Specificaţia tehnică completată

Denumire Ultrasonograf pentru investigatii Generale pediatrice, performanţă înaltă

Model: Logiq E10s; Producător: GE Helthcare, GE ULTRASOUND KOREA si GE Medical Systems SCS; Ţara: SUA, KOREA si Franta

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină solicitată de către ofertant
Denumire Ultrasonograf pentru investigatii Generale pediatrice, performanţă înaltă	Denumire Ultrasonograf pentru investigatii Generale pediatrice, performanţă înaltă **DA**
Descriere Ultrasonograful este un dispozitiv utilizat pentru vizualizarea țesuturilor cu ajutorul ultrasunetelor	Descriere Ultrasonograful este un dispozitiv utilizat pentru vizualizarea țesuturilor cu ajutorul ultrasunetelor **DA**
APLICAŢII CLINICE generale, obstetrica, ginecologie elastografie, pediatrie	APLICAŢII CLINICE generale, obstetrica, ginecologie elastografie, pediatrie **DA**
PROBE PORTURI ≥4	PROBE PORTURI - 4 **DA**
Diapazon frecventa MHz	Diapazon frecventa MHz
p/u probe Liniare ≥2-18 MHz	p/u probe Liniare - 2-18 MHz **DA (L2-9-D + L8-18i-D)**
p/u probe sectoriale ≥1-9MHz	p/u probe sectoriale - 1-9MHz **DA (M5Sc-D 1-5 Mhz)**
p/u probe radiale ≥5-10 MHz	p/u probe radiale ≥5-10 MHz **DA (IC5-9 3-10 Mhz)**
p/u probe Bi-plane ≥2-14 MHz	p/u probe Bi-plane ≥2-14 MHz **DA (RIC5-9**
p/u probe convexe ≥1-13MHz	p/u probe convexe ≥1-13MHz **DA**
PROBE TIP, MHz Liniara (investigatii parti mici), L>38mm ≥ 5- 18MHz	PROBE TIP, MHz Liniara (investigatii parti mici), L- 25 mm - **4 - 18MHz Model: L8-18i-D**
Convex, (investicatii abdominale) tehnologie monocristal ce permite o sensibilitate si rezolutie inalta ≥ 2 - 8 MHz	Convex, (investicatii abdominale) tehnologie monocristal ce permite o sensibilitate si rezolutie inalta - 1 - 6 MHz **Model: C1-6-D – din motiv ca poate sa scaneze in regim de elastografie Shear Wave.**
Endocavitar 200 grade (investigatii transrectale si transvaginale) ≥2-10 MHZ	Endocavitar 180 grade (investigatii transrectale si transvaginale) - 3-10 MHZ **DA Model: IC5-9-D**
NIVELE DE GRI ≥ 256	NIVELE DE GRI - 256 **DA**
GAMA DINAMICĂ ≥ 270 dB	GAMA DINAMICĂ > **270 dB DA**
PREPROCESARE, Canale digitale ≥575 000	PREPROCESARE, Canale digitale > **5.000.000 DA**
Adâncimea scanării ≥ 40 cm	Adâncimea scanării - **50 cm maxim în dependeţa de tipul sondei folosit**
POSTPROCESARE	POSTPROCESARE
Imagine Moduri M-mod color da	Imagine Moduri M-mod color **DA**
M-mod şi 2-D da	M-mod şi 2-D **DA**
CW Doppler da	CW Doppler **DA**
Regim ce ar permite redarea imaginilor cu rezolutie inalta atit in vasele cu flux mare cit si in acele cu flux mai mic da	Regim ce ar permite redarea imaginilor cu rezolutie inalta atit in vasele cu flux mare cit si in acele cu flux mai mic **DA present instrumente speciliazate pentru Doppler si regimul non Doppler B-Flow.**
Regim elastografie in timp real ce ar include si masurarile Strain Ratio, inclusiv softul de analiza a histogramelor acesteia ,valabil pentru toate tipurile de sonde da	Regim elastografie in timp real ce ar include si masurarile Strain Ratio, inclusiv softul de analiza a histogramelor acesteia ,valabil pentru toate tipurile de sonde **DA valabil pentru ML6-15-D, L2-9-D, L2-9VN-D, IC5-9-D, C2-9-D, C2-9VN-D, C1-6-D, C1-6VN-D, si L8-18i-D.**
Regim Shear Wave Measurement mode,regim de masurare a vitezei de propagare a undei in tesut pentru a carecteriza densitatea si elasticitatea acestuia, parametrui necesar pentru diferentierea diferitor formatiuni da	Regim Shear Wave Measurement mode,regim de masurare a vitezei de propagare a undei in tesut pentru a carecteriza densitatea si elasticitatea acestuia, parametrui necesar pentru diferentierea diferitor formatiuni **DA valabil pentru C1-6-D, C1-6VN-D, L2-9-D, L2-9VN-D si ML6-15-D sonda**
Regim ce ne permite posibilitatea analizei complexe automate a contractarii globale si locale a miocardului cu ajutorul urmaririi automate dupa structura inimei. da,obtional (posibilitate)	Regim ce ne permite posibilitatea analizei complexe automate a contractarii globale si locale a miocardului cu ajutorul urmaririi automate dupa structura inimei. da,obtional (posibilitate) **DA permite aceta optiune**
Regim Stress Echo (ECG;PcG; Puls si Respiratie) da, obtional (posibilitate)	Regim Stress Echo (ECG;PcG; Puls si Respiratie) da, obtional (posibilitate) **DA permite aceste optiune**
Regim ce ar permite lucru cu agentul de contrast	Regim ce ar permite lucru cu agentul de contrast da,obtional

da,obtional (posibilitate)	(posibilitate) **DA permite aceasta optiune.**
Regim rezolutie inalta, ce ne permite ca calitatea imaginei sa nu depinda de tipul de sonda ori pacient da	Regim rezolutie inalta, ce ne permite ca calitatea imaginei sa nu depinda de tipul de sonda ori pacient **DA avint o regim de focusare pe toata adincimea de scanare**
Regim masurare automata a IMT (Intima-Media) da	Regim masurare automata a IMT (Intima-Media) **DA**
Regim Real Time 3D (4D) regim ce ar permite primirea imaginilor 3D in timp real da, obtional (posibilitate)	Regim Real Time 3D (4D) regim ce ar permite primirea imaginilor 3D in timp real da, obtional (posibilitate) **DA ca optiune**
Regim panoramic, regim ce permite efectuarea masurarilor ce dapasesc cimpul de scanare a sondelor liniare da	Regim panoramic, regim ce permite efectuarea masurarilor ce dapasesc cimpul de scanare a sondelor liniare **DA Virtual Convex**
Regim ce ne-ar permite vizualizarea simultan a spectrelor Doppler de pe doua sectoare diferite in timp real pentru masurarile directe a coeficientului E/e da	Regim ce ne-ar permite vizualizarea simultan a spectrelor Doppler de pe doua sectoare diferite in timp real pentru masurarile directe a coeficientului E/e **DA**
DOPPLER Tip Spectral : PW, CW, HPRF-PW	DOPPLER Tip Spectral : PW, CW, HPRF-PW
Power Doppler: (directional; High Resolution), Color Flow Mode, TDI,	Power Doppler: (directional; High Resolution), Color Flow Mode, TDI, **DA**
Afișare frecvenţă da	Afișare frecvenţă **DA**
Afișare viteză da	Afișare viteză **DA**
Power Doppler da	Power Doppler **DA**
Duplex da	Duplex **DA**
Triplex da	Triplex **DA**
FUNCŢIONALITĂŢI	FUNCŢIONALITĂŢI
Măsurători digitale automatizate, bazate pe o baza interna de date da	Măsurători digitale automatizate, bazate pe o baza interna de date **DA**
Diapazon dinamic selectabil da	Diapazon dinamic selectabil **DA**
Focalizare de transmisie ajustabilă da	Focalizare de transmisie ajustabilă **DA**
Focalizare de recepţie dinamică da	Focalizare de recepţie dinamică **DA**
PAN/ZOOM	PAN/ZOOM
imagine în timp real da	imagine în timp real **DA**
imagine îngheţată da	imagine îngheţată **DA**
STOCARE IMAGINI Capacitate ≥ 1TB	STOCARE IMAGINI Capacitate - **1TB SSD DA**
USB da, >5	USB da,- 5 b**DA**
Cine da, >60 000cadre	Cine da, - 60 000cadre / 1 Gb = 1000 Mb
DICOM 3.0 (SR,QR) da	DICOM 3.0 (SR,QR) **DA**
MONITOR integrat de control,TFT LCD ≥ 10 "	MONITOR integrat de control,TFT LCD **12,1 "** **DA**
PACHETE DE ANALIZĂ	PACHETE DE ANALIZĂ
Abdominal, da	Abdominal, **DA**
obstetrical ginecologic, Da	obstetrical ginecologic, **DA**
urologic Da	urologic **DA**
parti mici,	parti mici, **DA**
elastografie da da	elastografie **DA**
Posibilitatea efectuării Up Grade da	Posibilitatea efectuării Up Grade **DA**
MONITOR ≥21", LED, min WXGA, DIVIZARE MONITOR da	MONITOR - **22", OLED,** DIVIZARE MONITOR b**DA**
Printer incorporat da	Printer incorporat **DA**
Cerinţe faţă de furnizor	Cerinţe faţă de furnizor
Inginerul companiei să deţină certificat de instruire Pe clasa dată de dispozitive de la producător	Inginerul companiei să deţină certificat de instruire Pe clasa dată de dispozitive de la producător **DA**
Certificat de reprezentanţă oficială valabil Da	Certificat de reprezentanţă oficială valabil **DA**
Instruire	Instruire
Training pentru utilizatori Da	Training pentru utilizatori **DA**
Module necesare: Prezentare generală, pregătire de lucru, operarea cu dispozitivul, întreţinere și dezinfectare	Module necesare: Prezentare generală, pregătire de lucru, operarea cu dispozitivul, întreţinere și dezinfectare **DA direct de producător va fi făcută în limba romînă.**
Training pentru personal tehnic Da	Training pentru personal tehnic **DA**
Module necesare: Modul de efectuare a mentenanţei periodice, modul de testare a funcţionalităţii	Module necesare: Modul de efectuare a mentenanţei periodice, modul de testare a funcţionalităţii **DA**
Documentaţie	Documentaţie
Manualul de utilizare română sau rusă, tipărit și în format	Manualul de utilizare română sau rusă, tipărit și în format

electronic	electronic **DA**
Manualul de utilizare Engleză	Manualul de utilizare Engleză **DA**
Manualul de service Engleză, tipărit și în format electronic	Manualul de service Engleză, tipărit și în format electronic **DA**
Logistică	Logistică
Transportare la adresa solicitată Da	Transportare la adresa solicitată **DA**
Instalare Da	Instalare **DA**
Testare Da	Testare **DA**
Garanție	Garanție
Perioada de garanție Minim 3 ani	Perioada de garanție 3 ani **DA**
Efectuarea mentenanței în perioada de garanție de către furnizor Conform recomandărilor producătorului	Efectuarea mentenanței în perioada de garanție de către furnizor Conform recomandărilor producătorului **DA**
Ajustarea și efectuarea paternurilor Da	Ajustarea și efectuarea paternurilor **DA**

EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC Annex II
and of the directive 2011/65/EU, directive 2012/19/EU, directive 2014/53/EU)

We

Manufacturer	EU Authorized Representative
GE Ultrasound Korea, Ltd.	**GE Medical Systems SCS**
9, Sunhwan-ro 214beon-gil,	**283 rue de la Minière**
Jungwon-gu, Seongnam-si	**78530 BUC, France**
Gyeonggi-do, Republic of Korea	

Equivalent to
65-1, Sangdaewon-dong,
Jungwon-gu, Seongnam-si
Gyeonggi-do 462-120, Korea

Declare under our sole responsibility that the device:

LOGIQ E10s including accessories and components
Ref. See addendum
GMDN Code: **40761**
UDI-DI code: **LOGIQ E10s / 840682146531**
UMDNS Code: **15-976**
Classification rule (93/42/EC Annex IX): **Rule 10, Class: IIa**

To which this declaration relates, is in conformity with the requirements of:

● The medical devices directive 93/42/EEC (MDD)

- Technical documentation ref.: DOC2238699 / DHF ref.: DOC2063399, of the product to which this declaration relates.

- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by *GMED SAS (Notified Body n° 0459)*, Certificate N °7697

- List of harmonized standards applied on the product to which this declaration relates:

  ▪ *EN 60601-1 : 2006 + A12 : 2014 (Edition 3.1)*
  ▪ *EN 60601-1-2 : 2015*
  ▪ *EN 60601-1-6 : 2010 + A1 : 2015*
  ▪ *EN 60601-2-37 : 2008 + A1 : 2015 (Edition 2.1)*
  ▪ *EN 62304 : 2006 + A1: 2015*
  ▪ *EN 62366-1 : 2015*
  ▪ *EN ISO 15223-1: 2016*
  ▪ *EN 1041 : 2008*

- The directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

    - Technical documentation ref.: DOC2238699 / DHF ref.: DOC2063399, of the product to which this declaration relates.

- The directive 2012/19/EU on the waste electrical and electronic equipment (WEEE)

    - Technical documentation ref.: DOC2238699 / DHF ref.: DOC2063399, of the product to which this declaration relates.

- The directive 2014/53/EU on the radio equipment (RED)

    - Technical documentation ref.: DOC2238699 / DHF ref.: DOC2063399, of the product to which this declaration relates.

- The Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

    - Technical documentation ref.: DOC2238699 / DHF ref.: DOC2063399, of the product to which this declaration relates.

This EC declaration of conformity supersedes the previous declaration dated 19-Febuary-2020**.**

Qingmeng Chen

Qingmeng Chen
Product Regulatory Affairs Manager

Date: 06-April-2020

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
dated 06-April-2020

Product Description	Catalog Number[1]
Ultrasound Console	
LOGIQ E10s console	H46612LC
	5814175
Probe Options[2]	
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
TEE Probe Accessories[2]	
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
Software Options	
Advanced Security	H46622LL
Coded Contrast	H46622LM
Cardiac AFI	H46622LN
DVR	H4918DR
Report Writer	H46622LR
Stress Echo	H46622LS
Trice	H46622LT
LOGIQ Apps	H46622LW
KOIOS SW	H46622LY
Scan Assistant	H46622LZ
Advanced Probes	H46612LS
AUTO IMT	H46612LT
B Steer+	H46612LW
B-FLOW	H46612LY
Compare Assistant	H46612LZ

Product Description	Catalog Number[1]
DICOM	H46622LA
FLOW QA	H46622LB
Measure Assist Breast	H46622LC
Measure Assist OB	H46622LD
Shear Wave Elastgraphy	H46622LE
Strain Elasto	H46622LF
SRI HD Type2	H4920SR
UGAP	H46622LH
SonoNT SonoIT	H46622LJ
Sono AVC for renal cyst	H46642LP
Hardware Options[2]	
LOGIQ Exx Bin - Large	H4918B
LOGIQ Exx Bin - Twin	H4918BT
CW Doppler	H46612LJ
Realtime 4D	H46612LK
ECG	H46612LD
Gel Warmer	H46612LG
Power Assistant with Scan on Battery	H46612LP
Power Assistant	H46612LR
Volume Navigation	H46612LM
Wireless	H46612LH
S-Video	H46612LL
Pencil CW	H46612LN
DVD Drive	H46612LE
Peripheral Options[2]	
USB FOOTSWITCH 3 BUTTON	H46732LF
SONY UPD25MD COLOR PRINTR	H4911JT
Onboard Printer	H46612LF
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
Keyboard Options	
LOGIQ E10s German KB	H4918DY
LOGIQ E10s French Can KB	H4918FC
LOGIQ E10s French KB	H4918FY
LOGIQ E10s Greek KB	H4918GY
LOGIQ E10s Norwegian KB	H4918NY
LOGIQ E10s Danish KB	H4918DK
LOGIQ E10s Swedish KB	H4918SY
Accessories[2]	
Ultrasound Probe Rack	E8363JF
ASUS Z380M-A2-GR ZenPad 8 Commerical Grade Tablet - for use with GE E10 Ultrasound	E8376AA
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

Product Description	Catalog Number[1]
VNav Probe sensors	H4913PS
VNav MR Active Tracker	H4915MT
LE9 Probe Holder Insert 2	H4915P
Power Cords Destination Sets	
Power Cord 220V for EU	H46342LZ
DESTINATION SET UK	H46712LM
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION KIT AUS/NZ	H46712LZ
DESTINATION SET ITALY	H46722LD
V-nav Options[2]	
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
Biopsy Kits[2]	
IC5-9-D Needle guide	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
PEC74 BIOPSY KIT FOR RAB LIGHT	H48621Y
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
L3-12-D Biopsy Kit	H48302AA
L3-12-D Multi Angle Biopsy Set	H78652PA
Veterinary Options	
Vet Kit	H46622LK

Notes:

[1] *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 E10s and included relevant information to users with the LOGIQ E10s instructions for use.*

End of Document

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
BS-MDR-099

TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 075707 0078 Rev. 00

Manufacturer:

GE Healthcare Austria GmbH & Co OG
Tiefenbach 15
4871 Zipf
AUSTRIA

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713175299

Preceding certificate No.: this certificate is issued for the first time

Valid from: 2020-05-14
Valid until: 2025-05-13

Date of initial issuance / Rev.00: 2020-05-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-05-14

TÜV®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ CEPTИФИКАТ ◆ 認證證書 ◆ CERTIFICAT ◆ CERTIFICADO ◆ CERTIFICAT

TÜV
SÜD

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 075707 0078 Rev. 00

Device Group	**Risk Classification**
Echographic Instruments	IIa

The validity of this certificate depends on conditions and/or is limited to the following: None

Revision History including Changes: 00 / 2020-05-13 / 713175299

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICAT ◆ CERTIFICADO ◆ CERTIFICAT

TÜV®

Certificate of Completion

This certifies that

Ion Negru

has successfully completed

Proficient_UL Service Training (DL)

Completed on 3/26/2021

(date format: mm/dd/yyyy)

_____

Certificate of Completion

This certifies that

Ion Negru

has successfully completed

Proficient_UL Exam (DL)

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

_____

C e r t i f i c a t e

**The Certification Body of
TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-17
Certificate Registration No.:	SX 60146260 0001
An audit was performed. Report No.:	32090188 001
This Certificate is valid until:	2021-11-04

Certification Body

((DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-17

Balazs Bozsik

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60146260 0001
Report No.: 32090188 001

Organization: GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

Scope: Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Site Included:
GE Ultrasound Korea, Ltd.
65-1,Sangdaewon-dong, Jungwon-gu
Seongnami-si, Gyeonggi-do
462-120 Republic of Korea

Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-03-17

Bałazs Bozsik

LOGIQ™ E10s

EMPOWERING YOU TO MAKE THE DIFFERENCE

gehealthcare.com
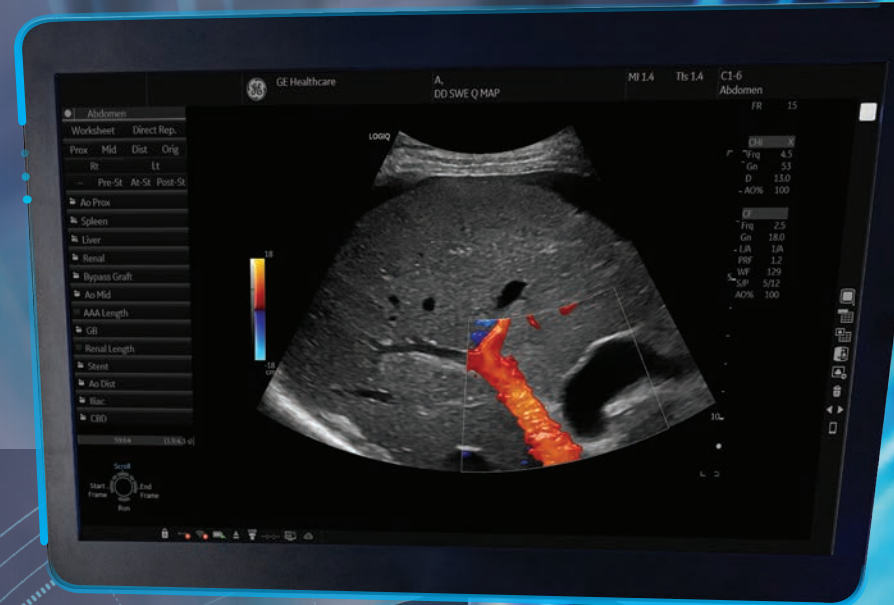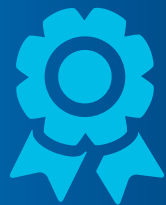
Next-generation, leadership ultrasound, the new LOGIQ E10s system from GE Healthcare provides multi-purpose capabilities in a scalable configuration – a smart investment that will meet your patient needs and support your growth for years to come.

EMPOWERING
Confident Diagnosis

Experience the exceptional images and increased clinical flexibility to address a wide range of patients and facilitate an accurate diagnosis.

Scalable to a whole-body solution: Our full suite of robust, standard features and scalable options allow you to configure the optimal system to meet your imaging needs – head to toe, obese to thin, neonate to geriatric.

Exceptional imaging: Next-generation cSound™ Architecture automatically delivers images of exceptional uniformity, from near to far field. The system acquires and reconstructs data with 48x the data throughput and 10x the processing power of our previous systems. There's no need to adjust the focus – the information you need is there, instantly.

cSound

E-Series and XDclear™ probes: Powerful high fidelity and broad bandwidth produce high resolution images whether scanning superficial or deep targets, or at any point in between.

Optimized for small vessel imaging: An innovative new tool, Radiant*flow*™ provides a near-3D look when visualizing blood flow in tiny vessels, especially when combined with Micro Vascular Imaging (MVI).

EMPOWERING
Comprehensive Tools

Choose from a robust offering of tools to help improve the speed and precision of diagnosis, guidance and treatment in abdominal, cardiac, OB/GYN, vascular, breast, pediatrics and musculoskeletal applications. Among the available capabilities:

2D Shear Wave & Strain Elastography: Determine qualitative, quantitative and semi-quantitative assessment of tissue elasticity. Now available with a Shear Wave Elastography Quality Indicator to support confident measurements.

Ultrasound-Guided Attenuation Parameter (UGAP): Quantifies liver steatosis to aid in early identification and monitoring of patients with NAFLD, NASH or ASH.

Contrast-enhanced ultrasound (CEUS): Visualize tissue structure and lesion vascularity clearly to optimize diagnostic accuracy.

Photo Assistant app: Acquire photos of relevant anatomy via an Android™ smart device and include them with the clinical images in the report, providing valuable context.

Liver Shear Wave measurement, C1-6-D
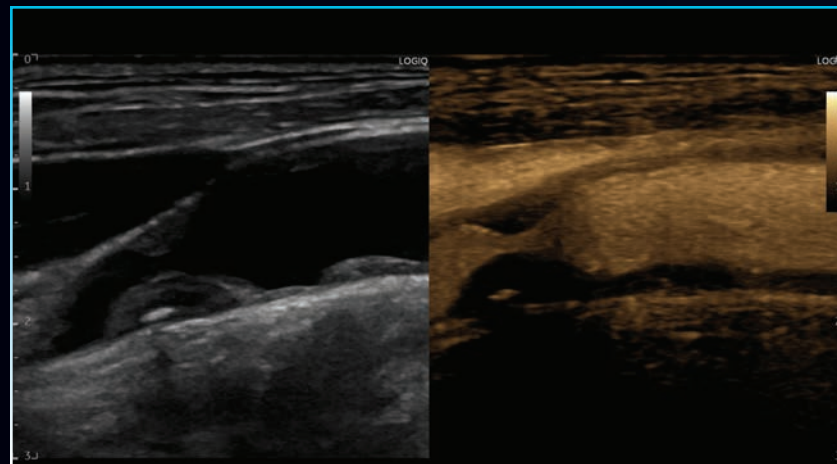
Lymph node, L8-18i-D

Carotid with plaque, L2-9-D
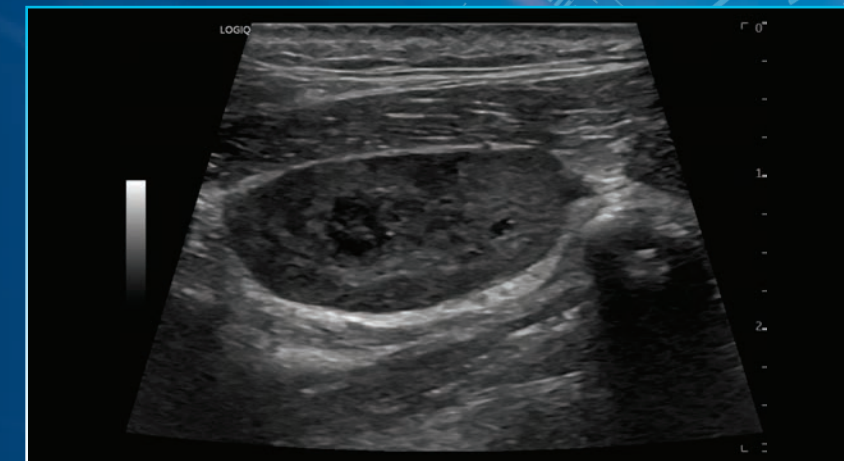
Liver UGAP, C1-6-D
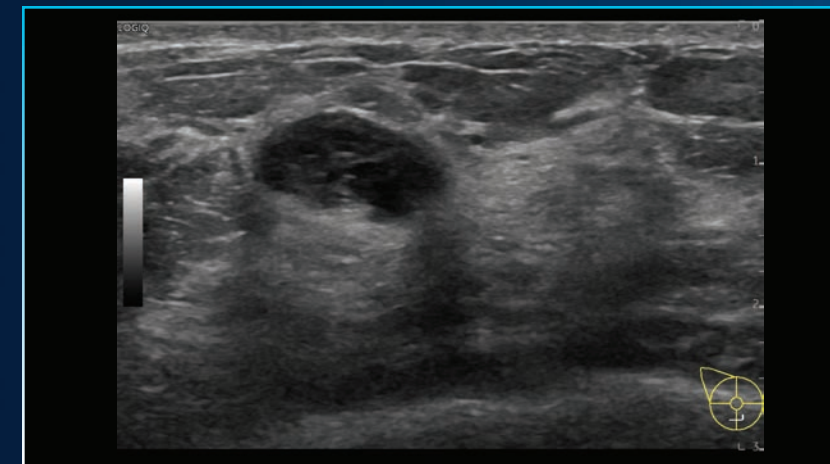
Breast mass, ML6-15-D
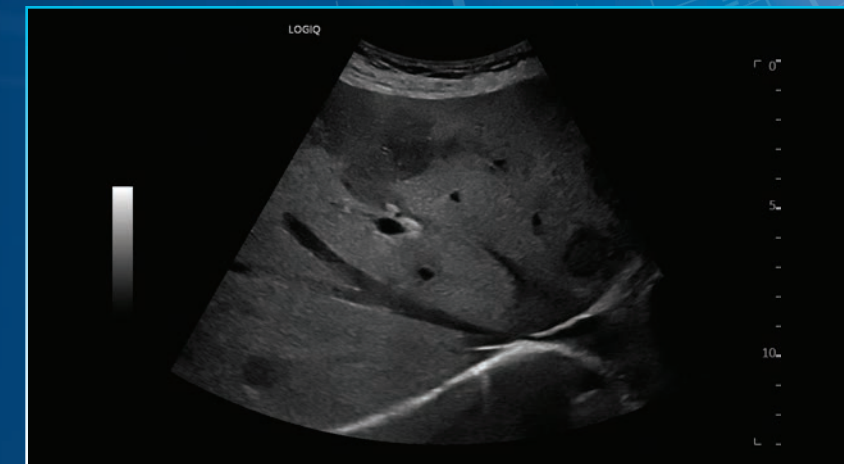
Liver with metastatic lesions, C1-6-D

> EMPOWERING
Concise Workflow

Achieve new levels of workflow efficiency to stay ahead of your daily challenges. By leveraging the power of artificial intelligence (AI), the LOGIQ E10s helps reduce the number of steps required for excellent image optimization for the entire exam.

AI-based tools, powered by Edison

Among the AI-based tools available to help improve exam efficiency and consistency:

- **Auto Doppler Assistant:** Automatically adjusts the color box and angle, so users can complete exams in 20% less time with 50% fewer keystrokes
- **Auto Lesion Segmentation:** Automatically traces lesion boundaries and generates two-dimensional measurements with just a few keystrokes
- **OB Measure Assistant:** Reduces keystrokes and enhances reproducibility by automating key fetal measurements

Productivity enhancers

Integrated technologies function as virtual assistants to help users do more in less time with greater ease. Options include:

- **Scan Assistant:** Provides customizable automation at each step of an ultrasound exam, helping to reduce keystrokes and exam times
- **Compare Assistant:** View a prior study – ultrasound, mammography, CT or MR – and current images together in real time via a split screen on the monitor
- **Start Assistant:** Automatically launches the preferred setting when the user selects an exam description

Exceptional ergonomics

The LOGIQ E10s system is designed for busy departments – easy to use in any environment and clinical scenario.

- **Familiar user interface:** The new system offers greater functionality while maintaining the ease of operation and satisfying user experience that has become a hallmark of LOGIQ interface design
- **Exceptional mobility:** The system easily fits into crowded suites. With the optional Power Assistant battery, there's no need for re-boot, and you can even scan on battery power
- **Streamlined archiving and reporting:** Robust DICOM® connectivity allows images to be saved to a central location and reviewed alongside other imaging modalities

Powered By
Edison

› EMPOWERING
Smart Investment

Ultrasound for today, platform for tomorrow

The LOGIQ E10s is the smart choice now and for the future with multi-purpose versatility and scalability to address your specific patient population.

A to A digital platform: From awareness to assistance, stay at the forefront of clinical imaging with our A to A digital platform, specifically engineered so you can add next-generation capabilities in the years ahead.

SonoDefense: Our multi-layer approach to cybersecurity helps keep the system safe and functional in the face of cyberthreats and helps protect patient data from unauthorized access.

Digital support: Wide choice of efficiency tools to help users, administrators, and operations staff improve productivity, including remote preset management, performance analytics, software/security updates, live clinical training, and advanced system diagnostics.

LOGIQ™ E10s

Data sheet

The LOGIQ E10s is GE's premium ultrasound imaging system designed for abdominal, vascular, obstetric, gynecologic, neonatal, pediatric, urological, transcranial, cardiac and small parts applications.

General specifications

Dimensions and weight *(Dimensions given with floating keyboard stowed and display tilted for transport)*	
Height	1300 mm, (51")
Width	585 mm, (23")
Depth	900.9 mm, (35.5")
Weight	115 kg, (254 lbs)

Electrical power
Voltage 100 – 240 VAC
Frequency 50/60 Hz
Power Consumption maximum of 0.9 KVA with peripherals

Console design
4 active probe ports
1 inactive probe storage port
Integrated SSD (1 TB)
Integrated DVD-R Multi Drive
On-board storage of thermal printer
Integrated speaker
Integrated locking mechanism that provides rolling lock and caster swivel lock
Integrated cable management
Front and rear handles
Easily removable air filters

User interface

Operator keyboard	
Floating keyboard adjustable in three dimensions	• Height • Rotation • Extension
Full-sized, backlit alphanumeric keyboard	
Ergonomic hard key layout	
Interactive back-lighting	
Integrated recording keys for remote control of up to 4 peripheral or DICOM® devices	
Integrated gel warmer (Option)	

Touch screen
12.1" High-resolution, color, touch, display screen
Interactive dynamic software menu
Brightness adjustment
User-configurable layout

Display monitor
22" Wide screen high-resolution OLED display
Display translation (independent of console)
350 mm, (13.7") horizontal (both directions)
120 mm, (4.7") vertical
90° swivel (both directions)
Fold-down and lock mechanism for transportation
Resolution: 1920 X 1080
Anti-glare
Viewing angle 89/89/89/89°

System overview

Applications
Abdominal
Obstetrical
Gynecological
Breast
Small Parts
Peripheral Vascular
Transcranial (adult and neonatal)
Pediatric and neonatal
Musculoskeletal (general and superficial)
Urological
Cardiac (adult and pediatric)

Operating modes
B-Mode
M-Mode
Color Flow Mode (CFM)
B-Flow™ (option)

System overview *(cont.)*

Operating modes *(cont.)*

Extended field of view (LOGIQView)

Power Doppler Imaging (PDI)

PW Doppler

CW Doppler (Option)

Volume Modes (3D/4D) (Option)	• 3D Static • 4D Real Time

Anatomical M-Mode

Coded Contrast Imaging (option)

Strain elastography

Shear wave elastography (option)

UGAP (option)

Scanning methods

Electronic sector

Electronic convex

Electronic linear

Mechanical volume sweep

Probe types

Sector phased array

Convex array

Micro convex array

Linear array

Matrix array

Volume probes (4D)

Split crystal

System standard features

Advanced user interface with high-resolution 12.1" display touch panel

Automatic optimization

CrossXBeam™

Speckle Reduction Imaging (SRI HD Type1)

Fine angle steer

Coded harmonic imaging

Virtual convex

Patient information database

System standard features *(cont.)*

Image archive on integrated CD/DVD and hard drive

Advanced 3D

Raw data analysis

Real-time automatic Doppler calculations

OB calculations

Fetal trending

Multigestational calculations

Hip dysplasia calculations

Gynecological calculations

Vascular calculations

Urological calculations

Renal calculations

Cardiac calculations

InSite™ capability

On-board electronic documentation

Auto CF/PW positioning feature

Privacy and security, including user and rights management

LOGIQView

Auto IMT

Breast productivity package

Thyroid productivity package

External USB printer connection

HDMI output available for compatible devices

Options

Tricefy®

DICOM

B-Flow

Compare Assistant

Scan Assistant

OB measure assistant

Color quantification

Strain elastography

Advanced privacy and security (vulnerability scan)

Power assistant and scan on battery

Storage bins

System overview *(cont.)*

Options *(cont.)*

SonoNT SonoIT

SRI HD Type 2

Peripheral options

Integrated options for	• Digital B&W thermal printer • DVD video recorder

Digital color thermal printer

Digital A6 color thermal printer

Foot switch, with programmable functionality

Console protective cover

LOGIQ smart device apps	• Photo Assistant • Remote Control

Display modes

Live and stored display format	• Full size and split screen – both w/ thumbnails. For still and CINE
Review image format	• 4x4, and thumbnails. For still and CINE
Time line display	• Independent Dual B or CrossXBeam/ PW Display • CW • Display formats top/bottom selectable format • Side/side selectable format

Virtual convex

Simultaneous capability

B or CrossXBeam/PW

B or CrossXBeam/CW (Option)

B or CrossXBeam/CFM or PDI

B/M

B/CrossXBeam

B-Flow/PW

Real-time Triplex Mode

(B or CrossXBeam + CFM or PDI/PW)

Selectable alternating modes

B or CrossXBeam/PW

B or CrossXBeam + CFM (PDI)/PW

B/CW (Option)

Multi-image (split/quad screen)

Live and/or frozen

B or CrossXBeam + B or CrossXBeam/CFM or PDI

PW/M

Independent Cine playback

Display annotation

Patient name: first, last and middle

Patient ID

Alternate patient ID

Age, sex and date of birth

Hospital name

Date format: three types selectable	• MM/DD/YY • YY/MM/DD	• DD/MM/YY
Time format: two types selectable	• 24 hours	• 12 hours
Gestational age from	• LMP • EDD	• GA • BBT

Probe name

Map names

Probe orientation

Depth scale marker

Lateral scale marker

Image depth

Zoom depth

B-Mode	• Gain • Imaging frequency • Gray map	• Dynamic range • Frame averaging • SRI-HD
M-Mode	• Gain • Time scale	• Dynamic range
Doppler Mode	• Gain • Sample volume depth and width • Spectrum inversion • Time scale • Doppler frequency	• Angle • Wall filter • Velocity and/or frequency scale • PRF

System overview *(cont.)*

Display annotation *(cont.)*

Color Flow Doppler Mode	• Line density • Frame averaging • Color Scale: 3 types: power, directional PDI, and symmetrical velocity imaging • Color velocity range and baseline • Color threshold marker • Color gain • PDI • Spectrum inversion • Doppler frequency

TGC curve

Acoustic frame rate

CINE gage, image number/frame number

Body pattern: multiple human and animal types

Application name

Measurement results

Operator message

Displayed acoustic output	• TIS: Thermal Index Soft Tissue • TIC: Thermal Index Cranial (Bone) • TIB: Thermal Index Bone • MI: Mechanical Index

% of maximum power output

Biopsy guide line and zone

Heart rate

General system parameters

System setup

Pre-programmed categories

User programmable preset capability

Factory default preset data

Languages: English, French, German, Spanish, Italian, Brazilian Portuguese, Russian, Greek, Swedish, Danish, Dutch, Finnish, Norwegian

OB Report Formats including Tokyo Univ., Osaka Univ., USA, Europe and ASUM and WHO

User defined annotations

Body patterns

Customized comment home position

Complete user manual available on board through Help (F1)

User manual and service manual are included on USB with each system. A printed manual is available upon request.

CINE memory/image memory

1 GB of CINE memory

Selectable CINE sequence for CINE review

Prospective CINE mark

Measurements/calculations and annotations on CINE playback

Scrolling timeline memory

Dual Image CINE display

Quad Image CINE display

CINE gauge and CINE image number display

CINE review loop

CINE review speed

Image storage

On-board database of patient information from past exams

Storage formats: DICOM	• Compressed/uncompressed • Single/multi-frame • Enhanced (3D/4D) • With/without raw data

Export JPEG, JPEG 2000, WMV (MPEG 4) formats

Storage devices	• USB memory stick: 64 MB to 64 GB (for exporting individual images/clips) • CD-R storage: 700 MB • DVD storage: -R (4.7 GB) • Hard drive image storage: ~730GB

Compare previous exam images with current exam

Reload of archived data sets

General system parameters *(cont.)*

Connectivity

Ethernet network connection

Wireless LAN 802.11ac/a/b/g/n (Option)

DICOM 3.0	• Verify • Print • Store • Modality worklist • Storage commitment • Modality performed procedure step (MPPS) • Media exchange • Off network/mobile storage queue • Query/retrieve

Public SR template

Structured Reporting – compatible with vascular and OB, cardiac and breast standard

InSite capability

Advanced privacy and security (Option)

Physiological input panel (Option)

Physiological input	• ECG, 1 channel • PCG, 1 channel • AUX, 1 channel • Dual R-Trigger • Pre-settable ECG R delay time • Pre-settable ECG position • Adjustable ECG gain control • Pre-settable PCG position • Adjustable PCG gain control • Pre-settable AUX position • Adjustable AUX gain control

Automatic heart rate display

Auto Ejection Fraction

Report writer (Option)

On-board reporting package automates report writing

Formats various exam results into a report suitable for printing or reviewing on a standard PC

Exam results include patient info, exam info, measurements, calculations, images, and comments Standard templates provided

Customizable templates

Scanning parameters

Displayed imaging depth: 0 – 50 cm

Minimum depth of field: 0 – 2 cm (zoom) (probe dependent)

Maximum depth of field: 0 – 50 cm (probe dependent)

Continuous dynamic receive focus/continuous dynamic receive

Aperture

Adjustable dynamic range	Adjustable field of view (FOV)

Image reverse: right/left

Image rotation of 0°, 90°, 180°, 270°

Digital B-Mode

Adjustable	• Acoustic power • Gain • Dynamic range • Frame averaging • Gray scale map • Frequency • Speed of sound (application dependent) • Framerate • Scanning size (FOV or Angle – Depending on the probe, see probe specifications) • CrossXBeam • B colorization • Reject • Suppression • SRI-HD

Digital M-Mode

Adjustable	• Acoustic power • Dynamic range • Frequency • M colorization • Rejection	• Gain • Gray scale map • Sweep speed • M display format

Anatomical M-Mode

M-mode cursor adjustable at any plane

Can be activated from a CINE loop from a live or stored image

M & A capability

Available with Color Flow Mode

General system parameters *(cont.)*

Digital Spectral Doppler Mode

Adjustable	
• Acoustic power • Dynamic range • Transmit frequency • PW colorization • Sweep speed • Sample volume length • Spectrum inversion • Baseline shift • Time resolution • Trace direction	• Gain • Gray scale map • Wall filter • Velocity scale range • Angle correction • Steered linear • Trace method • Doppler auto trace • Compression • Trace sensitivity

Digital Color Flow Mode

Adjustable	
• Acoustic power • Gain • Velocity scale range • Wall filter • Packet size • Spatial filter • Baseline shift • Threshold • Accumulation mode • Flash suppression • Shortcuts	• Color maps, including velocity-variance maps • Line density • Steering angle • Frame average • Auto ROI placement and steering on linear

Digital Power Doppler Imaging

Adjustable	
• Acoustic power • Gain • Velocity scale range • Wall filter • Packet size • Spatial filter • Frame average • Accumulation mode • Shortcuts	• Color maps, including velocity-variance maps • Line density • Steering angle • Threshold • Flash suppression

Continuous Wave Doppler (Option)

Available on M5Sc-D, P2D and P6D probes

Steerable CW mode included

Adjustable	
• Acoustic power • Dynamic range • Transmit frequency • CW colorization • Sweep speed • Angle correction • Trace method • Baseline shift • Compression • Trace direction	• Gain • Gray scale map • Wall filter • Velocity scale range • Spectrum inversion • Doppler auto trace • Trace sensitivity

Automatic optimization

Optimize B-Mode image to help improve contrast resolution

Selectable amount of contrast resolution improvement (low, medium, high)

CTO (Continuous Tissue Optimization) – continuously adjusts B-Mode axial and lateral gain uniformity and overall gain level suppressing the noise

Auto-spectral optimize – adjusts baseline, invert, PRF (on live image), and angle correction

Auto CF and PW positioning – adjusts ROI position, sample volume position and steering

Coded Harmonic Imaging

Available on all 2D and 4D probes

B-Flow (Option)

Available on 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, ML6-15-D, M5Sc-D and L8-18i-D probes

Background

Sensitivity/PRI

Acoustic power

Frequency

Line density

Frame average

Gray scale map

Tint map

Dynamic range

Rejection

Gain

Suppression

SRI-HD

Accumulation

Visualization

Radiant*flow*™

Easy, fast visualization of tiny vessels, displaying as a 3D effect

B Steer+

Available on the following probes: L2-9-D, ML6-15-D, L8-18i-D, L2-9VN-D

General system parameters *(cont.)*

Coded contrast imaging (Option)

Available on C1-6-D, C1-6VN-D, C2-9-D, C2-9VN-D, C2-7-D, C2-7VN-D, C3-10-D, IC5-9-D, L2-9-D, L2-9VN-D, M5Sc-D, ML6-15-D, RAB6-D, RIC5-9-D

2 contrast timers

Timed updates: 0.05 – 10 seconds

Accumulation mode, seven levels

Maximum enhance mode

Flash

Time intensity curve (TIC) analysis

Parametric imaging

The LOGIQ E10 is designed for compatibility with most commercially available ultrasound contrast agents. Because the availability of these agents is subject to government regulation and approval, product features intended for use with these agents may not be commercially marketed nor made available before the contrast agent is cleared for use. Contrast related product features are enabled only on systems for delivery to an authorized country or region of use.

LOGIQView

Extended field of view Imaging

Up to 160 cm (63") scan length

Available on all 2D imaging probes

For use in B-Mode

CrossXBeam is available on linear probes

Auto detection of scan direction

Pre-or post-process zoom

Rotation

Auto best fit on monitor

Measurements in B-Mode

3D

Allows unlimited rotation and planar translations

3D reconstruction from CINE sweep

Advanced 3D

Acquisition of color data

Automatic rendering

3D landscape technology

3D movie

Real Time 4D (Option)

Acquisition modes	• Real Time 4D • Spatio-Temporal • Static 3D Image Correlation
Visualization modes	• 3D rendering (diverse surface and intensity projection modes) • Sectional planes (3 section planes perpendicular to each other) • Omniview • Volume contrast imaging-static • Volume contrast imaging – Omniview • Tomographic ultrasound imaging • Volume Analyses – VOCAL: semi-auto/manual segmentation tool (segmentation using touch screen), (3D Static only) + Threshold Volume: measure volume below and above a threshold
Render mode	• Surface texture, surface smooth, max-, min- and X-ray (average intensity projection), mix mode of two render modes • HD*live*™

SonoRender*live*

Curved 3-point render start

3D movie

Scalpel: 3D cut tool

Display format	• Quad: A-/B-/C-Plane/3D • Dual: A-Plane/3D • Single: 3D or A- or B- or C-Plane

Automated volume calculation – VOCAL II

Betaview

Volume navigation (Option)

Available on the C1-6VN-D, C2-9VN-D, C2-7VN-D, C3-10-D, L2-9VN-D, ML6-15-D, IC5-9-D, L8-18i-D, M5Sc-D probes

Sensor-based acquisition

Position markers

Needle tip tracking

Virtual tracking

Auto image registration

Tru3D feature includes	Display of data in: main-, parallel-, angular-mode

Render modes: gray surface, texture, min-, max-, average-intensity

Measurements: distance, angle, area, volume

3D movie

General system parameters *(cont.)*

Scan assistant (Option)

Factory programs

User-defined programs

Steps include image annotations, mode transitions, basic imaging controls and measurement initiation

Compare assistant (Option)

Allows side-by-side comparison of previous ultrasound and other modality exams during live scanning

Breast productivity package

Auto measurement

Worksheet summary includes measurements and locations for lesions and lymph nodes

Feature assessment

BI-RADS™ assessment

User editable

Thyroid productivity package

Auto measurement

Worksheet summary includes measurements and locations for nodule, parathyroid and lymph node

Feature assessment

TI-RADs assessment

User editable

Start Assistant

Automatically select category, probe, preset, or scan assistant from worklist exam description

Learn the category, probe, preset, and scan assistant based on exam description

Shear Wave Elastography (Option)

Available on C1-6-D, C1-6VN-D, L2-9-D, L2-9VN-D and ML6-15-D probes

User programmable measurement display in kPa and meters per second

Single and dual view display

Strain elastography (Option)

Available on ML6-15-D, L2-9-D, L2-9VN-D, IC5-9-D, C2-9-D, C2-9VN-D, C1-6-D, C1-6VN-D, and L8-18i-D probes

Relative analysis tool

UGAP (Option)

Available on C1-6-D and C1-6VN-D

Measures liver attenuation* (attenuation coefficient [dB/cm/MHz]) by auto measure algorithm with reference B-mode

Simple and 2D color map (attenuation color map and Measurement Position Indicator Map)

Quantitative flow analysis (Option)

Available in color and power Doppler

TVI (Option)

Myocardial Doppler imaging with color overlay on tissue image

Available on M5Sc-D probe

Tissue color overlay can be removed to show just the 2D image, still retaining the tissue velocity information

Curved anatomical M-Mode: free (curved) drawing of M-Mode generated from the cursor independent from the axial plane

Q-Analysis: multiple time-motion trace display from selected points in the myocardium

Stress echo (Option)

Advanced and flexible stress echo examination capabilities

Provides exercise and pharmacological protocol templates

6 default templates

Template editor for user configuration of existing templates or creation of new templates

Reference scan display during acquisition for stress level comparison (dual screen)

Baseline level/previous level selectable

Raw data continuous capture

Over 100 sec. available

Wall motion scoring (bulls-eye and segmental)

Smart stress: Automatically set up various scanning parameters (e.g. geometry, frequency, gain) according to same projection on previous level

General system parameters *(cont.)*

Auto EF (Option)

Allows semi-automatic measurement of the global EF (Ejection Fraction)

User editable

Cardiac AFI (Option)

Allows assessment of the complete left ventricle with all segments at a glance by combining three longitudinal views into one comprehensive bulls-eye view

2D strain based data moves into clinical practice

Virtual convex

Provides a convex field of view

Compatible with CrossXBeam

Available on all linear and sector probes

SRI-HD

Speckle reduction imaging

Provides multiple levels of speckle reduction

Compatible with side-by-side DualView display

SRI type: two types selectable	• Type 1
	  – Compatible with all linear, convex and sector probes
	• Type 2 (option)
	  – Compatible with OB/GYN application

CrossXBeam

Provides variable angle spatial compounding

Live side-by-side DualView display

Compatible with	• Color mode • SRI-HD • Virtual convex	• PW • Coded harmonic imaging

Available on all curved and linear probes

Controls available while "live"

Magnification Zoom: Magnifies the entire image on the screen without zoom ROI

Pan Zoom: Magnifies the display of the data within the ROI

HD Zoom: Magnifies the image within the zoom ROI, with higher spatial resolution than original images

Controls available while "live" *(cont.)*

B/M/CrossXBeam-Mode	• Gain • Dynamic range • Framerate control • CrossXBeam angle	• TGC • Acoustic output • Sweep speed for M-Mode
PW-Mode	• Gain • Acoustic output • PRF • Wall filter • Sample volume gate: length, depth	• Dynamic range • Transmission frequency • Spectral averaging • Velocity scale
Color Flow Mode	• CFM gain • Acoustic output • Wall echo filter • Frame rate control • CFM frame averaging • Frequency/velocity baseline shift	• CFM velocity range • Packet size • CFM spatial filter • CFM line resolution

Controls available on "freeze" or recall

Automatic optimization

SRI-HD

CrossXBeam – display non-compounded and compounded image simultaneously in split screen

3D reconstruction from a stored CINE loop

B/M/CrossXBeam mode	• Gray map optimization • TGC • Colorized B and M • Frame average (loops only) • Dynamic range

Anatomical M-Mode

Magnification zoom

Pan zoom

Baseline shift

Sweep speed

PW mode	• Gray map • Baseline shift • Invert spectral wave form • Colorized spectrum • Doppler audio • Quick angle correct	• Post gain • Sweep speed • Compression • Rejection • Display format • Angle correct • Auto angle correct

General system parameters *(cont.)*

Controls available on "freeze" or recall *(cont.)*	
Color flow	• Overall gain (loops and stills) • Color map • Transparency map • Frame averaging (loops only) • Flash suppression • CFM display threshold • Spectral invert for color/Doppler
Anatomical M-Mode on cine loop	
4D	• Gray map, colorize • Post gain • Change display – single, dual, quad sectional or rendered

Measurements/calculations

General B-Mode
Depth and distance
Circumference (ellipse/trace)
Area (ellipse/trace)
Volume (ellipsoid)
% Stenosis (area or diameter)
Angle between two lines
Dual B-Mode capability

General M-Mode
M-Depth
Distance
Time
Slope
Heart rate

General Doppler measurements/calculations
Velocity
Time
A/B ratio (velocities/frequency ratio)
PS (Peak Systole)
ED (End Diastole)
PS/ED (PS/ED Ratio)
ED/PS (ED/PS Ratio)
AT (Acceleration Time)

General Doppler measurements/calculations *(cont.)*
ACCEL (Acceleration)
TAMAX (Time Averaged Maximum Velocity)
Volume flow (TAMEAN and vessel area)
Heart rate
PI (Pulsatility Index)
RI (Resistivity Index)

Real-time Doppler auto measurements/calculations
PS (Peak Systole)
ED (End Diastole)
MD (Minimum Diastole)
PI (Pulsatility Index)
RI (Resistivity Index)
AT (Acceleration Time)
ACC (Acceleration)
PS/ED (PS/ED Ratio)
ED/PS (ED/PS Ratio)
HR (Heart Rate)
TAMAX (Time Averaged Maximum Velocity)
PVAL (Peak Velocity Value)
Volume Flow (TAMEAN and Vessel Area)

Abdominal measurements/calculations
Shear Elasto velocity
Shear Elasto stiffness
Attenuation rate
Attenuation coefficient
Summary reports

Small Parts measurements/calculations
Breast Lesion
Thyroid
Parathyroid
Lymph Node
Nodule
Isthmus AP
Shear Elasto velocity

Measurements/calculations *(cont.)*

Small Parts measurements/calculations *(cont.)*

Shear Elasto stiffness

Summary reports

OB measurements/calculations

Gestational age by	• GS (Gestational Sac) • CRL (Crown Rump Length) • FL (Femur Length) • BPD (Biparietal Diameter) • AC (Abdominal Circumference) • HC (Head Circumference) • APTD x TTD (Anterior/Posterior Trunk Diameter by Transverse Trunk Diameter) • FTA (Fetal Trunk Cross-sectional Area) • HL (Humerus Length) • BD (Binocular Distance) • FT (Foot Length) • OFD (Occipital Frontal Diameter) • TAD (Transverse Abdominal Diameter) • TCD (Transverse Cerebellum Diameter) • THD (Thorax Transverse Diameter) • TIB (Tibia Length) • ULNA (Ulna Length) • OOD (Outer Orbital Diameter) • IOD (Inner Orbital Diameter) • FIB (Fibula length) • Radius (Radius length) • LV (Lateral Ventricle width) (= SL)

Fetal graphical trending

Growth percentiles

Multi-gestational calculations (4)

Fetal qualitative description (anatomical survey)

Fetal environmental description (biophysical profile)

Programmable OB tables

Over 20 selectable OB calculations

Expanded worksheets

Estimated fetal weight (EFW) by:

AC, BPD

AC, BPD, FL

AC, BPD, FL, HC

AC, FL

AC, FL, HC

AC, HC

BPD, APTD, TTD, FL

BPD, APTD, TTD, SL

Calculations and ratios

FL/BPD

FL/AC

FL/HC

HC/AC

CI (Cephalic Index)

AFI (Amniotic Fluid Index)

CTAR (Cardio-Thoracic Area Ratio)

Measurements/calculations by: Alexander, ASUM, ASUM 2001, Bahlmann, Baschat, Berkowitz, Bertagnoli, Brenner, Campbell, CFEF, Chervenak, Chitty, Doubilet, Ebing, Eik-Nes Goldstein, Hadlock, Hansmann, Hellman, Hill, Hohler, Jeanty, JSUM, Kramer, Kurmanavicius, Kurtz, Mari, Mayden, Mercer, Merz, Moore, Nelson, Osaka University, Paris, Pexsters, Rempen, Robinson, Shepard, Shepard/Warsoff, Sonek, Tokyo University, Tokyo/Shinozuka, WHO, Williams, Yarkoni

OB measure assistant

Allows automatic measurement of BPD, HC, FL and AC

User editable

SonoNT and SonoIT

SonoNT measures the contour detection of the NT border

SonoIT is a system supported measurement for Intracranial Translucency

GYN measurements/calculations

Right ovary length, width, height

Left ovary length, width, height

Uterus length, width, height

Cervix length, trace

Ovarian volume

ENDO (Endometrial thickness)

Ovarian RI

Uterine RI

Follicular measurements

Fibroid measurements

Summary reports

Qualitative description (anatomical survey)

Measurements/calculations *(cont.)*

Vascular measurements/calculations

SYS DCCA (Systolic Distal Common Carotid Artery)

DIAS DCCA (Diastolic Distal Common Carotid Artery)

SYS MCCA (Systolic Mid Common Carotid Artery)

DIAS MCCA (Diastolic Mid Common Carotid Artery)

SYS PCCA (Systolic Proximal Common Carotid Artery)

DIAS PCCA (Diastolic Proximal Common Carotid Artery)

SYS DICA (Systolic Distal Internal Carotid Artery)

DIAS DICA (Systolic Distal Internal Carotid Artery)

SYS MICA (Systolic Mid Internal Carotid Artery)

DIAS MICA (Diastolic Mid Internal Carotid Artery)

SYS PICA (Systolic Proximal Internal Carotid Artery)

DIAS PICA (Diastolic Proximal Internal Carotid Artery)

SYS DECA (Systolic Distal External Carotid Artery)

DIAS DECA (Diastolic Distal External Carotid Artery)

SYS PECA (Systolic Proximal External Carotid Artery)

DIAS PECA (Diastolic Proximal External Carotid Artery)

VERT (Systolic Vertebral Velocity)

SUBCLAV (Systolic Subclavian Velocity)

Automatic IMT

Summary reports

Urological calculations

Bladder volume

Prostate volume

Left/right renal volume

Generic volume

Post-void bladder volume

Pelvic floor measurements

Probes *(All Optional)*

C1-6-D, XDclear™ convex probe

Applications: abdomen, OB/GYN, pediatric, peripheral vascular, general musculoskeletal

Biopsy guide: multi-angle, disposable with a reusable bracket (H4917VB)

C1-6VN-D, VNav inside XDclear convex probe

VNav sensor inside probe for Volume Navigation tracking without sensor cables

Applications: abdomen, OB/GYN, pediatric, peripheral vascular, general musculoskeletal

Biopsy guide: multi-angle, disposable with a reusable bracket (H4917VB)

C2-9-D, XDclear convex probe

Applications: abdomen, OB/GYN, pediatric, peripheral vascular, neonatal, neonatal transcranial, general musculoskeletal

Biopsy guide: multi-angle, disposable with a reusable bracket (H4913BA)

C2-9VN-D, VNav inside XDclear convex probe

VNav sensor inside probe for Volume Navigation tracking without sensor cables

Applications: abdomen, OB/GYN, pediatric, peripheral vascular, neonatal, neonatal transcranial, general musculoskeletal

Biopsy guide: multi-angle, disposable with a reusable bracket (H4913BA)

C2-7-D, micro convex biopsy probe

Applications: abdomen, pediatric

Biopsy guide: multi-angle, disposable with a reusable bracket (H40482LK), Multi-Angle, reusable stainless bracket (H40482LL)

C2-7VN-D, VNav inside micro convex biopsy probe

VNav sensor inside probe for Volume Navigation tracking without sensor cables

Applications: abdomen, pediatric

Biopsy guide: multi-angle, disposable with a reusable bracket (H40482LK), Multi-Angle, reusable stainless bracket (H40482LL)

C3-10-D, XDclear micro convex probe

Applications: abdomen, neonatal, pediatric, peripheral vascular, neonatal transcranial, small parts

IC5-9-D, micro convex probe

Applications: OB/GYN, urology

Biopsy guide: single angle, disposable with a disposable bracket (E8385MJ) or reusable bracket (H40412LN)

Probes *(cont.)*

P6D, CW split crystal probe

Applications: adult cardiac, pediatric cardiac, peripheral vascular, adult cephalic

M5Sc-D, XDclear sector probe

Applications: adult cardiac, pediatric cardiac, adult cephalic, abdominal

Biopsy guide: multi-angle, disposable with a reusable bracket (H45561FC)

L2-9-D, XDclear linear probe

Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal, superficial musculoskeletal, neonatal, neonatal transcranial

Biopsy guide: multi-angle, disposable with a reusable bracket (H44901AM)

L2-9VN-D, VNav inside XDclear linear probe

VNav sensor inside probe for Volume Navigation tracking without sensor cables

Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal, superficial musculoskeletal, neonatal, neonatal transcranial

Biopsy guide: multi-angle, disposable with a reusable bracket (H44901AM)

ML6-15-D, matrix array linear probe

Applications: abdomen, small parts, peripheral vascular, neonatal, pediatric, neonatal transcranial, general musculoskeletal, superficial musculoskeletal

Biopsy guide: multi-angle, disposable with a reusable bracket (H40432LJ)

L8-18i-D, linear probe

Applications: small parts, peripheral vascular, neonatal, neonatal transcranial, general musculoskeletal, superficial musculoskeletal, intraoperative

RAB6-D, convex volume probe

Applications: abdomen, OB/GYN, pediatric, neonatal

Biopsy guide: single angle, reusable bracket (H46701AE)

RIC5-9-D, convex volume probe

Applications: OB/GYN, urology

Biopsy guide: single angle, reusable (H46721R)

P2D, CW split crystal probe

Applications: adult cardiac, pediatric cardiac, peripheral vascular, adult cephalic

External Inputs and outputs (not including on-board peripherals)

HDMI

Ethernet

Multiple USB 3.0 ports

Safety conformance

The LOGIQ E10 is:
Classified to UL 60601-1 by a Nationally Recognized Test Lab
Certified to CAN/CSA-C22.2 No. 601.1-M90 by an SCC accredited test lab
CE Marked to Council Directive 93/42/EEC on medical devices
Compliant to Council Directive 2011/65/EU for RoHS

Conforms to the following standards for safety (including national deviations)	• EMC Emissions group 1 class A device requirements as per sub clause 4.2 of CISPR 11 • IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety • IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbance – Requirements and tests • IEC 60601-1-6 Medical electrical equipment Part 1-6 general requirements for basic safety and essential performance – Collateral standard: usability • IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment • IEC 62304 Medical device software – Software life-cycle processes • IEC 62366-1 Medical devices – Application of usability engineering to medical devices • ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Supplement: cardiac measurements/calculations

B-Mode measurements	
Aorta	• Aortic Root Diameter (Ao Root Diam) • Aortic Arch Diameter (Ao Arch Diam) • Ascending Aortic diameter (Ao Asc) • Descending Aortic Diameter (Ao Desc Diam) • Aorta Isthmus (Ao Isthmus) • Aorta (Ao st junct)
Aortic valve	• Aortic Valve Cusp Separation (AV Cusp) • Aortic Valve Area Planimetry (AVA Planimetry) • (Trans AVA)

B-Mode measurements *(cont.)*	
Left atrium	• Left Atrium Diameter (LA Diam) • LA Length (LA Major) • LA Width (LA Minor) • Left Atrium Diameter to AoRoot Diameter Ratio (LA/Ao ratio) • Left Atrium Area (LAA(d), LAA(s)) • Left Atrium Volume, Single Plane, Method of Disk (LAEDV A2C, LAESV A2C) (LAEDV A4C, LAESV A4C), (LAEDV A-L, LAEDV Index A-L, LAESV A-L, LAESV Index A-L)
Left ventricle	• Left Ventricle Mass (LVPWd, LVPWs) • Left Ventricle Volume, Teichholz/Cubic (LVIDd, LVI Ds) • Left Ventricle Internal Diameter (LVIDd, LVI Ds) Left Ventricle Length (LVLd, LVLs) • Left Ventricle Outflow Tract Diameter (LVOT Diam) • Left Ventricle Posterior Wall Thickness (LVPWd, LVPWs) • Left Ventricle Length (LV Major) • Left Ventricle Width (LV Minor) • Left Ventricle Outflow Tract Area (LVOT) • Left Ventricle Area, Two Chamber/Four Chamber/Short Axis (LVA (d), LVA (s)) • Left Ventricle Endocardial Area, Width (LVA (d), LVA(s)) • Left Ventricle Epicardial Area, Length (LVAepi (d), LVAepi (s)) • Left Ventricle Mass Index (LVPWd, LVPWs) • Ejection Fraction, Teichholz/Cube (LVIDd, LVIDs) • Left Ventricle Posterior Wall Fractional Shortening (LVPWd, LVPWs) • Left Ventricle Stroke Index, Teichholz/Cube (LVIDd, LVIDs and Body Surface Area) • Left Ventricle Fractional Shortening (LVIDd, LVIDs) • Left Ventricle Stroke Volume, Teichholz/Cubic (LVIDd, LVIDs) • Left Ventricle Stroke Index, Single Plane, Two Chamber, Method of Disk (LVI Dd, LVIDs, LVSd, LVSs) • Left Ventricle Stroke Index, Single Plane, Four Chamber, Method of Disk (LVI Dd, LVIDs, LVSd, LVSs) • Left Ventricle Stroke Index, Bi-Plane, Bullet, Method of Disk (LVAd, LVAs) • Interventricular Septum (IVS) • Left Ventricle Internal Diameter (LVI D) • Left Ventricle Posterior Wall Thickness (LVPW)

Supplement: cardiac measurements/calculations *(cont.)*

B-Mode measurements *(cont.)*	
Mitral valve	• Mitral Valve Annulus Diameter (MV Ann Diam) • E-Point-to-Septum Separation (EPSS) • Mitral Valve Area Planimetry (MVA Planimetry)
Pulmonic valve	• Pulmonic Valve Area (PV Planimetry) • Pulmonic Valve Annulus Diameter (PV Annulus Diam) • Pulmonic Diameter (Pulmonic Diam)
Right atrium	• Right Atrium Diameter, Length (RAD Ma) • Right Atrium Diameter, Width (RAD Mi) • Right Atrium Area (RAA) • Right Atrium Volume, Single Plane, Method of Disk (RAAd) • Right Atrium Volume, Systolic, Single Plane, Method of Disk (RAAs)
Right ventricle	• Right Ventricle Outflow Tract Area (RVOT Planimetry) • Left Pulmonary Artery Area (LPA Area) • Right Pulmonary Artery Area (RPA Area) • Right Ventricle Internal Diameter (RVIDd, RVIDs) • Right Ventricle Diameter, Length (RVD Ma) • Right Ventricle Diameter, Width (RVD Mi) • Right Ventricle Wall Thickness (RVAWd, RVAWs) • Right Ventricle Outflow Tract Diameter (RVOT Diam) • Left Pulmonary Artery (LPA) • Main Pulmonary Artery (MPA) • Right Pulmonary Artery (RPA)
System inferior vena cava	• Systemic Vein Diameter (Systemic Diam) • Patent Ductus Arterosis Diameter (PDA Diam) • Pericard Effusion (PEs) • Patent Foramen Ovale Diameter (PFO Diam) • Ventricular Septal Defect Diameter (VSD Diam) • Interventricular Septum (IVS) Fractional Shortening (IVSd, IVSs)
Tricuspid valve	• Tricuspid Valve Area (TV Panimetry) • Tricuspid Valve Annulus Diameter (TV Annulus Diam)

M-Mode measurements	
Aorta	• Aortic Root Diameter (Ao Root Diam) • Aortic Valve • Aortic Valve Diameter (AV Diam) • Aortic Valve Cusp separation (AV Cusp) • Aortic Valve Ejection Time (LVET)
Left atrium	• Left Atrium Diameter to AoRoot Diameter Ratio (LA/Ao Ratio) • Left Atrium Diameter (LA Diam)
Left ventricle	• Left Ventricle Volume, Teichholz/Cubic (LVIDd, LVI Ds) • Left Ventricle Internal Diameter (LVIDd, LVI Ds) • Left Ventricle Posterior Wall Thickness (LVPWd, LVPWs) • Left Ventricle Ejection Time (LVET) • Left Ventricle Pre-Ejection Period (LVPEP) • Interventricular Septum (IVS) • Left Ventricle Internal Diameter (LVI D) • Left Ventricle Posterior Wall Thickness (LVPW)
Mitral valve	• E-Point-to-Septum Separation (EPSS) • Mitral Valve Leaflet Separation (D-E Excursion) • Mitral Valve Anterior Leaflet Excursion (D-E Excursion) • Mitral valve D-E Slope (D-E Slope) • Mitral Valve E-F Slope (E-F Slope) • Mitral Annular Plane Systolic Excursion (MAPSE)
Pulmonic valve	• QRS Complex to End of Envelope (Q-PV close)
Right ventricle	• Right Ventricle Internal Diameter (RVIDd, RVIDs) • Right Ventricle Wall Thickness (RVAWd, RVAWs) • Right Ventricle Outflow Tract Diameter (RVOT Diam) • Right Ventricle Ejection Time (RVET) • Right Ventricle Pre-Ejection Period (RVPEP)
System	• Pericard Effusion (PE (d))
Tricuspid valve	• QRS Complex to End of Envelope (Q-TV close) • Tricuspid Annular Plane Systolic Excursion (TAPSE)

Supplement: cardiac measurements/calculations *(cont.)*

Doppler Mode measurements	
Aortic valve	• Aortic Insufficiency Mean Pressure Gradient (AR Trace) • Aortic Insufficiency Peak Pressure Gradient (AR Vmax) • Aortic Insufficiency End Diastole Pressure Gradient (AR Trace) • Aortic Insufficiency Mean Velocity (AR Trace) • Aortic Insufficiency Velocity Time Integral (AR Trace) • Aortic Valve Mean Velocity (AV Trace) • Aortic Valve Velocity Time Integral (AV Trace) • Aortic Valve Mean Pressure Gradient (AV Trace) • Aortic Valve Peak Pressure Gradient (AR Vmax) • Aortic Insufficiency Peak Velocity (AR Vmax) • Aortic Insufficiency End-Diastolic Velocity(AR Trace) • Aortic Valve Peak Velocity (AV Vmax) • Aortic Valve Peak Velocity at Point E (AV Vmax) • Aorta Proximal Coarctation (Coarc Pre-Duct) • Aorta Distal Coarctation (Coarc Post-Duct) • Aortic Valve Insufficiency Pressure Half Time (AR PHT) • Aortic Valve Flow Acceleration (AV Trace) • Aortic Valve Pressure Half Time (AV Trace) • Aortic Valve Acceleration Time (AV Acc Time) • Aortic Valve Deceleration Time (AV Dec Time) • Aortic Valve Ejection Time (AVET) • Aortic Valve Acceleration to Ejection Time Ratio (AV Acc Time, AVET) • Aortic Valve Area(VTI): AVA (Vmax)
Left ventricle	• Left Ventricle Outflow Tract Peak Pressure Gradient (LVOT Vmax) • Left Ventricle Outflow Tract Peak Velocity (LVOT Vmax) • Left Ventricle Outflow Tract Mean Pressure Gradient (LVOT Trace) • Left Ventricle Outflow Tract Mean Velocity (LVOT Trace) • Left Ventricle Outflow Tract Velocity Time Integral (LVOT Trace) • Left Ventricle Ejection Time (LVET)
Mitral valve	• E' Early diastolic mitral valve annular velocity (E') • E' Avg Averaged early diastolic mitral valve annular velocity (E' Avg) • E' Lat Early diastolic mitral valve lateral annular velocity (E' Lat) • E' Medial Early diastolic mitral valve medial annular velocity (E' Medial) • E' Sept Early diastolic mitral valve septal annular velocity (E'Sept)

Doppler Mode measurements *(cont.)*	
Mitral valve *(cont.)*	• Mitral inflow E velocity to E' ratio (E/E') • Mitral inflow E velocity to E' Avg ratio (E/E' Avg) • Mitral inflow E velocity to E' Lat ratio (E/E' Lat) • Medial Mitral inflow E velocity to E' Medial ratio (E/E') • Mitral inflow E velocity to E' Sept ratio (E/E' Sept) • Mitral Valve Regurgitant Flow Acceleration (MR Trace) • Mitral Valve Regurgitant Mean Velocity (MR Trace) • Mitral Regurgitant Mean Pressure Gradient (MR Trace) • Mitral Regurgitant Velocity Time Integral (MR Trace) • Mitral Valve Mean Velocity (MV Trace) • Mitral Valve Velocity Time Integral (MV Trace) • Mitral Valve Mean Pressure Gradient (MV Trace) • Mitral Regurgitant Peak Pressure Gradient (MR Vmax) • Mitral Valve Peak Pressure Gradient (MV Vmax) • Mitral Regurgitant Peak Velocity (MR Vmax) • Mitral Valve Peak Velocity (MV Vmax) • Mitral Valve Velocity Peak A (MV A Velocity) • Mitral Valve Velocity Peak E (MV E Velocity) • Mitral Valve Area According to PHT (MV PHT) • Mitral Valve Flow Deceleration (MV DecT) • Mitral Valve Pressure Half Time (MV PHT) • Mitral Valve Flow Acceleration (MV AccT) • Mitral Valve E-Peak to A-Peak Ratio (A-C and D-E) (MV E/ARatio) • Mitral Valve Acceleration Time • (MV Acc Time) • Mitral Valve Deceleration Time (MV Dec Time) • Mitral Valve Ejection Time ((MVET) • Mitral Valve A-Wave Duration (MV A Dur) • Mitral Valve Time to Peak (MV TTP) • Mitral Valve Acceleration Time/Deceleration Time Ratio (MVAcc/Dec Time) • Stroke Volume Index by Mitral Flow (MVA Planimetry, MVTrace)
Pulmonic valve	• Pulmonic Insufficiency Peak Pressure Gradient (PR Vmax) • Pulmonic Insufficiency End-Diastolic Pressure Gradient (PRTrace) • Pulmonic Valve Peak Pressure Gradient (PV Vmax) • Pulmonic Insufficiency Peak Velocity (PR Vmax)

Supplement: cardiac measurements/calculations *(cont.)*

Doppler Mode measurements *(cont.)*	
Pulmonic valve *(cont.)*	• Pulmonic Insufficiency End-Diastolic Velocity (Prend Vmax) • Pulmonic Valve Peak Velocity (PV Vmax) • Pulmonary Artery Diastolic Pressure (PV Trace) • Pulmonic Insufficiency Mean Pressure Gradient (PR Trace) • Pulmonic Valve Mean Pressure Gradient (PV Trace) • Pulmonic Insufficiency Mean Square Root Velocity (PR Trace) • Pulmonic Insufficiency Velocity Time Integral (PR Trace) • Pulmonic Valve Mean Velocity (PV Trace) • Pulmonic Valve Velocity Time Integral (PV Trace) • Pulmonic Insufficiency Pressure Half Time (PR PHT) • Pulmonic Valve Flow Acceleration (PV Acc Time) • Pulmonic Valve Acceleration Time (PV Acc Time) • Pulmonic Valve Ejection Time (PVET) • QRS Complex to End of Envelope (Q-to-PV Close) • Pulmonic Valve Acceleration to Ejection TIme Ratio (PV Acc Time, PVET)
Right ventricle	• Right Ventricle Outflow Tract Peak Pressure Gradient (RVOT Vmax) • Right Ventricle Outflow Tract Peak Velocity (RVOT Vmax) • Right Ventricle Outflow Tract Velocity Time Integral (RVOTTrace) • Right Ventricle Ejection Time (RV Trace) • Stroke Volume by Pulmonic Flow (RVOT Planimetry, RVOTTrace) • Right Ventricle Stroke Volume Index by Pulmonic Flow (RVOT Planimetry, RVOT Trace)
System	• Pulmonary Artery Peak Velocity (PV Vmax) • Pulmonary Vein Velocity Peak A (Reverse) (P Vein A) • Pulmonary Vein Peak Velocity (P Vein D, P Vein S) • Systemic Vein Peak Velocity (PDA Diastolic, PDA Systolic) • Ventricular Septal Defect Peak Velocity (VSD Vmax) • Atrial Septal Defect (ASD Diastolic, ASD Systolic) • Pulmonary Vein A-Wave Duration (P Vein A Dur) • IsoVolumetric Relaxation Time (IVRT) • IsoVolumetric Contraction Time (IVCT)

Doppler Mode measurements *(cont.)*	
System *(cont.)*	• Pulmonary Vein S/D Ratio (P Vein D, P Vein S) • Ventricular Septal Defect Peak Pressure Gradient (VSD Vmax) • Pulmonic-to-Systemic Flow Ratio (Qp/Qs)
Tricuspid valve	• Tricuspid Regurgitant Peak Pressure Gradient (TR Vmax) • Tricuspid Valve Peak Pressure Gradient (TV Vmax) • Tricuspid Regurgitant Peak Velocity (TR Vmax) • Tricuspid Valve Peak Velocity (TV Vmax) • Tricuspid Valve Velocity Peak A (TV A Velocity) • Tricuspid Valve Velocity Peak E (TV E Velocity) • Tricuspid Regurgitant Mean Pressure Gradient (TR Trace) • Tricuspid Valve Mean Pressure Gradient (TV Trace) • Tricuspid Regurgitant Mean Velocity (TR Trace) • Tricuspid Regurgitant Velocity Time Integral (TR Trace) • Tricuspid Valve Mean Velocity (TV Trace) • Tricuspid Valve Velocity Time Integral (TV Trace) • Tricuspid Valve Time to Peak (TV TTP) • Tricuspid Valve Ejection Time (TV Acc/ Dec Time) • Tricuspid Valve A-Wave Duration (TV A Dur) • QRS Complex to End of Envelope (Q-TV Close) • Tricuspid Valve Pressure Half Time (TV PHT) • Stroke Volume by Tricuspid Flow (TV Planimetry, TV Trace) • Tricuspid Valve E-Peak to A-Peak Ratio (TV E/A Velocity)

Color Flow Mode measurements	
Aortic valve	• Proximal Isovelocity Surface Area: Regurgitant Orifice Area (AR Radius) • Proximal Isovelocity Surface Area: Radius of Aliased Point (AR Radius) • Proximal Isovelocity Surface Area: Regurgitant Flow (AR Trace) • Proximal Isovelocity Surface Area: Regurgitant Volume Flow (AR Trace) • Proximal Isovelocity Surface Area: Aliased Velocity (AR Vmax)

Supplement: cardiac measurements/calculations *(cont.)*

Color Flow Mode measurements *(cont.)*

Mitral valve	• Proximal Isovelocity Surface Area: Regurgitant Orifice Area (MR Radius) • Proximal Isovelocity Surface Area: Radius of Aliased Point (MR Radius) • Proximal Isovelocity Surface Area: Regurgitant Flow (MR Trace) • Proximal Isovelocity Surface Area: Regurgitant Volume Flow (MR Trace) • Proximal Isovelocity Surface Area: Aliased Velocity (MR Vmax)

Combination Mode measurements

Aortic valve	• Aortic Valve Area (Ao Root Diam, LVOT Vmax, AV Vmax) • Aortic Valve Area by Continuity Equation by Peak Velocity (Ao Root Diam, LVOT Vmax, AV Vmax) • Stroke Volume by Aortic Flow (AVA Planimetry, AV Trace) • Cardiac Output by Aortic Flow (AVA Planimetry, AV Trace, HR) • Aortic Valve Area by Continuity Equation VTI (Ao Root Diam, LVOT Vmax, AV Trace)
Left ventricle	• Cardiac Output, Teichholz/Cubic (LVIDd, LVI Ds, HR) • Cardiac Output Two Chamber, Single Plane, Area-Length/Method of Disk(Simpson) (LVAd, LVAs, HR) • Cardiac Output Four Chamber, Single Plane, Area-Length/Method of Disk (Simpson) (LVAd, LVAs, HR) • Ejection Fraction Two Chamber, Single Plane, Area-Length/Method of Disk (Simpson) (LVAd, LVAs) • Ejection Fraction Four Chamber, Single Plane, Area-Length/Method of Disk (Simpson) (LVAd, LVAs) • Left Ventricle Stroke Volume, Single Plane, Two Chamber/Four Chamber, Area-Length (LVAd, LVAs) • Left Ventricle Stroke Volume, Single Plane, Two Chamber/Four Chamber, Method of Disk (Simpson) (LVIDd, LVIDs, LVAd, LVAs) • Left Ventricle Volume, Two Chamber/Four Chamber, Area-Length (LVAd, LVAs)

Combination Mode measurements *(cont.)*

Left ventricle *(cont.)*	• Ejection Fraction, Bi-Plane, Method of Disk (LVAd, LVAs, 2CH, 4CH) • Left Ventricle Stroke Volume, Bi-Plane, Method of Disk (LVAd, LVAs, 2CH, 4CH) • Left Ventricle Volume, Bi-Plane, Method of Disk (LVAd, LVAs, 2CH, 4CH) • Left Ventricle Stroke Index, Single Plane, Two Chamber/Four Chamber, Area-Length (LVSd, LVSs and BSA) • Left Ventricle Volume, Single Plane, Two Chamber/Four Chamber, Method of Disk (LVAd, LVAs) • Left Ventricle Volume, Apical View, Long Axis, Method of Disk (LVAd, LVAs)
Mitral valve	• Stroke Volume by Mitral Flow (MVA Planimetry, MV Trace) • Cardiac Output by Mitral Flow (MVA Planimetry, MV Trace, HR)
Pulmonic valve	• Stroke Volume by Pulmonic Flow (PV Planimetry, PV Trace) • Cardiac Output by Pulmonic Flow (PV Planimetry, PV Trace, HR)
Tricuspid valve	• Cardiac Output by Tricuspid Flow (TV Planimetry, TV Trace, HR)

Cardiac worksheet

Parameter: lists the mode, the measurement folder and the specific measurement
Measured Value: Up to six measurement values for each item. Average, maximum, minimum or last

Generic study in cardiology

Stroke Volume (SV)
Cardiac Output (CO)

Ultrasound General Imaging

GE LOGIQ E10s

GE LOGIQ E10s

H46612EC– LOGIQ E10s

GENERAL PURPOSE HIGH END PREMIUM ULTRASOUND SYSTEM

LOGIQ E10s High End Ultrasound System - Overview

Empowering You to Make the Difference

Every day, you have the opportunity to **make a real difference in the lives of your patients**. At GE Healthcare, we want to enable you to do just that with the new **LOGIQ™ E10s** – by supporting your expertise and helping you to elevate your practice to the **next level. LOGIQ E10s** is designed for you – so you can make **confident diagnosis** using **comprehensive tools** and achieve a **new standard of concise workflow.**

The **LOGIQ E10s** is GE's premium ultrasound imaging system designed for abdominal, vascular, obstetric, gynecologic, neonatal, pediatric, urological, transcranial, cardiac and small parts applications.

The Next Generation Imaging System delivers :

- **Huge data throughput**
- **Massive compute power**
- **Real-time deep learning inference engine**

The Next Gen Digital Platform :

- **Cloud connected**
- **Smart device compatibility**
- **Big data enabled**

The heart of the Imaging systems is the

cSound™ Architecture

Combines the power **of XDclear™** probes with a new **cSound Imageformer** to enable confident diagnosis, comprehensive tools and concise workflow.

cSound Imageformer

Significantly more data is collected and used to create every image, requiring extraordinary processing power and data throughput. Enables focus at every pixel, as well as improved spatial and contrast resolution.

The **cSound** Architecture is a new imaging platform that has taken ultrasound to a higher level processing all the RF channel data, and presenting it in meaningful ways.
Enabled by incredible data throughput 48x and 10x processing power
- Better focusing for improved spatial and contrast resolution.
- Increased uniformity throughout image
- Fewer transmits, no Focal Zones ⟶ higher frame rates
- More like CT & MR with acquisition and then reconstruction… but in real time
- The **cSound Imageformer** runs on advanced GPU hardware technology
- Image formation algorithms are software based, allowing for future flexibility

As a result, **cSound acquires more data up front, achieves consistent information**

across a wide variety of patients and may reduce the number of suboptimal
cSound performance elevates patient care by providing exceptional visualization quality with impressive penetration and/or high sensitivity while maintaining high spatial resolution in 2D, color flow, Doppler and 4D formats.

⟹ **2D** Elevated performance in:
- o **Crystal clear near field - *Low haze, High contrast***
- o *Uniformity throughout the image - No focal zone required*
- o **Fast frame rates - *Scan quickly without blurring***
- o Penetration

⟹ **Color/PDI** mode :
- o *Up to 3X frame rate*
- o High spatial resolution/sensitivity
- o Easy to use **-** *Simplified user interface, Customizable flow shortcuts*

⟹ **Doppler** mode :
- o *Strong PW signal - Improved sensitivity- Enhanced axial and lateral resolution*
- o *Great simultaneous – Triplex, B-Flow™ + PW, CW Simul*
- o *Clean CW - No horizontal line noise*
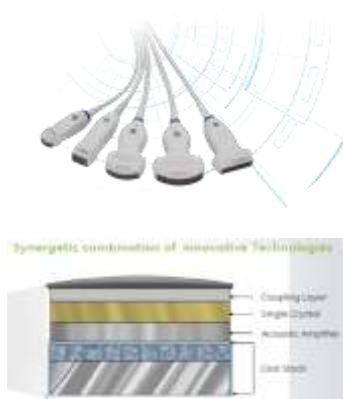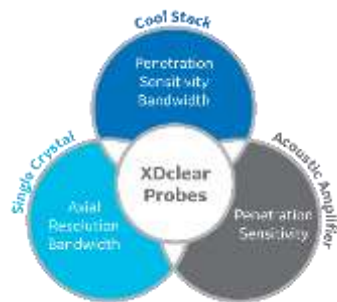
Advanced Probe Technology

❖ **XDclear probes** **XDclear probes deliver the high fidelity acoustic input that is at the heart of any great ultrasound image - XDclear helps increase penetration and simultaneously delivers high definition resolution throughout the image.** XD = Extreme Resolution at Extended Depth

Achieve exceptional tissue and detail resolution with **XDclear probes** – the combination of **single crystal**, **acoustic amplification,** and **cool stack technology** offers sharp imaging even with difficult to scan patients

- ▪ **Single Crystal:** Advanced piezoelectric material that delivers high quality acoustic signal
- ▪ **Acoustic Amplifier:** Innovative design that captures and redirects the unused energy that passes through the crystal
- ▪ **Cool Stack:** Patented technology integrated into the transducer's internal architecture that relieves inherent heat generation that can otherwise reduce sensitivity and penetration
- ▪ **XDclear probes supported** :
  - **L2-9-D/L2-9VN-D** linear probe with XDclear technology
  - **M5Sc-D** Matrix sector probe with XDclear technology for cardiac imaging
  - **C1-6-D/C1-6VN-D** Convex probe with XDclear technology helps achieve impressive depth on patients with difficult body habitus
  - **C2-9-D/C2-9VN-D** Convex probe with XDclear technology provides ultra-wide bandwidth and superb image quality for pediatric, obstetric and abdominal exams
  - **C3-10-D** Convex probe for pediatric and neonatal exams

❖ **Active Matrix Array probe technology**
Exceptional image quality and versatility by using matrix array technology. Elements arranged in rows and columns. Enables beamforming in 3 dimensions. Uniform beam thickness. Longer focal zone. Improved 'ouf of plane' focus. Multiple focusing. No compromise between penetration & near field resolution problem. Versatility. Increased contrast and spatial resolution from near to far field.

The Next Gen Digital Platform – Vision of 'Digital Assistant' for the future

Smart device compatibility

Cloud connectivity

Generate big data and deploy deep learning

The Digital Platform is Aware of what is all around to be able to Assist with several solutions. The Digital platform can be represented with the following main pillars:

- **App Assistant**, requiring a Smart connectivity to devices (Photo Assistant and Remote scanning);
- **Analytical Assistant**, availability of Data to perform **Remote Clinical and Apps support, APM,** Cloud connectivity
- **Anatomical Assistant**, AI-based algorithms to help improve productivity and support diagnosis (e.g. Lesion Auto segmentation, OB Auto measurements, Doppler Assistant). The machine becomes aware of what you are scanning while it is scanned

Refer to : "A to A' Digital Platform White Paper" for in-depth information

The Next generation ergonomics

Console design
- **4 active probe ports + 1 inactive probe storage port**
- Integrated **SSD** (**1 TB**)
- Integrated **DVD-R Multi Drive**
- On-board storage of thermal printer
- Integrated locking mechanism that provides rolling lock and caster swivel lock
- Front and rear handles
- Easily removable air filters

Operator keyboard
Floating keyboard adjustable in three dimensions
- • Height
- • Rotation
- • Extension

Full-sized, backlit alphanumeric keyboard

Touch screen 12.1'' High-resolution, color, touch, display screen.
Possibility to optimize the UI and Touchscreen icons and settings to create a personalized UI. Research and Clinical Modes available.

Display monitor
- **22'' Wide screen** high-resolution **OLED** display
- Display translation (independent of console)
- Fold-down and lock mechanism for transportation
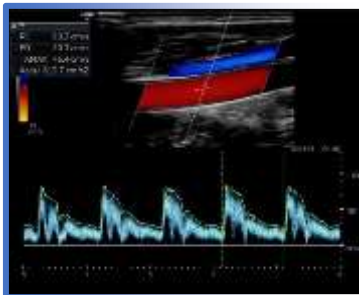- Monitor locking system

Designed for easy disinfection

- Sealed keyboard
- 23 compatible cleaners
- Embedded speakers
- Digital TGCs
- Single surface touch panel

LOGIQ E10s configuration offer – Technical description
## Modes of Operation

- **Modes of operation**: B-Mode (2D), M-Mode, PW Doppler, Color Flow Mode (CFM), Power Doppler Imaging, Double / triplex capability, Tissue Doppler Imaging – **Real Time Triplex** . Dual & Quad capability B-Mode

- **PDI** Incorporates GE proprietary Coded Excitation Technology for a new flow processing chain.

    - Achieves high spatial resolution and high sensitivity at shallow depth, and simultaneously penetrate more at a deep depth

- **Microvascular imaging (MVI) : High definition flow** Help assess blood flow with ease in the joints, lymph nodes, and other small structures. Available on : **C1-6-D, L2-9-D, ML6-15-D, L8-18i-D.**

    Provides :

    - Continuous scan sequence
    - Achieve high frame rate - Show hemodynamics
    - Remarkable sensitivity with high resolution - Detects slow flow and small vessels with new clutter filtering
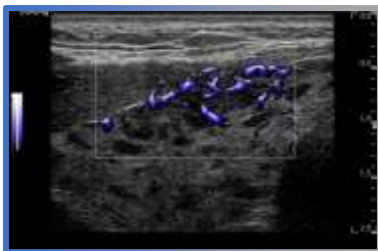
    Applications :

    - Finger or wrist to assess inflammation
    - Improve visualization of a foreign body
    - Renal (transplants, etc.) to assess perfusion in areas of ischemia
    - Superficial liver lesions for flow patterns
    - Pediatric scrotal imaging to assess inflammation or torsion
    - Lymph node to note inflammation or suspicious breast CA
    - Pediatric imaging to evaluate lumps/bumps
    - Neonatal head perfusion

- **Radiantflow™** Easy, fast visualization of tiny vessels, displaying as a 3D effect. **Supports detailed vascular imaging**

    - Optimized for small vessel imaging
    - Provides a near-3D look
    - Excellent when combined with Micro Vascular Imaging (MVI)

- **Coded Tissue Harmonic Imaging** – for improved S/N Ratio and Contrast Resolution especially on difficult to scan patients. Available on all 2D/3D/4D

probes

- **Anatomical M-Mode** Can be activated from a CINE loop from a live or stored image. Available also with Color Flow Mode

- **Curved anatomical M-Mode:** Free (curved) drawing of M-Mode generated from the cursor independent from the axial plane

- **Advanced 3D** – Multiplanar display of Anatomy

- **Speed of sound** (application dependent)

- **Transducer types**: Convex Array, Linear Array, Active Matrix Array (Linear, Sector), Sector phased array, Single Crystal, Volume Probes (convex, microconvex) with WIDE BAND multifrequency technology.

- Maximum Penetration **Depth : 50 cm**

- **HD-Zoom** High Definition Zoom (Write) Read Zoom (Real Time, Frozen, recalled images)

- **1 GB** cine memory

- *Post processing & Pre-processing*

CLINICAL EXCELLENCE

Advanced Techniques (Integrated)

❖ **CrossXBeam CRI (Compound Resolution Imaging)** Spatial compounding acquisition technique for enhancing tissue and border differentiation. CRI acquiries images from different beam steering directions. The images are combined to enhance physiological features and reduce artifacts and speckle. It offers:
- Improved appearance of physiological structures. Enhanced contrast through reduction of speckle and noise.
- Less artifacts (shadowing)
- Available on all convex, microconvex and linear probes & on all modes

❖ **Speckle Reduction Imaging (SRI-HD)** is a technology improving both contrast resolution and border detection. At the same time the unwanted ultrasound characteristic patterns (SPECKLE) are greatly reduced. Optimized Algorithm offers:
- Enhancement of object boundaries and small physiological features.
- Reduction of noise and speckle in homogenous regions
- Feature detection optimizes enhancement based on the size and orientation of physiological structures
- Selective adjustment of the smoothing reduces speckle and noise while preserving detail
- Available on all probes.

SRI Type 1
- – Compatible with all linear, convex and sector probes

SRI Type 3
- – Compatible with selected linear probes for MSK

❖ **Automatic Optimization**

Automatic Optimization – "Optimal Image Quality upon your Finger Tip"
- Optimizes B-Mode
- Auto-spectral optimize– adjusts baseline, invert, PRF, (on live image), and angle correction
- **Doppler Assistant Tool** using AI algoriths for **Auto CF and PW positioning** - vessel recognition for automated ROI placement and steering (*powered by Edison– Anatomical Assistant tool*)

AI-based Auto Doppler Assistant (*powered by Artificial Intelligence*)

Doppler Assistant determines the location and direction of vessels
Benefit:
- Keystrokes are reduced as the color ROI and Doppler gate are automatically placed
- Results are appropriate for venous versus atrial exams even when both types of vessels are present

Auto Lesion Segmentation - liver, breast & thyroid *(powered by Artificial Intelligence)*

User clicks on the lesion and simply expands a graphical circle to encompass it
- **Benefit:** User identifies a lesion with a single click

The algorithm segments the lesion, providing a trace and extents of the lesion
- **Benefit:** Calipers are automatically placed to measure the lesion, saving keystrokes and providing consistency

B-Flow (integrated)

Technology to visualize real-time hemodynamic flow and vessel wall definition. B-Flow helps provide high resolution / high frame rates of B-Mode imaging with the ability to detect and display real-time blood flow. Sensitivity adjustments for excellent visualization of high and low flow states, small vessels and enhanced sensitivity. Displays true haemodynamics and enables direct visualization of blood flow **without the limitations of Doppler** :
- No overwriting of vessel walls
- No tissue overwriting
- No frame rate impact
- Less angle dependency
- Less 'blooming'
- Background image clearly visible
- High resolution Imaging

B-Flow imaging is based on GE's patented **Digitally Encoded Ultrasound technique** that boosts weak blood signals and suppresses strong tissue signals. Advantages of direct hemodynamic visualization include:
- Vascular stenosis
- Carotid plaque for vulnerability study (e.g. ulceration)
- Interaction of blood flow with anatomical structures inside the vessel such as venous valve cusps and thrombi
- Grafts for monitoring (e.g. dialysis graft or pseudoaneurysms)
- Kidney perfusion (e.g. after transplants)
- Vascular complications after transfemoral catheterization (e.g. AV fistula, dissections, hematomas)
- Liver and spleen vasculature
- Neonatal head vessels
- Fetal cardiac septal defects (e.g. PFO, VSD, ASD)

Available on **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, ML6-15-D, M5Sc-D and L8-18i-D** probes

Hybrid B-Flow (integrated)

- Side-by-side, simultaneous display of B-Mode and B-Flow` images to facilitate assessment of carotid stenosis, fetal brain, and other studies
- B-Flow Capture with Reconstruction provides a three-dimensional view of blood vessels in which artifacts are automatically suppressed and weak vessel signals enhanced
-
- Available on **C1-6-D, C2-9-D, L2-9-D, ML6-15-D, L8-18i-D** probes

H46622LF   Strain Elastography including Quantification (included)

Strain Imaging Technology requiring a light manual compression or vessel pulsation to perform tissue deformation.

- Light manual compression to perform tissue deformation
- Qualitative and semi-quantitative information
- Focus: Oncology, inflammatory disease

Highlights:

- High sensitivity and persistence
- Consistent pattern
- User selectable color maps
- Dedicated color map for liver using physiological pulsation Dual measurements
- User support by pressure quality bar and graph
- Working in **combination with Volume Navigation (V Nav)**

Availability on the following probes :

- L2-9-D/L2-9VN-D (Small Parts, Abdomen, MSK)
- IC5-9-D (Urology, Gyn)
- C1-6-D/C1-6VN-D (Abdomen)
- C2-9-D/C2-9VN-D (Abdomen, Pediatrics)
- ML6-15-D (Small Parts/Breast, MSK)
- L8-18i-D (Small Parts/Breast, MSK)
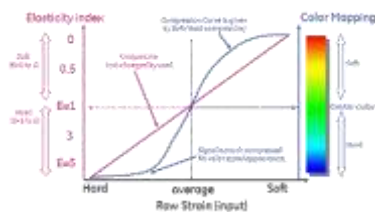
Elastography Quantification

Semi-quantitative assessment of tissue stiffness quantifies color distribution numerically and provides a more objective information with Q-Analysis: E-Index and E-Ratio over a multiframe acquisition

E-Index
- Selected ROI's elasticity value
- Round or manual tracing of ROI
- E-Index range from 0 – 6 >Based on GE Raw Data Processing

E-Ratio
- Calculated E-Index ratios between ROI's (up to 8)
- Representing relative stiffness

Q-Analysis
- Automatic skip of low quality frames
- Anchor function >Trace export in ASCII format

H46622LE   LE10s Shear Wave Elastography   (Included)
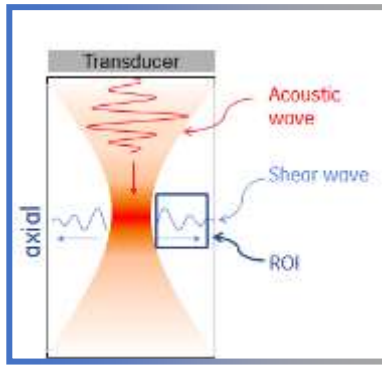

Liver Shear Wave Elastography, C1-6-D

2D Shear Wave elastography technique (visual and quantitative information in a color coded box)

Shear wave elastography on the LOGIQ E10 is an ultrasound imaging mode in which shear waves are generated in-vivo acoustically via the imaging ultrasound transducer. The motion of the shear waves is then tracked using ultrasound to determine their velocity of propagation, which is a quantifiable indicator of the mecha nical properties of the tissue through which it traveled.

- o Focused burst of acoustic energy to perform tissue deformation through a comb-push excitation
- o Color coded elastogram and quantitative measurements
- o Focus: Chronic liver disease, oncology
  - **Records up to 12 sample values for each series:**
  - **Displays Mean, Median, IQR and STD of the average of multiple series**
 - **Allows easy deletion, exclusion and quick replacement of**

measurements

- **Allows annotations for different organ measurements**
- User selectable color maps
- **Adjustable Color Box** and **ROI depth** and **size**
- Multiple measurements within a single shear wave image
- **Auto sequencing feature** for an automatic placement of measurement ROI within image
- Dual or Single display option
- Measurements in **kPa or m/s or both**
- Mean, Median, IQR and STD display for multiple measurements
- Fast acquisition time to reduce motion artifacts
- **Penetration mode** for technically challenging cases
- Summary worksheet
- Supporting GE Raw Data
- Measurements can be done on acquired clips after the exam is ended
- Working in combination with Volume Navigation and Needle Tracking
- Comprehensive tool for liver disease management

Available on the following Transducers
- **C1-6-D/C1-6VN-D (Abdomen)**
- **L2-9-D/L2-9VN-D (Small Parts, Breast, MSK)**
- **ML6-15-D (Small Parts, Breast, MSK)**

Both stiffness and velocity

Refer to : "2D-Shear Wave Elastography White Paper" for more information

H46622LM   LOGIQ E10s Coded Contrast Option (Included)

CEUS Renal Mass, C1-6VN-D

Prostate CEUS, IC5-9-D

CEUS Abdominal Mass, C1-6VN-D
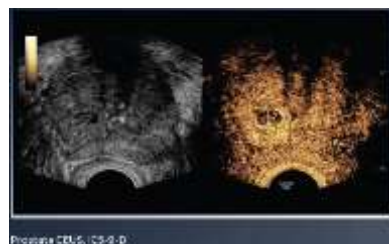
Contrast agent imaging with the LOGIQ™ E10 system enables clinicians to get a clear picture of tissue structure and lesion vascularity by optimizing the balance between penetration and resolution for improved contrast sensitivity. This helps enhance the clinician's ability to detect and characterize lesions. The system's next-generation **cSound™ Architecture** provides additional penetration power for even high BMI cases.

Auto-optimized images: The **cSound Imageformer** automatically and continuously delivers images of high quality across a wide range of clinical scenarios. Extraordinary images are quickly obtained resulting in efficient studies, particularly
- Static & Quick 3D Imaging
- Multiple displays: DualView, Single and Hybrid
- Accumulation: Adds/accumulates image frame by frame
- Max Enhance & Flash: Quick 100% acoustic output
- Intermittent Imaging: From .05 to 10 second delay

Amplitude Modulation (AM): This sophisticated, highly sensitive imaging technique enhances visualization by combining excellent tissue suppression with outstanding penetration. AM waveforms enable excellent imaging, particularly in technically difficult patients.

Phase Inversion (HRes) Multiple PI waveforms enable superb spatial and temporal resolution in a variety of clinical applications ranging from abdominal to superficial examinations.

Flexible imaging modes: Modes include:
- Single image (B-Mode, CEUS or Hybrid)
- Live dual display (B-Ref and CEUS)
- Hybrid Mode (overlay of B-Ref and CEUS)
- Static 3D creates a single volume image
- Quick 3D CEUS enables a continuous contrast volume sweep and store

in one step
- Volume Navigation
- B-Flow™ imaging can be used in combination with

Available with a **variety of probes** for **excellent clinical flexibility** :
- Abdominal imaging (C1-6-D, C1-6VN-D, C2-9-D, C2-9VN-D, C2-7-D, C2-7VN-D, C3-10-D)
- Superficial imaging (ML6-15-D, L2-9-D, L2-9VN-D)
- Endocavitary imaging (IC5-9-D, RIC 5-9-D)
- Vascular imaging (ML6-15-D, L2-9-D, L2-9VN-D)
- Cardiology (M5Sc-D)
- Interventional (C2-7-D, C2-7VN-D)
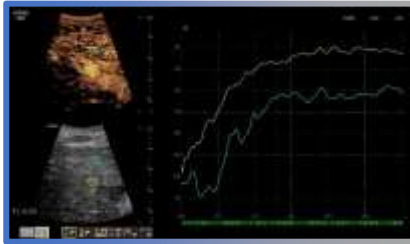
AM/PI: Combined waveforms enable excellent spatial resolution, image uniformity and penetration.

Time Intensity Curve (TIC) Using the raw data cine clip, clinicians can easily analyze the speed, intensity and dispersion of contrast microbubbles to assess wash-in/wash-out curves of multiple regions of interest.
- Up to eight user-selectable regions of interest (ROIs)
- Eight parameters for Q-Analysis on compressed and uncompressed data
- Motion correction
- ROI anchor function
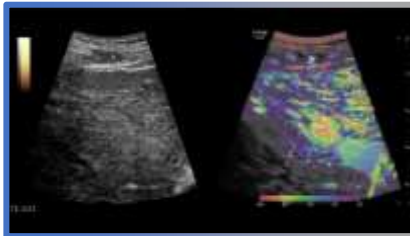
Contrast Parametric Imaging Arrival Time analysis of contrast-enhanced raw data cine clips. This raw data post-processing tool enables **visualization of microbubble arrival times** throughout the entire image. The resulting color-mapped image provides information that can help **support accurate lesion characterization.**

OPERATIONAL EFFICIENCY

Raw Data Processing (integrated)

The foundation for easy workflow - Now with dual display
Raw data capture enables you to build a thorough exam while reducing scan time. This **proprietary raw data format** from GE Healthcare captures data earlier in the image processing chain enabling users to make changes to the data during or even after the exam has ended.

Original Acoustic Data are stored before scan converting in a GE "raw" format to be easily accessed and re-processed any time after the exam completion.

Highlights
- Sub-optimal studies can be optimized
- Measurements can be re-done and reports regenerated
- All Imaging control parameters can be changed as:
  - B-Mode: Gain, DR, AO, Zoom, SRI
  - CFM: Gain, Threshold, DualView, DR
  - PW: Baseline, Invert, Angle, DR, Gain

Start Assistant (Integrated)

Automatically select category, probe, preset, or scan assistant from worklist exam description
Learn the category, probe, preset, and scan assistant based on exam description

Compare Assistant (Integrated)
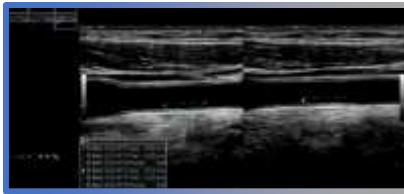
A workflow enhancement tool that **enables <u>easy side by side comparison of previous ultrasound or other modality images with live ultrasound image</u>**. Compare Assistant retrieves prior exams for side-by-side comparisons that assist in exam set-up and helps enable confident interpretations.
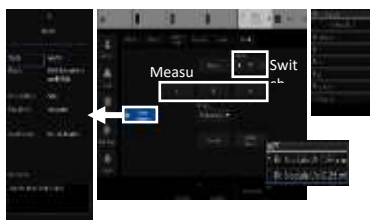
Easy access to past exam data on the scanner

Side-by-side compare and store past exam image to today's image

Set image settings of live scanning to match past exam image1

Create entire new exam to match old exam

Thyroid Productivity Package (Integrated)

Thyroid-specific measurement package that easily enables labeling, measuring and describing nodules, lymph nodes and parathyroids. Multiple measurements can be organized into a convenient worksheet. Send results via DICOM$^®$ SR.

Breast Productivity Package (Integrated)

A dedicated breast-specific measurement package that allows users to:

- Make labeling, measuring and describing lesion easy
- Leverage the BI-RADS® lexicon criteria/assessment
- Organizes multiple measurements into a convenient worksheet
- Send results via DICOM® SR

Invasive Procedures

The LOGIQ™ E10s system provides superb, high resolution images for clear visualization of soft tissue organs. The portability of the system along with its innovative navigation and workflow tools are designed to help increase the efficiency of interventional procedures.

Choice of high performance probes – The system offers both E-Series and XDclear probes, which are GEs highest performing probes. Advancements in acoustic engineering help increase penetration and deliver high definition resolution.

Measurements – Archiving – Connectivity (Integrated)

- ❖ Comprehensive software annotations, measurements, calculations, and worksheets supporting **general imaging, abdominal, renal, vascular, cardiac, gynecological, obstetrical, multigestational, Fetal Trending, neonatal, pediatric, Hip Dysplasia, urological transcranial, small parts** applications
- ❖ Measurements/Calculations & Annotations on CINE Playback
- ❖ Factory default preset data
- ❖ User programmable preset capability Onboard Tailored & programmable scanning protocols (increased exams standardization, operational efficiency -
- ❖ Real-time automatic doppler calculations

- ❖ **Internal Patient Archive** (Integrated Management Workstation) allows archiving of 2D, Doppler, Color Doppler still images as well as cine frames and Volume (3D/4D) images. Images are stored in a proprietary Raw Data Format which allows optimizing images on either frozen images as well as on retrieved images
    - Storage formats: DICOM
        - Compressed/uncompressed
        - Single/multi-frame
        - Enhanced (3D/4D)
        - With/without raw data
    - Export JPEG, JPEG 2000, WMV (MPEG 4) formats
    - Compare previous exam images with current exam
    - Reload of archived data sets
    - Easy Back Up – secure Backup of Patient data
    - On-board database of patient information from past exams
- ❖ **HDMI** output available for compatible devices
- ❖ **Ethernet**
- ❖ **Multiple USB 3.0 ports**

LOGIQ E10 Gel Warmer (integrated)

New digital features support security, uptime, and utilization

Privacy & Security Package -Sonodefence (Integrated)

SonoDefense is designed for maximum security protection with a defense-in-depth strategy that incorporates security controls deployed in multiple layers. This approach enhances security by protecting the system against any particular attack using several independent methods.

- Keeps the machine functional in the face of cyber threats
- Protects the patient data on the machine from unauthorized access
- Enables you to successfully implement their HIPPA and security policies and still manage your daily workflow

Facility Ecosystem : Seamlessly integrates into your facility's security ecosystem

Network FireWall : Blocks unnecessary ports. Limits the attack profile

Windows' 10 Operating system hardening : Disables unnecessary services. Reduces the attack surface

Malware Threat Protection : Whitelisting - Allows only known and trusted applications and libraries. Requires fewer updated

Local/Remote Access Control : Three (3) levels. Customizable

Patient Data encryption : At rest and in transit. Based on your requirements

DICOM (Integrated)

For transferring Ultrasound images and cine sequences utilizing the DICOM 3 standard. Supports the following protocols
- Verify
- Print
- Store
- Modality worklist
- Storage commitment
- Modality performed procedure step (MPPS)
- Media exchange

- Off network/mobile storage queue
- Public SR template
- Structured Reporting – compatible with vascular and OB, cardiac and breast standard
- **Multi-Modality Query / Retrieve :** Query Retrieve puts an end to running back and forth to view previously acquired PET, MR, CT, mammography or ultrasound images. The feature allows to retrieve   any CT or MR volume dataset onto the platform that can be scrolled to find the most relevant view of   the anatomical area in exam. View side-by-side with a real-time ultrasound image so you can quickly get to an area of interest.

InSite™ ExC capability (Integrated during warranty)

- Proactive / Real Time Monitoring
- Remote Diagnosis
- Real time support with GE experts
- Console Control Sharing
- Remote System File Repair
- Life Interaction with Expert
- Remote Software Download
- Preset Enhancement
- Remote Probe Assessment
- Remote Application support

PROBES (included in basic configuration)

H40472LT   C1-6-D XDclear broad-spectrum Convex Probe

Convex transducer with XDclear technology helps achieve impressive depth on patients with difficult body habitus.
Applications: Abdominal, Obstetrics, Gynecology, Vascular, Musculoskeletal
Frequency Range : **1 – 6 MHz**
Biopsy guide available (optional)

H44901AI   L2-9-D XDclear broad-spectrum Linear Probe

Linear transducer with XDclear technology
Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal, superficial musculoskeletal, neonatal, neonatal transcranial
Frequency Range : **2 – 9 MHz**
Biopsy guide available (optional)

H40452LG   ML6-15-D Matrix array broad-spectrum linear Probe

Applications: small parts, peripheral vascular, neonatal, pediatric, neonatal transcranial, general musculoskeletal, superficial musculoskeletal
Frequency Range : **4 – 15 MHz**
Field of view : 50 mm
Biopsy guide available (optional)

H40442LK   IC5-9-D Micro Convex Endocavitary Probe

Applications: ob/gyn urology endocavity
Frequency range : **3 – 10 MHz**
Biopsy guide : Single-angle, disposable or Single-angle, reusable (optional)

New iCenter™ Asset Management (*Optional*)

Show department leaders how LOGIQ™ E10 can help improve system utilization and department efficiency.
Utilization Reports : Machine Data features on InSite connected systems allows you securely view system utilization, service, and exam performance data on the iCenter™ portal to optimize your department

System Health Dashboard (*Optional*)

Visualize system health alerts and service status on-board the LOGIQ E10. Gives GE service engineers and your in-house staff secure, easy access to critical system health data to guide maintenance and repair, including connected probes.

H46622LL   Advanced Security

Adds vulnerability scan functionality, designed for USA DOD/government accounts

H46622LW   LOGIQ E10s LOGIQ Apps *

Photo Assistant

Photograph relevant anatomy and include photos with the clinical images
Provides value context for documentation and comparison after a procedure. (Possibility to acquire pictures with mobile devices and transfer them to the machine within the patient dossier: Dual Imaging with Clinical picture)
Utilizes Android™ tablet or phone - Bar code reader

Remote Control

Remote control of the unit for increased productivity and extended capability. **Remotely operate** the system from tablet or phone that that has LOGIQ Smart App loaded.

Focused on ergonomics

Includes:

- Major modes
- Freeze/print
- Depth
- Gain
- ROI placement
- Dual Image

* Requires H46612LH Wireless Option Kit

H46622LT   Tricefy

Cloud connectivity.

Possibility to share images and patient reports in a Cloud server, for sharing with peers or patients.

H46622LP   DVR

## H46622LG   SRI HD Type2

Speckle Reduction Imaging – Compatible with OB/GYN application

H46612LK   Real Time 4D

- **Real Time 4D** Next generation Volume Ultrasound
- **3D Static (B-Mode / CFM)**
- **Frame Cine**
- **Translation/Rotation/Slice Cine**
- **Inversion Mode** Visualization of hypoechoic structures, which are difficult or impossible to display with conventional Ultrasound techniques.

- **Beta View**

- **Multi-planar imaging, surface rendering**

- **HD*live***

- **TUI - Tomographic Ultrasound Imaging Option**
  Makes analysis and documenting of dynamic studies easier by providing a simultaneous view of multiple slices of a volume data set. Top left is held as reference image. Adjustable slice thickness allows for a customized view of the region of interest. Capability to select and print individual images. Can apply to a saved volume and combine with SRI and CrossXBeam

- **VOCAL II Volume Calculation Option** VOCAL provides both contour detection (manual, semi-automated or automated) and automated volume calculation. The customer traces the Region of Interest (ROI) using the trackball to trace the ROI on the monitor. The user then sets the threshold of tissue differentiation and algorithms calculate the volume of the ROI.

  Broad range of applications in Oncology, Gynecology, Obstetrics, Pediatrics. With VOCAL the doctor can follow up the treatment in patients undergoing chemotherapy by calculating the volume of the tumors changes

- **Volume Contrast Imaging basic (VCI-static)** "VCI is GE's revolutionary volume acquisition technique that leads to contrast enhancement and speckle
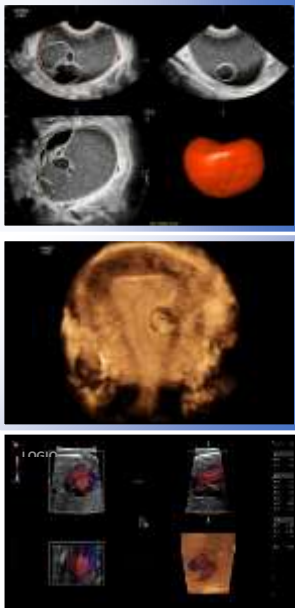
suppression in the 2D ultrasound image. Specifically, VCI utilizes GE's RealTime 4D transducers to automatically scan multiple adjacent slices resulting in a thin surface rendered image of a solid organ.

Better assessment of size, margins & internal structures of lesions.

- **Omniview** OmniView is the "Any-Plane" function for 3D and 4D data.

  Gives the ability to trace along any shape or structure

  Can be started from A, B or C. Up to 3 planes can be displayed simultaneously

  VCI OmniView is the "Any-Plane" function with thick slice detail.

- **STIC Spatio-Temporal Image Correlation (STIC)** captures one fetal heart cycle in 3D cine.
  - Adjustable acquisition time
  - Use with Color Doppler or Power Doppler modes
  - 3D manipulation in A, B and C planes

- **Sonorender*live***

  Automate render line placement in 3D/4D imaging, enabling clinicians to easily acquire surface-rendered images. Render start line is a "free" trace for optimal adaptation to the render object. Useful in fetal imaging

H46612LT   Automatic IMT Measurements
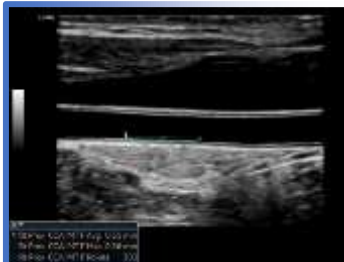
Auto IMT is an automated method of measuring the intima media thickness of the CCA or ICA from multiple samples across a user defined length.

- Simple and easy to operate
- Direct export of measurements to a worksheet and report page
- Including ECG trigger to help increase consistency and reliability
- Save offset distance and IMT measurement lengths to help increase reproducibility

H46622LZ   Scan Assistant

Assists the user with customizable automations
- Initiates and completes required measurements
- Automatically steers color Doppler
- Automatically sets up imaging controls and modes
- Automatically inserts comments
- **37% time savings using Scan Assistant**.

H46622LD Measure Assist OB

Powered by Edison - Anatomical Assistant Tool

Designed to work in OB exams

OB-specific measurement tool, using **'AI-based algorithms'** for measurement intensive studies, in OB exams. With user guidance, this technology allows automatic measurement of BPD, HC, FL and AC obstetrical measurements that can be easily edited or accepted

Scan Assistant:
- Freeze on anatomy
- Measurement auto applied
- Print to accept or easily edit if needed

H46622LC Measure Assist Breast

Powered by Edison - Anatomical Assistant Tool

Breast-specific measurement tool using **'AI-based algorithms'** for measurement intensive studies, in Breast exams. With user guidance, the technology allows automatic detection and measurements of breast lesions in a user selected ROI that can be easily edited or accepted.
Few simple steps to assist the user with breast measurements
- User bounds lesion with ROI
- System auto traces, generates height and width
- User prints to accept or easily edits as needed
- Messages on the status bar help guide the user

H46622LJ   SonoNT/SonoIT

❖ **SonoNT** (**Sonography-based Nuchal Translucency**)

provides semi-automatic, standardized measurements of the nuchal translucency in the 1st trimester. It helps avoid the inter- and intra-observer variability that comes with manual measurements, and helps provide you with the reproducibility you demand

❖ **SonoIT** (**Sonography-based Intracranial Translucency**) – provides semi-automatic, standardized measurements of the intracranial translucency in the 1st trimester.

H46622LN   Cardiac AFI
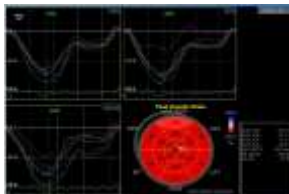
Access and quantify left ventricular wall motion at rest, calculating a large set of parameters

H46622LS   Stress Echo

Stress package with memory buffer offers   pharmaceutical, treadmill and bicycle stress exam protocols with user-configurable templates and shuffle mode. "SmartStress" function saving and "remembering" various imaging parameters from each imaging plane, that can be recalled in every stress stage, requiring no adjustments.
Score Index : bulls eye & segmental

H46612LW   B-Steer+

enables enhanced visualization of the needles structure during interventional procedures, helping improve user confidence.
Highlights
- Up to 12 selectable steering angles available (six each direction)
- Separate gain control for needle refleciton
- Available on all linear transducers
- Quick one-button operation

H46622LB   Flow Quantification

2D CFM/PDI Quantitative assessment of vascular feeding in a selected ROI. Can help in the assessment of inflammatory disease and vascular feeding of suspicious anatomical areas

- Consistent, repeatable and objective measurement
- Can help in treatment planning and monitoring protocols
- Provides data to support outcome measurements
- Up to 8 selectable ROIs
- Analysis over 4/5 heart beat cycles
- Automatic or manual ROI tracing
- *Save ROI* feature for monitoring
- Manual disabling & enabling of frames
- Ability to export traces for offline analysis

H46622LH   Ultrasound-Guided Attenuation Parameter (UGAP)
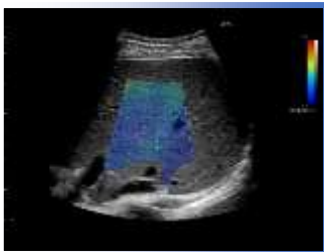
Quantifies liver steatosis to aid in early identification and monitoring of patients with NAFLD, NASH or ASH.

- Quality Indicator and user selectable color maps
- Attenuation Map
- Multiple measurements within a image
- **Auto measurement feature** for ROI placement
- Dual or single display option
- Measurements available in Attenuation Rate or Attenuation Coeffcient
- Mean and IQR display

H46612LJ   CW Doppler option kit

H46612LD   ECG Installation kit

H4911JC   ECG Cables IEC Style

H46612LN   Pencil CW Installation kit

H46612LR   Power Assistant option kit

H46612LP   Scan on Battery Option kit

Scan on battery provides battery power during transport to help decrease system shut-down and reboot time. It also enables a clinician to pick up a probe and scan, even when not plugged in – helping to achieve excellent productivity for high quality, portable exams.

Highlights

- Prompt in and out of battery operation mode to help improve system's portability
- Simple plug in and out operation
- System safely shuts down automatically before battery runs out
- ~50 minutes offline scanning is available
- Battery charges always when power cord is plugged into the power outlet

H46622LR　　　Report Writer

On-board reporting package automates report writing. Formats various exam results into a report suitable for printing or reviewing on a standard PC.

Exam results include patient info, exam info, measurements, calculations, images, comments and diagnosis. Standard templates provided. Customizable templates
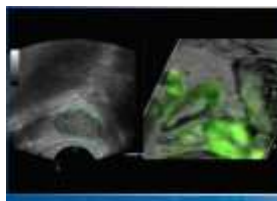
H46612LL　　　S-Video Option kit

H46732LF　　　USB FootSwitch - 3 Buttons

H4915P　　　Probe Holder Insert small

H46612LM　Volume Navigation kit

Sensor based technology, enabling fusion of real-time ultrasound images to a prior **CT, PET/CT, MR, CBCT, SPECT, 3D CEUS** DICOM volume data set. Also provides GPS markers for the ability to track anatomical landmarks from different scan planes and Tru3D capability for calibrated volume measurements.

Advanced Electromagnetic Navigation System. Volume Navigation combines the advantages of Volume Ultrasound with an on-board advanced navigation system.

Real-time ultrasound and **CT, PET/CT, MR, CBCT, 3D CEUS** volume data set from prior exam fusion

Guides your position with GPS-like technology

Highlights

- Easy to use & accurate tool
- Quick plane and point manual registration with internal or external anatomical markers for all modalities
- Quick and accurate fusion with Auto-Registration with CT while using the Active Tracker
- Innovative Magnetic Distorsion indicator based on GE Dual sensors position check (in case of a standard V Nav transducer)
- Save Patient Volume Registration file
- Multiple Volume support (CT, MR, PET/CT, CBCT and 3D CEUS)
- ***Volume Registration*** to fuse two Volume datasets from different exams and compare to live US
- ***Active reference sensor*** option, by selecting the reference sensor, allows patient movement and/or provide breathing compensation

Volume Navigation incorporates the following　:

- **Tru3D**

- **Fusion Imaging -** Real Time Imaging associated with High spatial/contrast of **CT, MR, PET/CT, CBCT,　3D CEUS**:
  - Helps increase precision and accuracy of imaging guided interventional procedures
  - Helps with the ablation of liver lesions potentially reducing the duration and number of needed sessions
  - Real Time versus still image
  - Add Flow or CEUS Information
  - Combining U/S high spatial resolution & MR contrast resolution
  - Guiding Interventions in Real Time … biopsies, drainages, RF ablation
  - Avoiding multiple exposure to radiation in interventions and follow up exams

- **GPS Tracking with unique dual sensor positioning system** - User benefits from the following :

  - Visually track position to save time and help improve confidence
  - Find an anatomical structure from a different view
  - Mark and track selected points in the body while scanning
  - Simplify counting structures such as masses, lesions, nodules
  - Help improve confidence that count was not duplicated.
  - Good for treatment planning and follow up
  - Guide procedures through needle tracking (*optional*) finding and drawing the most suitable angle
  - Help avoid anatomical structures (e.g. nerves, vessels) during interventions

- **Includes 3D magnetic field transmitter**

- **Probes with embedded Volume Navigation sensor** for enhanced scanning comfort:

  C1-6VN-D, C2-7VN-D, C2-9VN-D, L2-9VN-D

- **Brackets** are available for the following applications (***optional***) :
  - Musculoskeletal and small parts : L8-18i-D, ML6-15-D
  - Endocavitary imaging : IC5-9-D
  - Pediatric imaging : C3-10-D, L8-18i-D, ML6-15-D

H4908NS   Volume Navigation Stand

H4913PS   V NAV Probe Sensors

H4910NT   V Nav Needle Tracking Starter Kit
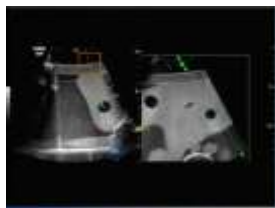
Magnetic sensor embedded in the tip of a needle
Reusable sensor helps you track the needle tip as you navigate through the body
View a live display of position and orientation
Guide in-plane or out-of-plane biopsies
Plan and monitor interventional procedures with real-time fused data
While selected as Reference Sensor, the Needle Tip sensor helps compensate for respiration and organ related motion
- Difficult biopsy guidance
- Drainages
- No RFA guidance yet

H4910NY   V Nav Virtual Needle Tracker
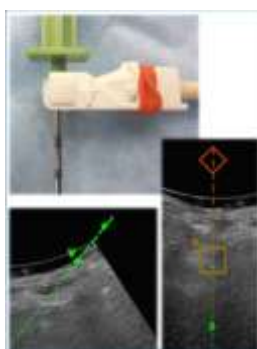
Enables the user to track an interventional needle during a procedure thanks to a sensor placed at the hub of the needle rather than in the tip.

The projected line is a virtual line and would not display the potential bending of the needle during the procedure (depending on needle thickness, length and examined anatomical area. Refer to manufacturer for recommendations

Applications:
- Live guidance of RFA/Microwave ablations
- Biopsy with thicker needles (ex. breast)
- Treatment planning

H4911NG   Virtual Tracker Sensor

H4915MT   VNav MR Active Tracker

Auto-Registration technique between **Live US and MR** datasets

An Active Tracker device (omniTRAX™) is placed on patient during a MR scan and then detected in the retrieved MR images to facilitate an auto registration during Fusion imaging Mode.

The Active Tracker can be removed from its bracket during intervention while not selected as Reference Sensor.

H4913AT   OmniTRAX (Active Tracker) kit

Auto-Registration technique between **Live US and a CT/CBCT** datasets

An Active Tracker device (omniTRAX™) is placed on patient during a CT/CBCT scan and then detected in the retrieved CT/CBCT images to facilitate an auto registration during Fusion imaging Mode.

The Active Tracker can be removed from its bracket during intervention while not selected as Reference Sensor.

H4913NS	**V Nav Needle Tracking storage insert**
H4913NT	**VNav eTRAX 18/20g st kt**
H4913NU	**VNav eTRAX 12-14g st kt**
H4913NV	**VNav eTRAX 14-16g st kt**
H40432LK	**ML6-15-D V Nav & Biopsy Bracket**
H40482LF	**C3-10 V Nav Bracket**
H4908NF	**IC5-9 V Nav Bracket**
H4908NH	**L8-18i V Nav Bracket**
H40432LK	**ML6-15-D V Nav & Biopsy Bracket**
H40482LF	**C3-10 V Nav Bracket**
H4908NF	**IC5-9 V Nav Bracket**
H4908NH	**L8-18i V Nav Bracket**
H44901AM	**L2-9-D/L2-9VN-D Biopsy Guide (Verza)**

(5-Angle Needle Guide)

H4917VB **C1-6-D/C1-6VN-D Verza Biopsy Starter Kit**

(5-Angle Needle Guide)

E8385MJ **E8C/IC5-9 Short Biopsy Kit (disposable)**

H40412LN **E8C/IC5-9 Re-usable Biopsy Device**

H40432LC **12L (L6-12) Multi Angle Biopsy**

H40432LJ **ML6-15 Multi angle Biopsy Starter Kit**

H40482LK **C2-7-D /C2-7VN-D Biopsy Starter Kit, Multi- Angle**

H40482LL **C2-7-D /C2-7VN-D Reusable Biopsy Starter Kit, Single Angle**

H45561FC **M5S Biopsy Kit**

H46701AE **RAB2-5D / RAB4-8D Reusable Biopsy Kit, Single Angle**

H46721R **RIC5-9A-RS Reusable Biopsy Starter kit**

H48621Y **Re-Usable Biopsy Kit for RAB Light / 4D3C-L Probe**

H4908SD **S1-5 Biopsy Starter Kit, Multi-Angle**

H4913BA **C2-9 Biopsy Starter Kit, Multi-Angle**

OPTIONAL PROBES

H40472LT **C1-6-D XDclear broad-spectrum Convex Probe**

Convex transducer with XDclear technology helps achieve impressive depth on patients with difficult body habitus.
Applications: Abdominal, Obstetrics, Gynecology, Vascular, Musculoskeletal
Frequency Range : **1 – 6 MHz**
Biopsy guide available (optional)

H40472LW **C1-6VN-D XDclear broad-spectrum Convex Probe**

Convex transducer with XDclear technology helps achieve impressive depth on patients with difficult body habitus.
Applications: Abdominal, Obstetrics, Gynecology, Vascular, Musculoskeletal
Frequency Range : **1 – 6 MHz**
Biopsy guide available (optional)

H40462LN **C2-9-D XDclear Convex Probe**

Applications: Abdominal, Obstetrics, Gynecology, Pediatrics, Vascular, Musculoskeletal
Frequency range : **2 – 9 MHz**
Biopsy guide : Multi-angle, disposable with a reusable bracket (optional)

H40472LY   **C2-9VN-D XDclear Convex Probe – VNav Inside**

Applications: Abdominal, Obstetrics, Gynecology, Pediatrics, Vascular, Musculoskeletal
Frequency range : **2 – 9 MHz**
Biopsy guide : Multi-angle, disposable with a reusable bracket (optional)

H46422LM   **C2-7-D Microconvex Probe**

This microconvex probe has a wide FOV that reduces blind spots, particularly in intercostal areas, for abdomen applications
Frequency range : **1 – 6 MHz**
Biopsy guide : Multi-angle, disposable with a reuseable bracket or a reusable stainless bracket (optional)

H46422LN   **C2-7VN-D Microconvex Probe – VNav Inside**

This microconvex probe has a wide FOV that reduces blind spots, particularly in intercostal areas, for abdomen applications
Frequency range : **1 – 6 MHz**
Biopsy guide : Multi-angle, disposable with a reuseable bracket or a reusable stainless bracket (optional)

H40482LB   **C3-10-D XDclear Broad-spectrum convex probe**

Applications: Neonatal, Pediatrics, Vascular, Small Parts

Frequency Range : **2 – 11 MHz**

H40442LK   **IC5-9-D Micro Convex Endocavitary Probe**

Applications: ob/gyn urology endocavity
Frequency range : **3 – 10 MHz**
Biopsy guide : Single-angle, disposable or Single-angle, reusable (optional)

H44901AI   **L2-9-D XDclear broad-spectrum Linear Probe**

Linear transducer with XDclear technology
Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal, superficial musculoskeletal, neonatal, neonatal transcranial
Frequency Range : **2 – 9 MHz**
Biopsy guide available (optional)

H44901AJ   **L2-9-D XDclear broad-spectrum Linear Probe – VNav inside**

Linear transducer with XDclear technology
Applications: peripheral vascular, small parts, pediatric, abdomen, OB/GYN, general musculoskeletal, superficial musculoskeletal, neonatal, neonatal transcranial
Frequency Range : **2 – 9 MHz**
Biopsy guide available (optional)

H40452LG   **ML6-15-D Matrix array broad-spectrum linear Probe**

Applications: small parts, peripheral vascular, neonatal, pediatric, neonatal transcranial, general musculoskeletal, superficial musculoskeletal
Frequency Range : **4 – 15 MHz**
Field of view : 50 mm
Biopsy guide available (optional)

H40452LL   **L8-18i-D Linear Array Hockeystick Probe**

Applications : Small Parts, Vascular, Musculoskeletal, Intraoperative, Neonatal
Frequency range : **4 – 18 MHz**

H48681MG   **RAB6-D 4D Volume Convex Probe**

Applications : Abdominal, Obstetrics, Gynecology, Pediatrics
Frequency range : **2 – 8 MHz**
Biopsy guide : Multi-angle, disposable with a reusable bracket (optional)

H48651MS   **RIC5-9-D 4D Volume Endocavitary Probe**

Applications : Obstetrics, Gynecology, Urology
Frequency range : **3 – 10 MHz**
Biopsy guide : Single-angle, reusable (optional)

H44901AE   **M5Sc-D XDclear Broad-spectrum Sector Phased Array Probe**

Applications: Cardiac, Transcranial, Abdominal
Frequency Range : **1 – 5 MHz**
Field of view : 120°
Biopsy guide available (optional)

H4830JE   **P2D- CWD Pencil Probe**

CW split crystal pencil probe

Applications: Cardiac, Vascular
Frequency Range : **1 – 3 MHz**

H4830JG   **P6D- CWD Pencil Probe**

CW split crystal pencil probe

Applications: Cardiac, Vascular, Transcranial
Frequency Range : **5 – 7 MHz**

Registered No.　　　　　　　2020　-　1881

NOTARIAL   CERTIFICATE

APEX LLC

Belong to Seoul Central District Prosecutors' Office

4F, Wooduk Building, (Yeoksam-dong), 330, Gangnam-daero, Gangnam-gu, Seoul, Korea

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 détails sur addendum / *See attachment for additional information*

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 :* **February 14th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

On behalf of the President
Béatrice LYS
Technical Director

GMED - 7697 rev. 14
Modifie le certificat 7697-13

GMED_b2p3-F-V0-07-2018

Addendum à l'attestation N° 7697 rev.14   page 1 / 2
Addendum of the certificate N° 7697 rev.14
Dossiers / *Files* N°: P183396, P601203

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P7**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P9**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S6**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8t**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10 Expert**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P6**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P8**	IIa

GMED | **0459**

On behalf of the President
Béatrice LYS
Technical Director

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

ADD - 720 DM 0701-31 rev 6 du 01/08/2018

Addendum à l'attestation N° 7697 rev.14   **page 2 / 2**
Addendum of the certificate N° 7697 rev.14
Dossiers / *Files* N°: P183396, P601203

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S8**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Expert**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Pro**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 XDclear2.0**	IIa
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ E10s**	IIa

14 alinéas / *14 indented lines.*

Identification du site couvert et des activités / *Identification of location and 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

GMED   0459

On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr
ADD - 720 DM 0701-31 rev 6 du 01/08/2018

공증인가 법무법인(유한) 에이펙스

등부 2020 년 제 1881 호	Registered No. 2020 ‑ 1881

인   증

NOTARIAL CERTIFICATE

위   증명서   사본 은

As a result of checking at my office, I have found that the attached

원본과 대조하여 그와 부합함을

CERTIFICATE   copy

exactly corresponds with the original.

인정한다.

2020 년 3 월 6 일

This is hereby attested on this 6th day of March, 2020 at this office

이 사무소에서 위 인증한다.

공증인가 법무법인(유한)에이펙스
소속: 서울중앙지방검찰청
서울특별시 강남대로 330,
우덕빌딩 4층(역삼동)

APEX LLC
Belong to Seoul Central District Prosecutors' Office
4F, Wooduk Building, (Yeoksam-dong), 330,
Gangnam-daero, Gangnam-gu, Seoul, Korea

공증담당
변 호 사
Attorney-at-law

Dong-Yoon Kim

This office has been authorized by the Minister of Justice, the Republic of Korea to act as Notary Public since September 28, 2009 under Law No. 27.