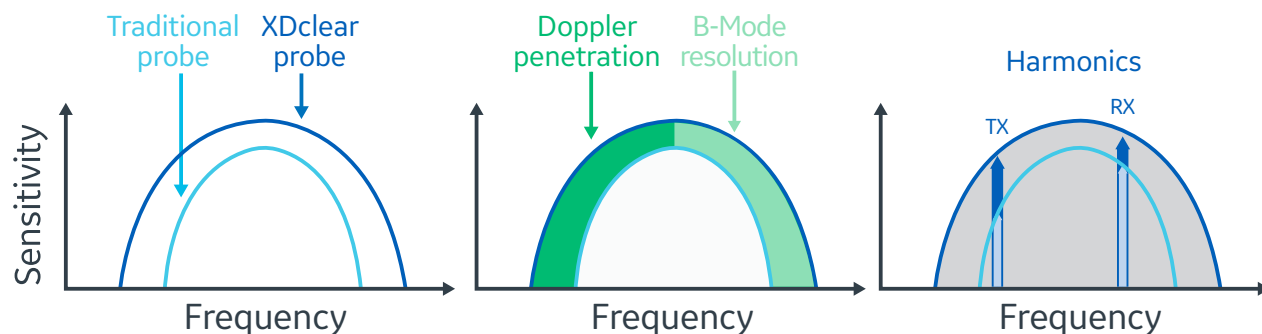


Figure 14. XDclear probe performance benefits are derived from improved sensitivity and wider bandwidth.

## cSound Architecture Summary

The cSound Architecture leverages next-generation data rates and processing power that were previously unavailable, allowing significantly more data to be collected and used to create every image. This additional data is used to achieve focus at every point and to increase contrast and spatial resolution—all while significantly improving frame rates. Combined with the performance advantages of XDclear probes and the Advanced Raw Data Post Processor, these advancements make the cSound Architecture an excellent imaging system for today and its flexible design makes it a powerful imaging platform for tomorrow.



\*As compared to the LOGIQ™ E9.

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March 2022  
JB19417XX





## EC DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745

Following the directive 2011/65/EU, directive 2014/53/EU

We

Manufacturer and manufacturing site	EU Authorized Representative
<b>GE Ultrasound Korea, Ltd.</b> 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si Gyeonggi-do 13204, Republic of Korea SRN: KR-MF-000001860	<b>GE Medical Systems SCS</b> 283 rue de la Minière 78530 BUC, France SRN: FR-AR-000000344

Declare under our sole responsibility that the device:

### LOGIQ Fortis

Basic UDI-DI: **8406821BUG00214GZ**

Identification number:

REF Catalog	H-Catalog Number	UDI-DI
<b>LOGIQ Fortis HDU</b>	<b>H43302LA</b>	<b>00195278405326</b>
<b>LOGIQ Fortis LCD</b>	<b>H43302LB</b>	<b>00195278405333</b>

Intended Purpose: The LOGIQ Fortis is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

EMDN Code: **Z110401**

EMDN Description: Ultrasound Scanners

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

UMDNS Code: **15-976**

Classification: **Ila**

Classification rule (Annex VIII): **Rule 10, Class: Ila**

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and the directive 2014/53/EU on the radio equipment (RED).



This conformity is based on the following elements:

- Technical Documentation reference: DOC2379389, of the product to which this declaration relates.
- EC certificate No. HZ 2004702-01:
  - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
  - Delivered by TUV Rheinland LGA Products GmbH (Notified Body n° 0197)

This EC declaration of conformity is the initial release.

SIGNATURE:

Date of issue: 13-12-2021  
Place of issue: China  
Name: Qingmeng Chen  
Function: Regulatory Affairs Program Manager  
Signature:

*Qingmeng Chen*



**ADDENDUM TO THE EC DECLARATION OF CONFORMITY**  
**LOGIQ Fortis including accessories and components**  
**dated 13-12-2021**

Product Description	H-Catalog Number <sup>1</sup>
<b>Ultrasound Console</b>	
LOGIQ Fortis HDU Console	H43302LA / 6602000
LOGIQ Fortis LCD Console	H43302LB / 6601000
<b>Probe Options<sup>2</sup></b>	
IC5-9-D	H40442LK
ML6-15-D	H40452LG
L8-18i-D	H40452LL
C2-9-D (XDClear)	H40462LN
C1-6-D (XDClear)	H40472LT
C1-6VN-D (XDClear)	H40472LW
C2-9VN-D (XDClear)	H40472LY
C3-10-D (XDClear)	H40482LB
M5Sc-D (XDClear)	H44901AE
L2-9-D	H44901AI
L2-9VN-D	H44901AJ
6Tc-RS	H45551ZE
C2-7-D	H46422LM
C2-7VN-D	H46422LN
P2D	H4830JE
RIC5-9-D	H48651MS
RAB6-D	H48681MG
P6D	H4830JG
BE9CS-D	H40482LE
L3-12-D	H48062AA
6S-D	H45021RR
L6-24-D Probe	H4920HF
<b>TEE Probe Accessories<sup>2</sup></b>	
TEE RS-DLP Adapter	H46352LK
Adult TEE Clip-on Bite Guard	H45511EE
Adult TEE Clip-on Bite Guard Opr.	H45521CB
Adult TEE Scanhead Protection Cover	H45521CK
Adult TEE Conventional Bite Guard	H45521JH
BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
<b>Software Options</b>	
Advanced Security	H46622LL
Coded Contrast	H43332LA
Parametric Imaging	H43332LB
Cardiac AFI	H46622LN
LOGIQ Exx DVR	H4918DR
Report Writer	H46622LR
Stress Echo	H46622LS
Tricefy	H46622LT
LOGIQ Apps	H46622LW
KOIOS SW	H46622LY
LOGIQ Exx KOIOS Thyroid	H4920KT
LOGIQ E10 KOIOS INSTALL	H4919KI



Product Description	H-Catalog Number <sup>1</sup>
KOIOS 3.x INSTALL	H4921KY
Scan Assistant	H46622LZ
Advanced Probes	H46612LS
AUTO IMT	H46612LT
B Steer+	H46612LW
B-FLOW	H46612LY
Compare Assistant	H46612LZ
DICOM	H46622LA
FLOW QA	H46622LB
Measure Assist Breast	H46622LC
Measure Assist OB	H46622LD
Elastography	H43332LC
Elasto QA	H43332LD
Shear Wave Elastgraphy	H46622LE
LOGIQ Exx SRI HD Type2	H4920SR
UGAP	H46622LH
SonoNT SonoIT	H46622LJ
LOGIQ Exx VNAV Image	H4920VR
Hepatic Assistant - SWE-UGAP	H43332LE
Omni View	H43332LF
STIC	H43332LG
TUI	H43332LH
VCI-Static	H43332LJ
VOCAL_II	H43332LK
Thyroid Productivity	H43332LL
Breast Productivity	H43332LM
Vita on Demand	H43332LN
<b>Hardware Options<sup>2</sup></b>	
CW Doppler	H43342LA
Realtime 4D	H43342LB
ECG Option	H43342LC
Scan on battery option kit	H43342LD
Power Assistant	H43342LE
Volume Navigation	H43342LF
Volume Navigation for V-Nav Inside T1	H43372LK
Wireless Option	H43342LG
S-Video Option	H43342LH
Pencil CW	H43342LJ
<b>Peripheral Options<sup>2</sup></b>	
USB FOOTSWITCH 3 BUTTON	H46732LF
SONY UPD25MD COLOR PRINTR	H4911JT
BW Printer Installation Kit T1	H43342LK
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
LOGIQ Fortis High Cabinet	H43342LL
LOGIQ Fortis Low Cabinet	H43342LM
LOGIQ Fortis Side Cabinet	H43342LN
Sinch bay Option	H43342LP
<b>An Keyboard Assembly</b>	
AN Keyboard ENGLISH	H43342LR
AN Keyboard GERMAN	H43342LS
AN Keyboard FRENCH	H43342LT
AN Keyboard GREEK	H43342LW
AN keyboard NORWEGIAN	H43342LY



Product Description	H-Catalog Number <sup>1</sup>
AN Keyboard SWEDISH	H43352LA
<b>Accessories<sup>2</sup></b>	
Ethernet protection Cable	H43272LJ
FC389,ECG CABLE SET	H45521AL
VNav Stand (Offboard)	H4908NS
ECG CABLE - AHA STYLE	H4910EC
VNav NEEDLE TRACKING	H4910NT
VNav VirtuTRAX Starter Kit	H4910NY
ECG Cables IEC Style	H4911JC
VNav Virtual Tracker	H4911NG
VNav Active Tracker kit	H4913AT
VNav Needle Tracking storage insert	H4913NS
VNav Needle Tracking Kit - 18/20g or less	H4913NT
VNav ETRAX 12 14G ST KT	H4913NU
VNav ETRAX 14 16G ST KT	H4913NV
VNav Probe sensors	H4913PS
VNav MR Active Tracker	H4915MT
Small Probe Holder	H43352LC
VERTICAL TV PROBE HOLDER	H43352LD
TVTR Probe Holder	H43352LE
PROBE CABLE HANGER	H44412LA
OPTION TRAY BOX	H43372LF
OPTION TRAY Bracket	H43372LG
<b>Power Cords Destination Sets</b>	
Power Cord 220V for EU	H46342LZ
Power Cord DK STD C13 GRY	H46692LK
DESTINATION SET UK	H46712LM
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION SET ITALY	H46722LD
<b>V-nav Options<sup>2</sup></b>	
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
C3-10 VNav Holder Starter Kit	H40482LF
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
M5S V NAV BRACKET	H4908NM
<b>Biopsy Kits<sup>2</sup></b>	
E721 STARTER KIT	E8385MJ
IC5-9-D Reusable Biopsy Guide	H40412LN
ML6-15 M_BIOPSY_SKIT	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
L2-9 Needle Guide Starter Kit	H44901AM
M5Sc-D Biopsy Bracket	H45561FC
RAB BIOPSY STARTER KIT	H46701AE
RIC5-9-D Biopsy Guide	H46721R
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
C1-6-D Biopsy Starter Kit	H4913BB
L3-12-D Biopsy Kit	H48302AA
RAB6-D BIOPSY STARTER KIT	H48681ML
BE9CS Biopsy Kit 742-401	H42742LJ



Notes:

[1] *H-Catalog number identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sales contract, order processing documents and shipping documents.*

[2] *Probes and accessories may carry the CE-mark and when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Ultrasound Korea Ltd. has verified the mutual compatibility of the devices in combination with LOGIQ Fortis and included relevant information to users with the LOGIQ Fortis instructions for use.*

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End of Document



## **ATTESTATION CE / EC CERTIFICATE**

**Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System**

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

**ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices**

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

**For class III devices, a EC design certificate is required**

**Fabricant / Manufacturer**

**GE ULTRASOUND KOREA, Ltd.**

**9, Sunhwan-ro 214beon-gil, Jungwon-gu,**

**SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA**

**Catégorie du(des) dispositif(s) / Device(s) category**

**Dispositif ou système de diagnostic par ultrasons**

*Ultrasound diagnostic device or system*

**Voir document complémentaire GMED / See GMED additional document**

**n° 36988**

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P183396, P601203, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

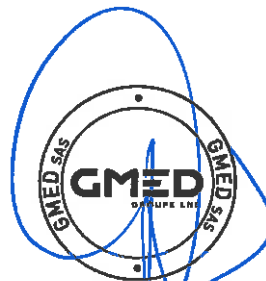
*GMED certifies that, on the basis of the results contained in the file referenced P183396, P601203, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.*

**La validité du présent certificat est soumise à une vérification périodique ou imprévue**

**The validity of the certificate is subject to periodic or unexpected verification**

**Début de validité / Effective date : September 14th, 2020 (included)**

**Valable jusqu'au / Expiry date : May 26th, 2024 (included)**



**Lionel DREUX**  
**Certification Director**

Ce document complémentaire GMED n° 36988 rev. 0 atteste de la validité du certificat CE n° 7697 rev. 18 au regard des informations listées ci-dessous.

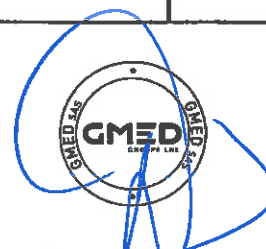
This GMED additional document N° 36988 rev. 0 attests to the validity of CE certificate n° 7697 rev. 18 with regard to the information listed below.

Fabricant / Manufacturer:

**GE ULTRASOUND KOREA, Ltd.**  
9, Sunhwan-ro 214beon-gil, Jungwon-gu,  
SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

### Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P7	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P9	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P10	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8t	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10	Ila



**Lionel DREUX**  
Certification Director

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON SWIFT	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON SWIFT+	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Pro	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 XDclear2.0	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ E10s	Ila

### Site couvert et Activités / Locations and Activities

Site / Location	Activités / Activities
GE ULTRASOUND KOREA, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, REPUBLIC OF KOREA équivalent à equivalent to GE ULTRASOUND KOREA, Ltd. 65-1, Sangdaewon-dong, Jungwon-gu, Seongnam-si, Gyeonggi-do - 462-120 REPUBLIC OF KOREA	Conception, fabrication et contrôle final Design, manufacture and final control



Lionel DREUX

Certification Director

GMED - 36988 rev. 0

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme notifié n° 0459  
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

720 GMED 0901-4 rev 0 du 31/08/2020



# Certificate

No. Q5 075707 0058 Rev. 02

**Holder of Certificate:** **GE Healthcare Austria GmbH & Co OG**  
Tiefenbach 15  
4871 Zipf  
AUSTRIA

**Facility(ies):** GE Healthcare Austria GmbH & Co OG  
Tiefenbach 15, 4871 Zipf, AUSTRIA  
  
Design and Development, Production  
and Distribution of Diagnostic Ultrasound  
Systems, Probes and Standalone Software  
for Ultrasound-Image Processing

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production  
and Distribution of Diagnostic Ultrasound  
Systems, Probes and Standalone Software  
for Ultrasound-Image Processing**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02)

**Report No.:** 713202497

**Valid from:** 2021-11-20  
**Valid until:** 2024-04-23

**Date,** 2021-11-11

Christoph Dicks  
Head of Certification/Notified Body

# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 14001:2015

Approval number(s): ISO 14001 – 0043295

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Bulgaria LTD</b> Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Česká republika, s.r.o.</b> Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Healthcare Danmark A/S</b> Park Allé 295, 2605 BRONDBY, Denmark	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare S.A.</b> 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Magyarország Kft.</b> Bence utca 3., 1138 BUDAPEST, Hungary	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Norge AS</b> Vitaminveien 1A, 0485 OSLO, Norway	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Polska Sp.z o.o.</b> ul. Woloska 9, 02-583 WARSAW, Poland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems SRL.</b> 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Holdings d.o.o.</b> Bulevar Mihaila Pupina 6/17 PC,, Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric International (Slovensko), s.r.o.</b> Prievozská 4, 821 09 BRATISLAVA, Slovakia	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelás 35-37, Urbanización La Florida, 28023 MADRID, Spain	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 45001:2018

Approval number(s): ISO 45001 – 00027009

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Bulgaria LTD</b> Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Česká republika, s.r.o.</b> Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare S.A.</b> 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Magyarország Kft.</b> Bence utca 3., 1138 BUDAPEST, Hungary	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Polska Sp.z o.o.</b> ul. Woloska 9, 02-583 WARSAW, Poland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. repair and installation of medical devices
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems SRL.</b> 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Holdings d.o.o.</b> Bulevar Mihaila Pupina 6/17 PC., Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. associated with sales, marketing, services, repair and installation of medical devices



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# Certificate Schedule

Location	Activities
<b>General Electric International (Slovensko), s.r.o.</b> Prievozská 4, 821 09 BRATISLAVA, Slovakia	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



001



# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 50001:2018

Approval number(s): ISO 50001 – 0043293

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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