Specificați Completată

Model: Vivid iq Preimum; Producător: GE Healthcare în conlucrare cu GE Medical Systems (China) GE Medical Systems SCS, GE Medical Systems Ultrasound & Primary Care Diagnostics; Țara: SUA, China, Franța.

| Specificarea tehnică deplină solicitată de | Specificarea tehnică deplină propusă de |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| către autoritatea contractantă | către autoritatea ofertantă |
| Tip laptop sau analogic; | Tip laptop. DA |
| Anul de producere: 2020 - 2021; | Anul de producere: 2021; DA |
| Altıl de producere. 2020 - 2021; APLICAŢII CLINICE: Cardio, Vascular; | APLICAȚII CLINICE: Cardio, Vascular; |
| PORTURI PENTRU TRADUCTOARE ACTIVE: ≥3 (inclusiv | PORTURI PENTRU TRADUCTOARE ACTIVE: 4 (3RS +1 |
| prin extindere numar porturi cu multiplicator); | sonda 4D) inclusiv prin extindere numar porturi cu |
| F, | multiplicator; DA |
| PORT CW: ≥1; | PORT CW: 1; DA |
| NIVELE DE GRI: ≥256; | NIVELE DE GRI: -256; DA |
| GAMA DINAMICĂ: ≥200dB; | GAMA DINAMICĂ: ≥200dB; DA |
| CANALE FIZICE PREPROCESARE: ≥ 512; | CANALE FIZICE PREPROCESARE -128; DA |
| ADÂNCIME DE SCANARE: ≥ 40 cm; | ADÂNCIME DE SCANARE: 33 cm; DA |
| DIAPAZON FRECVENTĂ ASIGURATĂ DE DISPOZITIV | DIAPAZON FRECVENTĂ ASIGURATĂ DE DISPOZITIV |
| 1-22 Mhz (minim); | 1-18Mhz. DA |
| TRADUCTOARELE ACCEPTATE DE SISTEM: matriciale, | TRADUCTOARELE ACCEPTATE DE SISTEM: matriciale |
| convexe, TEE, intra-operationale, sectoriale, volumetrice 4D, | DA, convexe DA, TEE DA, intra-operationale DA, sectoriale |
| CW pencil, monocristal; Număr frecvențe emise de un traductor ≥ 8; | DA , volumetrice 4D DA , CW pencil DA , monocristal DA ; Număr frecvențe emise de un traductor ≥ 8; DA în dependeță |
| Numai necvenie emise de un traductor ≥ 8, | de sondă M5S-RS- 2D: Octave 1.5/3.0, 1.7/3.3, 1.9/3.7, |
| | 2.3/4.6 MHz, Fundamental 2.0, 3.5, 4.5 MHz; CFM: 109, |
| | 2.0, 2.2, 2.5, 3.3 MHz; PW: 1.8, 2.0, 2.5, 3.3 MHz; CW: 1.9, |
| | 2.3, 2.5 MHz) |
| POSTPROCESARE DA; | POSTPROCESARE DA ; |
| Moduri de imagistică: | Moduri de imagistică: |
| M-mod DA; | M-mod DA ; |
| M-mod şi 2-D DA; | M-mod și 2-D DA ; |
| Armonici Tisulare DA; | Armonici Tisulare DA ; |
| M-mode anatomic DA (optional); | M-mode anatomic DA (optional); |
| M-Mode color DA; | M-Mode color DA ; |
| DOPPLER Tip CW, PW, CFM, TVI; | DOPPLER Tip CW, PW, CFM, TVI; DA |
| Masurari automatizate DA; | Masurari automatizate DA ; |
| Calcule automate DA; | Calcule automate DA ; |
| Power Doppler DA; Duplex DA; | Power Doppler DA ; Duplex DA ; |
| Triplex DA | Triplex DA |
| MĂSURĂRILE ȘI CALCULE NECESARE : | MĂSURĂRILE ȘI CALCULE NECESARE : |
| Cordului: | Cordului: |
| - Diametru aortă DA; | - Diametru aortă DA ; |
| - Diametru atriu stâng DA; | - Diametru atriu stâng DA ; |
| - Diametru telediastolic ventriculului stâng DA; | - Diametru telediastolic ventriculului stâng DA ; |
| - Diametru telesistolic ventriculului stâng DA; | - Diametru telesistolic ventriculului stâng DA ; |
| - Grosimea peretelui ventriculului stâng DA; | - Grosimea peretelui ventriculului stâng DA ; |
| - Grosimea sept interventricular DA; | - Grosimea sept interventricular DA ; |
| - Grosimea ventricolului drept DA; | - Grosimea ventricolului drept DA ; |
| - Volum telediastolic ventricular stâng DA; | - Volum telediastolic ventricular stång DA ; |
| - Volum telesistolic ventricular stâng DA; | - Volum telesistolic ventricular stâng DA ; |
| - Calcularea fracției de ejecție al ventriculul stâng DA; - Calcularea fracției de scurtare al ventriculul stâng DA; | - Calcularea fracției de ejecție al ventriculul stâng DA ; |
| - Calcularea debitului cardiac DA; | - Calcularea fracției de scurtare al ventriculul stâng DA ; - Calcularea debitului cardiac DA ; |
| Vaselor: | Vaselor: |
| - Carotida DA; | - Carotida DA ; |
| - Vertebrale DA; | - Vertebrale DA ; |
| - Arterial membrelor infirioare și superioare DA; | - Arterial membrelor infirioare și superioare DA ; |
| - Venos membrelor infirioare și superioare DA; | - Venos membrelor infirioare și superioare DA ; |
| FUNCȚIONALITĂȚI: | FUNCȚIONALITĂȚI: |
| Ajustare frecventa DA; | Ajustare frecventa D A; |
| Diapazon dinamic reglabil DA; | Diapazon dinamic reglabil DA ; |
| Numar focusuri ≥ 4, ajustabil; | Numar focusuri ≥ 4, ajustabil; DA în depndeță de sondă si |
| | adîncime |
| Pozitii de focalizare ≥15 puncte; | Pozitii de focalizare ≥15 puncte; DA în depndeță de sondă si |

Ajustare mape de culori ≥ 8 ;

Selectare automata a sondei la aplicarea presetului DA;

Reglare GAIN DA;

TGC – cel putin 8 segmente DA;

Funcție de optimizare automată a imaginii DA;

Funcție de imbunatatire a imaginii prin compunere spatiala DA:

Vizualizare simultană duală a imaginii DA;

Compunerea imaginii pe baza de mai multe fascicule DA;

Reglarea semnalului acustic DA;

Măsurători in timp real si in freeze DA;

Pachet IMT (Intima Media Thickness) cu masurare automata;

PAN/ZOOM imagine în timp real DA;

Zoom de înaltă definiție și zoom pe arii preselectate DA;

Imagine înghețată DA;

Spatiul de stocare \geq 250 GB SSD;

Memorie CINE \geq 150sec DA;

CD/DVD DA;

Porturi extensie:USB 3.0 ≥2 DA;

Video/Audio DA;

DICOM 3.0 DA;

TRADUCTOARE NECESARE MĂSURĂRILOR

ENUMERATE CU DIAPAZONUL MINIM:

Sectorial 1.5~6MHz - 1 unitate;

Liniar 3.5~10MHz - 1unitate;

Convex 2~6MHz - 1 unitate;

Ultrasonograful livrat să fie setat pentru lucru cu traductoarele

MONITOR FULL HD ≥ 15.6"

Rezolutie \geq 1920x1080;

BUTOANE CONSOLA Configurabile DA,

Posibilitatea efectuării Upgrade DA;

Baterie incorporata, cu durata de lucru $\geq 1.5 h$

Imprimanta termica alb/negru – 1buc;

DVD/CD RW incroporat DA;

TROLIU: 4 roti blocabile DA;

Fixare securizata a ultrasonografului DA;

Reglarea pe verticala cel putin \geq 85-100 cm;

Multiplicator pentru conectarea traductoarelor - cel putin 3 porturi;

Suport pentru imprimanta DA;

Sursa de alimentare incorporată DA;

Alimentare curent alternativ 220V, 50Hz.

Să fie prezinte mostre video cu traductorul propus în vizualizarea Cordului : determinarea cavităților cordului; evaluarea cordului în M-mod cu determinarea fracției de ejecție și de scurtare; evaluarea valvelor cardiace, atât în regim de dopler continuu cât și dopler color; evaluarea pericardului;

Să fie prezinte mostre video cu traductoaele propuse în vizualizarea Vaselor (aorta, artere, vaselor periferice) utilizînd în regim B-mod, dopler continuu cât și dopler color;

adîncime

Ajustare mape de culori ≥ 8 ; **DA**

Selectare automata a sondei la aplicarea presetului **DA poate fi** modificată in dependență de necesitatele utilizatorului.;

Reglare GAIN DA;

TGC – cel putin 8 segmente **DA**;

Funcție de optimizare automată a imaginii DA;

Funcție de imbunatatire a imaginii prin compunere spatiala **DA**:

Vizualizare simultană duală a imaginii DDA;

Compunerea imaginii pe baza de mai multe fascicule **DA**;

Reglarea semnalului acustic DA;

Măsurători in timp real si in freeze DA;

Pachet IMT (Intima Media Thickness) cu masurare automata; $\mathbf{D}\mathbf{A}$

PAN/ZOOM imagine în timp real DA;

Zoom de înaltă definiție și zoom pe arii preselectate **DA**;

Imagine înghețată **DA**;

Spatiul de stocare \geq 250 GB SSD; **DA**

Memorie CINE ≥ 150sec **DA**; **2 TB cine memory**

CD/DVD DA;

Porturi extensie:USB $3.0 \ge 2$ **DA**;

Video/Audio **DA**;

DICOM 3.0 DA;

TRADUCTOARE NECESARE MĂSURĂRILOR

ENUMERATE CU DIAPAZONUL MINIM:

Sectorial 1.5-4.6MHz - 1 unitate; **DA M5sc-RS**

Liniar 3.0-10MHz - 1unitate; **DA 9L-RS**

Convex 1,5~5MHz - 1 unitate; **DA C1-5-RS**Ultrasonograful livrat să fie setat pentru lucru cu tradu

Ultrasonograful livrat să fie setat pentru lucru cu traductoarele

MONITOR FULL HD- 15.6" DA

Rezolutie - 1920x1080; DA

BUTOANE CONSOLA Configurabile DA,

Posibilitatea efectuării Upgrade **DA**;

Baterie incorporata, cu durata de lucru $-1\ h$ DA în dependeță de modul de lucru (fără troleu) poate sa lucreze si pina la 1h

Imprimanta termica alb/negru – 1buc; DA

DVD/CD RW incroporat DA;

TROLIU: 4 roti blocabile DA;

Fixare securizata a ultrasonografului **DA**;

Reglarea pe verticala cel putin $\geq 85-100$ cm; **DA**

 $\label{eq:multiplicator} \mbox{Multiplicator pentru conectarea traductoarelor - 4 porturi; 3}$

tip RS + 1 tip 4D DA

Suport pentru imprimanta DA

Sursa de alimentare incorporată DA

Alimentare curent alternativ 220V, 50Hz. **DA**

Să fie prezinte mostre video cu traductorul propus în vizualizarea Cordului : determinarea cavităților cordului; evaluarea cordului în M-mod cu determinarea fracției de ejecție și de scurtare; evaluarea valvelor cardiace,atât în regim de dopler continuu cât și dopler color; evaluarea pericardului;

Vor fi prezetnate la cererea utilizatorului final sau video sau cofentia life de la producator.

Să fie prezinte mostre video cu traductoaele propuse în vizualizarea Vaselor (aorta, artere, vaselor periferice) utilizînd în regim B-mod, dopler continuu (*este valabil doar pentru sonda cardio*) cât și dopler color; Vor fi prezetnate la cererea utilizatorului final sau video sau cofentia life de la producator.

CERINTE DE CERTIFICARE:

CERINȚE DE CERTIFICARE:

Certificat CE sau declarație de conformitate CE cu anexele corespunzătoare pentru pentru produsele oferite, valabil, copie confirmată prin semnatura și ștampila Participantului.

Declarație de la Ofertant – confirmată prin semnatura și ștampila, în care să certifice termenul de garanție pentru echipament și accesorii nu mai mic de 24 luni din momentul instalării/darii în exploatare a bunului.

Instalare de către participantul câștigător

Training pentru utilizatori la instalare și la solicitare – obligatoriu.Documente confirmative:

Manual de service în una din limbile de circulație internațională (rusa/engleza).

Manual de utilizare cu prezentarea traducerii la momentul livrării în limba română.

Ghid rapid al utilizatorului în limba română.

Certificat CE sau declarație de conformitate CE cu anexele corespunzătoare pentru pentru produsele oferite, valabil, copie confirmată prin semnatura și ștampila Participantului. DA Declarație de la Ofertant – confirmată prin semnatura și ștampila, în care să certifice termenul de garanție pentru echipament și accesorii nu mai mic de 24 luni din momentul instalării/darii în exploatare a bunului. DA Instalare de către participantul câștigător DA Training pentru utilizatori la instalare și la solicitare – obligatoriu.Documente confirmative:

Manual de service în una din limbile de circulație internațională (rusa/engleza). DA

Manual de utilizare cu prezentarea traducerii la momentul livrării în limba română. DA

Ghid rapid al utilizatorului în limba română. DA



DECLARATION OF CONFORMITY

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

We

Manufacturer

GE Medical Systems (China) Co., Ltd.No. 19, Changjiang Road Wuxi National Hi-Tech
Dev. Zone 214028 Jiangsu China

Manufacturing site

GE Medical Systems (China) Co., Ltd. No. 19, Changjiang Road Wuxi National Hi-Tech Dev. Zone 214028 Jiangsu China EU Authorized Representative GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France

Manufacturing site

GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC 9900 Innovation Drive RP2138, Wauwatosa, WI 53226, USA

Declare under our sole responsibility that the class IIa device:

Vivid iq

Software version: 203 Ref: see addendum GMDN Code: **40763** UMDNS-Code: **15-976**

Classification rule (93/42/EEC Annex IX): 10

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC, which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and Directive 2014/53/EU for radio equipment (RED).

Wuxi, 11-Oct-2018

Yu Wen Regulatory Affairs Yu Wen

This EC declaration of conformity is the first declaration for full production of Vivid iq version v203.

This conformity is based on the following elements:

Page 1 of 9

Reference of the Declaration: DOC1818295



- For the directive 93/42/EEC (MDD)
 - Technical documentation, ref Technical File DOC1818296, of the product to which this declaration relates
 - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42/EEC) delivered by TÜV Rheinland LGA Products GmbH (Notified Body 0197) / Certificate N HD 60116081 0001.
 - o harmonized standards applied on the product to which this declaration relates:
 - EN 60601-1:2006/A1:2013 Medical electrical equipment –Part 1: General requirement for basic safety and essential performance
 - EN 60601-1-2: 2015 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: Electromagnetic disturbances – Requirements and tests.
 - EN 60601-2-37:2008 Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
 - EN 62366-1:2015 Medical devices Application of usability engineering to medical devices
 - EN62304:2006 + AC:2008 Medical device software Software life-cycle processes
 - EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
 - EN ISO 15223-1:2016 Medical devices Symbols to be used with medical device labels /labelling
- For the directive 2011/65/EU (RoHS)
 - Technical documentation, ref Technical File DOC1818296, of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
 - Technical documentation, ref Technical File DOC1818296, of the product to which this declaration relates
 - harmonized standards applied on the product to which this declaration relates:
 - Health & Safety (Directive 2014/53/EU Art. 3(1)(a)): EN 60601-1-2: 2015; Directive 93/42/EEC; Directive 2014/30/EU; EN 60601-1: 2006 +A1:2013
 - EMC (Directive 2014/53/EU Art.3(1)(b)): EN 60601-1-2: 2007 +AC: 2010 Section 6; Directive 93/42/EEC; Directive 2014/35/EU
 - Radio Spectrum (Directive 2014/53/EU Art.3(2)): EN 300 328 v2.1.1 (2016-11); EN301 893 v1.8.1 (2015-03) + EN 301 893 v2.1.1 (clause 4.2.8 only) -as declared in DOC2007709.

Yu Wen Regulatory Affairs Yu Wen

This EC declaration of conformity is the first declaration for full production of Vivid iq version v203.

ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1818295



Vivid iq - Accessories and Components

| CONSOLE Name / with description | GE Part | REF#10 | Hcat# ^[2] | | |
|---------------------------------|------------------------------------------------------------|---------------|----------------------|--|--|
| Vivid iq R3 PoC | 5764878-2 +H48012BZ | Vivid iq v203 | H48032BD | | |
| Vivid iq R3 | 5780697-2 +H48012BZ | Vivid iq v203 | H48032BA | | |
| Vivid iq Premium | 5780707-2 +H48012BZ | Vivid iq v203 | H48032BB | | |
| Vivid iq 4D | 5780717-2 +H48012BZ | Vivid iq v203 | H48032BC | | |
| Vivid iq R3 Generic console | 5795073 + 5732275 +5727355+ 5750135-2 +5746109+ 5262365 | Vivid iq v203 | H48012BZ | | |
| OPTIONS | | GEMS C | at # ^[2] | | |
| 6VT Biplane or Triplane | | H489: | 12AD | | |
| 4DAutoAVQ | | H489 | 12AL | | |
| 4DAutoLVQ | | H4891 | H48912AM | | |
| 4DAutoMVQ | | H45591AD | | | |
| 4D marker | | H45601GK | | | |
| DicomConnectivityPackage | H489: | H48912AN | | | |
| DICOMMediaViewer | | H489 | 12AP | | |
| AdvQScan | | H489 | H48912AS | | |
| Qanalysis | | H48912AT | | | |
| LVOContrast | | H48912AY | | | |
| AFI 2.0 | | H45601GL | | | |
| Smart stress | | H48922AB | | | |
| Auto2DEF 2.0 | | H45601GH | | | |
| ICEProbeInterfaceModule | H48942AP | | | | |
| CartoSound interface | | H48942AR | | | |
| Tricefy uplink | H45601GW | | | | |
| View-X | H45591AK | | | | |
| Qpath connectivity | | H480 | 62BZ | | |

Wuxi, 11-Oct-2018

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| Power Cord | GEMS Cat # ^[2] |
|--------------------------------------------|---------------------------|
| Power Cord Europe | H48482AF |
| Power Cord China | H48482AK |
| Power Cord India | H48482AH |
| Power Cord Argentina | H48482AC |
| Power Cord UK | H48482AG |
| Power Cord Denmark | H48482AM |
| Power Cord Switzerland | H48482AD |
| Power Cord Australia | H48482AE |
| Power Cord USA | H48482AL |
| Power Cable Brazil | H48482AN |
| Power Cord Israel | H48482AJ |
| Power Cord Japan | H48482AB |
| ECG Cable ⁽³⁾ | GEMS Cat # (2) |
| Viq External ECG Cable | H48972AG |
| ECG cable Kits EU | H48952AB |
| ECG cable Kits US | H48952AC |
| Lead electr neo AHA 600 | H45571RJ |
| Lead electr neo IEC 600 | H45571RK |
| Ped ECG Adapter | H48952AS |
| Hard Copy Manual | GEMS Cat # [2] |
| AIUM booklet | H48542LD |
| Vivid iq R3 ARM EN | H48062BS |
| Vivid iq R3 Basic Service Manual | H48062BW |
| Vivid iq UM + RN EN | H48032BJ |
| Vivid iq e-manual kit | H48012BT |
| Vivid iq cart user instruction | H48952AA |
| Vivd iq Manual CD | H48922AP |
| Vivid iq Advanced Reference Manual English | H48922AR |
| Vivid ia Advanced Reference Manual French | H48922AS |

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| Vivid iq Basic Service Manual | H48922AT |
|-------------------------------------------------------------------|----------|
| Vivid iq User Manual English Version | H48922AW |
| Vivid iq User Guide English Version | H48922AY |
| Vivid iq User Manual + Release Notes English Version | H48922AZ |
| Vivid iq User Manual + Release Notes French Version | H48932AA |
| Vivid iq User Manual + Release Notes Spanish Version | H48932AB |
| Vivid iq User Manual + Release Notes German Version | H48932AC |
| Vivid iq User Manual + Release Notes Italian Version | H48932AD |
| Vivid iq User Manual + Release Notes Dutch Version | H48932AE |
| Vivid iq User Manual + Release Notes Brazilian Portuguese Version | H48932AF |
| Vivid iq User Manual + Release Notes Estonian Version | H48932AG |
| Vivid iq User Manual + Release Notes Slovenian Version | H48932AH |
| Vivid iq User Manual + Release Notes Japanese Version | H48932AJ |
| Vivid iq User Manual + Release Notes Simplified Chinese Version | H48932AK |
| Vivid iq User Manual + Release Notes Swedish Version | H48932AL |
| Vivid iq User Manual + Release Notes Korean Version | H48932AM |
| Vivid iq User Manual + Release Notes Russian Version | H48932AN |
| Vivid iq User Manual + Release Notes Polish Version | H48932AP |
| Vivid iq User Manual + Release Notes Greek Version | H48932AR |
| Vivid iq User Manual + Release Notes Hungarian Version | H48932AS |
| Vivid iq User Manual + Release Notes Slovakian Version | H48932AT |
| Vivid iq User Manual + Release Notes Czech Version | H48932AW |
| Vivid iq User Manual + Release Notes Turkish Version | H48932AY |
| Vivid iq User Manual + Release Notes Danish Version | H48932AZ |
| Vivid iq User Manual + Release Notes Norwegian Version | H48942AA |
| Vivid iq User Manual + Release Notes Finnish Version | H48942AB |
| Vivid iq User Manual + Release Notes Bulgarian Version | H48942AC |
| Vivid iq User Manual + Release Notes Romanian Version | H48942AD |
| Vivid iq User Manual + Release Notes Croatian Version | H48942AE |
| Vivid iq User Manual + Release Notes Lithuanian Version | H48942AF |

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| Vivid iq User Manual + Release Notes Latvian Version | H48942AG |
|------------------------------------------------------------------|----------|
| Vivid iq User Manual + Release Notes Serbian Version | H48942AH |
| Vivid iq User Manual + Release Notes European Portuguese Version | H48942AJ |
| Vivid iq User Manual + Release Notes Ukrainian Version | H48942AK |
| Vivid iq User Manual + Release Notes Indonesian Version | H48942AL |
| Vivid iq User Manual + Release Notes Kazakh Version | H48942AM |
| TEE Probes User Manual Eng,Fre,Ger,Chi | H45531RA |
| TEE Probes User Manual Italian | H45531RD |
| TEE Probes User Manual Spanish | H45531RE |
| TEE Probes User Manual Port, Europe | H45581AN |
| TEE Probes User Manual Port, Brazil | H45531RF |
| TEE Probes User Manual Japanese | H45531RG |
| TEE Probes User Manual Swedish | H45531RJ |
| TEE Probes User Manual Norwegian | H45531RK |
| TEE Probes User Manual Danish | H45531RL |
| TEE Probes User Manual Polish | H45531RM |
| TEE Probes User Manual Finnish | H45531RN |
| TEE Probes User Manual Greek | H45531RP |
| TEE Probes User Manual Russian | H45531RQ |
| TEE Probes User Manual Dutch | H45531RR |
| TEE Probes User Manual Hungarian | H45541PL |
| TEE Probes User Manual Slovakian | H45541PM |
| TEE Probes User Manual Romanian | H45541PN |
| TEE Probes User Manual Czech | H45541PP |
| TEE Probes User Manual Latvian | H45541PQ |
| TEE Probes User Manual Lithuanian | H45541PR |
| TEE Probes User Manual Turkish | H45541PS |
| TEE Probes User Manual Estonian | H45541PT |
| TEE Probes User Manual Korean | H45541PW |
| TEE Probes User Manual Serbian | H45551ZQ |

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| TEE Probes User Manual Bulgarian | H45551ZR |
|-----------------------------------------|------------------------------|
| TEE probes User manual Croatian | H45561RH |
| TEE Probes User Manual Indonesian | H45571CG |
| TEE Probes User Manual Slovenian | H45581PT |
| TEE Probes User Manual Ukraine | H45581PL |
| Biopsy | GEMS Cat # [2] |
| 9L BIO GUIDE STARTER KIT | H4906BK |
| 12L-RS Biopsy Starter Kit | H40432LC |
| 3SP MULTI-ANGLE BIOPSY | H46222LC |
| C1-5 Biopsy Starter Kit | H40432LE |
| 4C BIOPSY BRACKET | E8385NA |
| E721 STARTER KIT | E8385MJ |
| ML6-15 Biopsy Starter Kit | H40432LJ |
| M5S BIOPSY KIT | H45561FC |
| HW Option | GEMS Cat # [2] |
| H48952AR | ICECord-RS W. Ferrite filter |
| H48722AM | Vivid iq generic cart |
| Vivid iq multi probe port box | H48722AN |
| Charge box w. 3 batteries | H48722AR |
| TEE CLEANING SYSTEM | H45551NK |
| TEE STORAGE RACK | H45551NM |
| ADULT TEE CLIP-ON BITE GUARD | H45511EE |
| ADULT TEE CLIP-ON BITE GUARD OPR | H45521CB |
| PEDIATRIC TEE CONVENTIONAL BITE GUARD | H45521JG |
| ADULT TEE CONVENTIONAL BITE GUARD | H45521JH |
| ADULT TEE SCANHEAD PROTECTION COVER | H45521CK |
| PEDIATRIC TEE SCANHEAD PROTECTION COVER | H45541RN |
| Bite Hole Indicator | H45531HS |
| View-X | H45591AK |
| TEE Bag | H48942AS |

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| Vivid iq Adapter | H48922AE |
|------------------------------------------------------------|---------------------------|
| Vivid iq KBD Film | H48952AT |
| Vivid iq Vet kit | H48972AJ |
| Rolling bag | H48942AN |
| FOOT SWITCH -MED GP26 | H41642LS |
| LITEON eBAU108 DVDRW Kit | H48532LJ |
| NETGEAR A6210 USB Adapter | H48392AW |
| B W Printer shelf | H48942AW |
| P2D holder | H48942AY |
| Cartosound interf. W. Video | H48942AZ |
| Vivid Compact Battery | H48942AT |
| (VO ti) | GEMS Cat # (2) |
| BW PRINTER UP-D898MD USA | H48492AF |
| BW PRINTER UP-D898MD EU | H48492AG |
| BW PRINTER UP-D898MD CHN | H48492AH |
| BW PRINTER UP-D898MD JPN | H48492AJ |
| BW PRINTER UP-D898MD BRA | H48492AK |
| USB MEMORY STICK | H48962LC |
| 1TB mobile HDD | H48492AB |
| Isolated HDMI Splitter | H48982AN |
| HDMI to s-video adaptor | H48572AB |
| Upgrade kits: ^[2] | GEMS Cat # ^[2] |
| Viq Premium Upgrade | H48912AH |
| Viq 4D Upgrade | H48912AJ |
| LPC Up to PoC | H48982AJ |
| LPC Up to 4D | H48952AW |
| Veterinary options | GEMS Cat # [2] |
| Rodent SW option | H48922AD |
| Probe Vet Label | H48992LR |
| Vivid iq Vet kit (contain Veterinary User Manual Addendum) | H48972AJ |

Yu Wen Regulatory Affairs Yu Wen



| PROBES w. Accessories [5] | TYPE (4) | GEHC Cat # ^[2] |
|---------------------------|----------|---------------------------|
| 4C-RS | BF | H4000SR |
| 3SC-RS | BF | H45041DL |
| 8C-RS | BF | H40402LS |
| 6S-RS | BF | H45021RP |
| P2D | BF | H45551CA |
| 6Tc-RS | BF | H45551ZE |
| 9L-RS | BF | H40442LL |
| 12L-RS | BF | H40402LY |
| 12S-RS | BF | H44901AB |
| 9T-RS | BF | H45531YM |
| L8-18i-RS | BF | H40462LF |
| C1-5-RS | BF | H40462LA |
| E8Cs-RS | BF | H48062AF |
| M5Sc-RS | BF | H44901AG |
| ML6-15-RS | BF | H40462LM |
| 6VT-D | BF | H45581BJ |

Notes used in the table:

 GE Part # identifies the device(s) in the manufacturer's design, manufacturing and service documentation. REF is usually affixed to the device(s) in the form of a product identification or model on the rating label.

2. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

3. I/O-devices 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 Medical Systems (China) Co., Ltd** has verified the mutual compatibility of the devices in combination with Vivid T8, and included relevant information to users with the Vivid T8 instructions for use. This activity was subject to appropriate methods of internal control and inspection.

4. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

Wuxi, 11-Oct-2018

Yu Wen Regulatory Affairs Yu Wen





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

Issue date: 2020-05-14 Head of Certification/Notified Body

7



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 Echographic Instruments **Risk Classification** lla

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

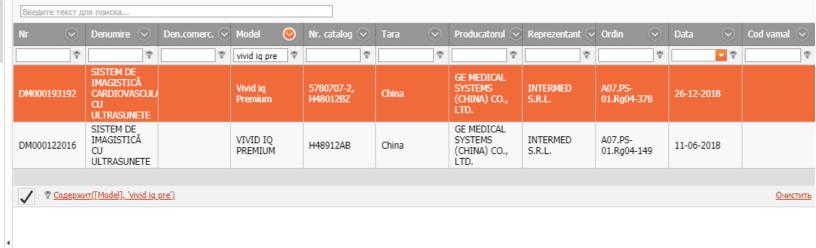
Revision History including Changes:

00 / 2020-05-13 / 713175299



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

| Tip | Denumire |
|---------------------------------------|-------------------------------|
| I.2. Declarația de conformitate CE | Declaratie de conformitate CE |
| I.3. Certificatul CE | Certificat CE |





Certificate

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



Date 2020-03-17



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



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: **Report No.:**

SX 60146260 0001

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

Akkreditierungsstelle D-ZM-14169-01-02

Date: 2020-03-17



Balazs Bozsik



Vivid™ *iq* Ultra Edition

Cardiovascualar Ultrasound **Probe guide**

Comprehensive cardiovascular scanning.

Vivid™ iq Ultra Edition features a wide range of applications that help increase the system's versatility. The system's probes feature a miniaturized RS connector, that helps maximize ease of use and patient comfort. A lightweight probe cable helps minimize strain for the user, facilitating probe placement. There is also a D connector on the cart.

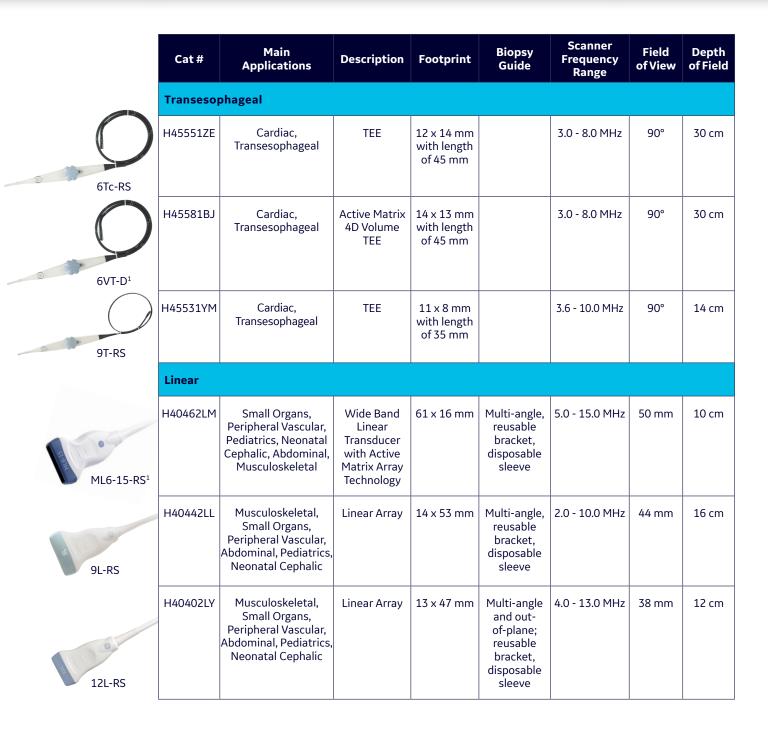


gehealthcare.com/vivid



| | Cat# | Main Applications | Description | Footprint | Biopsy Guide | Scanner Frequency Range | Field of View | Depth of Field |
|----------------------|----------|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------|-------------------------------------------------------------|-------------------------------|------------------|-------------------|
| | Sector | | | | | | | |
| 3Sc-RS | H45041DL | Cardiac, Pediatric, Abdominal, Fetal/ Obstetrics, Adult Cephalic, Transcranial | Phased Array | 18 x 24 mm | Multi-angle disposable, with a reusable bracket | 1.3 - 4.0 MHz | 120° | 30 cm |
| M5Sc-RS ¹ | H44901AG | Cardiac, Pediatric, Abdomeninal, Fetal/Obstetrics, Transcranial, Adult Cephalic | XDclear [™] Active Matrix Single Crystal Phased Array | 18 x 27 mm | Multi-angle disposable, with a reusable bracket | 1.5 - 4.6 MHz | 120° | 30 cm |
| % 6S-RS | H45021RP | Pediatric, Neonatal Cephalic, Fetal/Obstetrics, Abdominal | Phased Array | 17 x 24 mm | | 2.0 - 7.0 MHz | 120° | 30 cm |
| 125-RS | H44901AB | Pediatric, Abdominal, Neonatal Cephalic | Phased Array | 13 x 18 mm | | 4.2 - 12.0 MHz | 90° | 14 cm |







| | Cat# | Main Applications | Description | Footprint | Biopsy Guide | Scanner Frequency Range | Field of View | Depth of Field |
|----------------------|------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------|-------------------------------------------------------------|-------------------------------|------------------|-------------------|
| | Convex | | | | | | | |
| 4C-RS ² | H4000SR | Abdominal, Pediatric, Fetal/Obstetrics, Musculoskeletal | Curved Array | 18 x 66 mm | Multi-angle disposable, with a reusable bracket | 1.5 - 5.0 MHz | 58° | 33 cm |
| 8C-RS | H40402LS | Cardiac, Abdominal, Pediatric, Transcranial, Neonatal Cephalic, Peripheral Vascular, Musculoskeletal, Small Organ | Curved Array | 18 x 66 mm | | 3.5 - 10.0 MHz | 131° | 14 cm |
| C1-5-RS ¹ | H40462LA | Abdominal, Fetal/ Obstetrics, Pediatrics, Musculoskeletal | Curved Array | 17 x 69 mm | Multi-angle disposable, with a reusable bracket | 1.5 - 5.0 MHz | 70° | 33 cm |
| | Doppler | | | | | | | |
| P2D | H45551CA | Cardiac | Pencil Probe | 16 mm | | 1.9 - 2.1 MHz | | |
| | Special | | | | | | | |
| E8Cs-RS | H48062AF | Fetal/Obstetrics, Transrectal, Transvaginal, Abdominal | Endo Curved Array | 19 x 24 mm | Fixed-angle, disposable | 3.5 - 10.0 MHz | 168° | 14 cm |
| | Intraopera | ative | | | | | | |
| L8-18i-RS¹ | H40462LF | Peripheral Vascular, Small Organs, Musculoskeletal, Intraoperative | Linear IO Transducer | 11 x 35 mm | | 4.5 - 18 MHz | 25 mm | 10 cm |
| | | | | | | | | |

 $^{^{1}\}mbox{Probe}$ or Feature only available for Premium and 4D configurations

² Probe or Feature not available for Premium and 4D configurations



| | Cat# | Main Applications | Description | Footprint | Biopsy Guide | Scanner Frequency Range | Field of View | Depth of Field |
|---------------------------|----------|----------------------------------|-------------|-------------------|-----------------|-------------------------------|------------------|-------------------|
| | ICE | | | | | | | |
| | H45021YE | | | | | | | |
| Catheter Cable for ICE | | | | | | | | |
| | t | Intracardiac and Intraluminal | Catheter | 8 Fr diameter | | 4.2 - 11.5 MHz | 90° | 16 cm |
| AcuNav 8F* | | | | | | | | |
| | + | Intracardiac and Intraluminal | Catheter | 10 Fr diameter | | 4.2 - 11.5 MHz | 90° | 16 cm |
| AcuNav 10F* | | | | | | | | |
| | + | Intracardiac and Intraluminal | Catheter | 10 Fr diameter | | 4.2 - 11.5 MHz | 90° | 16 cm |
| SOUNDSTAR 3D 10F G* | | meralamma | | didiffeter | | | | |
| SOUNDSTAR eco 10F G* | t | Intracardiac and Intraluminal | Catheter | 10 Fr diameter | | 4.2 - 11.5 MHz | 90° | 16 cm |
| SOUNDSTAR eco 8F G* | t | Intracardiac and Intraluminal | Catheter | 8 Fr diameter | | 4.2 - 11.5 MHz | 90° | 16 cm |

 $^{^{\}rm 1}{\rm Probe}$ or Feature only available for Premium and 4D configurations

 $^{^{\}scriptscriptstyle{\dagger}}$ Distributed by Biosense Webster Inc.

^{*}Not available in all countries. Please contact Biosense Webster directly.



| | Transducers | | | | | | | | | |
|--------------------|-------------------------------------------|--------|----------|-------|--------|--------|--------------------|-------|-------|--------|
| | | 3Sc-RS | M5Sc-RS¹ | 6S-RS | 12S-RS | 6Tc-RS | 6VT-D ¹ | 9T-RS | 9L-RS | 12L-RS |
| | 2D | | | | | | | | | |
| | 4D ⁵ | | | | | | | | | |
| | AdvQScan (Strain, SR, TSI) ^{1,3} | | | | | | | | | |
| | AdvVascular (B-Flow, BFI)4 | | | | | | | | | |
| | AFI ^{1,3} | | | | | | | | | |
| | AMM | | | | | | | | | |
| | Angio⁴ | | | | | | | | | |
| | Auto2DEF ³ | | | | | | | | | |
| | AFI RV | | | | | | | | | |
| | AFILA | | | | | | | | | |
| S | Al Auto Measure - 2D | | | | | | | | | |
| Modes and Features | Al Auto Measure - Spectrum Recognition | | | | | | | | | |
| Б | Biplane or Triplane ¹ | | | | | | | | | |
| s ar | Color | | | | | | | | | |
| ode | Curved AMM¹ | | | | | | | | | |
| Σ | CW Doppler | | | | | | | | | |
| | Smart Stress ³ | | | | | | | | | |
| | Harmonics | | | | | | | | | |
| | IMT | | | | | | | | | |
| | LOGIQ View ¹ | | | | | | | | | |
| | LVO Contrast ^{1,3} | | | | | | | | | |
| | M-Mode | | | | | | | | | |
| | PW Doppler | | | | | | | | | |
| | Q Analysis | | | | | | | | | |
| | Rodent | | | | | | | | | |
| | Tissue Tracking ³ | | | | | | | | | |
| | TVI ² | | | | | | | | | |
| | Virtual Apex | | | | | | | | | |
| | Virtual Convex | | | | | | | | | |

| _ | | | |
|------|--------|---------|-------|
| Siin | norted | on this | nrohe |
| | | | |

☐ Not supported on this probe

¹ Probe or Feature only available for Premium and 4D configurations

² Probe or Feature not available for Premium and 4D configurations

³ Only for cardiac applications/presets

⁴ Only for non-cardiac applications/presets 5 Probe or Feature only available for 4D configuration



| | Transducers | | | | | | | | |
|--------------------|-------------------------------------------|------------------------|------------|--------------------|----------------------|-------|---------|-----|------|
| | | ML6-15-RS ¹ | L8-18i-RS¹ | 4C-RS ² | C1-5-RS ¹ | 8C-RS | E8Cs-RS | P2D | ICE* |
| | 2D | | | | | | | | |
| | 4D ⁴ | | | | | | | | |
| | AdvQScan (Strain, SR, TSI) ^{1,3} | | | | | | | | |
| | AdvVascular(B-Flow, BFI)4 | | | | | | | | |
| | AFI ^{1,3} | | | | | | | | |
| | AMM | | | | | | | | |
| | Angio ⁴ | | | | | | | | |
| | Auto2DEF ³ | | | | | | | | |
| | AFI RV | | | | | | | | |
| | AFI LA | | | | | | | | |
| Si | Al Auto Measure - 2D | | | | | | | | |
| Modes and Features | Al Auto Measure - Spectrum Recognition | | | | | | | | |
| d F | Biplane or Triplane ¹ | | | | | | | | |
| s ar | Color | | | | | | | | |
| ape | Curved AMM¹ | | | | | | | | |
| Σ | CW Doppler | | | | | | | | |
| | Smart Stress ³ | | | | | | | | |
| | Harmonics | | | | | | | | |
| | IMT | | | | | | | | |
| | LOGIQ View ¹ | | | | | | | | |
| | LVO Contrast ^{1,3} | | | | | | | | |
| | M-Mode | | | | | | | | |
| | PW Doppler | | | | | | | | |
| | Q Analysis | | | | | | | | |
| | Rodent | | | | | | | | |
| | Tissue Tracking ³ | | | | | | | | |
| | TVI ³ | | | | | | | | |
| | Virtual Apex | | | | | | | | |
| | Virtual Convex | | | | | | | | |

| Cupportod | an | +hic | nroho |
|-----------|----|-------|-------|
| Supported | | 11115 | DIODE |

☐ Not supported on this probe

 $^{^{\}rm 1}$ Probe or Feature only available for Premium and 4D configurations $^{\rm 2}$ Probe or Feature not available for Premium and 4D configurations

Only for cardiac applications/presets
 Only for non-cardiac applications/presets
 Probe or Feature only available for 4D configuration
 Not available in all countries. Please contact Biosense Webster directly.

About GE Healthcare

GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges. From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226 USA www.gehealthcare.com

Note: Some applications depend on the availability of certain options. Note: Some of the probes, options or features described in this data sheet may NOT be available for sale in all countries.

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GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC, a General Electric Company, doing business as GE Healthcare.

Ultra Edition is not a product name, it refers to the 2020 release of the Vivid portfolio $\,$





Vivid iq



Product Description

The Vivid[™]iq combines the proven high performance of the Vivid product line with an ultra-modern and lightweight laptop. The Vivid iq is a comprehensive digital color flow Doppler ultrasound system. It is designed for cardiac and shared service imaging with support for the following applications: cardiac, pediatric, fetal/obstetrics, abdominal, transesophageal, intracardiac and Intraluminal, intraoperative, peripheral vascular, adult cephalic, neonatal cephalic, small organ, musculoskeletal conventional, musculoskeletal superficial, transcranial, transrectal, transvaginal, and interventional guidance.

System Architecture

GE's exclusive, patented, beamforming technology provides the power for this multi-purpose ultrasound system. Using both coherent and harmonic image processing, the system provides computational power, ease of imaging, workflow flexibility and product upgradeability.

The Vivid iq excels in the following areas:

Exceptional image quality on the Vivid iq is created through ultradefinition clarity filtering and virtual apex (larger field-of-view) for the FPA probes. **Coded Harmonics** – Produces excellent quality images from even difficult-to-image patients.

Ergonomic Design – The Vivid iq's new and improved ergonomic design is based on real users' feedback and extensive testing. A new ergonomic user interface design makes the Vivid iq an easy-to-learn and highly productive system for experienced and novice users, and similarly for rightand left-hand scanning users alike. The combination of the full touch screen control, new trackpad swipe and click gestures, and a conventional user control panel helps operators maintain their wrist on an ergonomic wrist rest, and focus on the patient and ultrasound images during the exam. Other ergonomic features include a touch LCD monitor with easily adjustable viewing and typing angles and a height-adjustable cart for comfortable standing and sitting positions.

Extreme productivity in 2D imaging is provided by the GE's exclusive technology delivering auto optimized excellent image quality with little manipulation, along with a host of new automated quantification tools such as the new Al-based auto measurements for 2D and Doppler modes, 2D Auto EF 3.0, AFI 3.0, AFI for LA, and AFI for RV.

Portability and Flexible Workflow -

The Vivid iq's innovative compact design and touch user interface is ultra portable and lightweight. The battery option provides additional scanning time without a power supply and instant boot up from standby mode. Additionally, the Vivid iq uses the proven **raw data format technology** that allows for advanced processing on archived images by applying many of the same scan controls and advanced quantitative tools as are available during the original exam.

General Specifications

Dimensions and Weight

- Height: 64 mm (2.5")
 with feet: 73 mm (2.87")
- Width: 390 mm (15.35")
- Depth: 362 mm (14.25")
- Weight with battery: 5.2 kg (11.5 lbs)

Electrical Power

- Voltage: 100-240 VACFrequency: 50/60 Hz
- Power: max. 130 VA
- Scanning time from battery without power supply is approximately one hour¹
- An extended battery is integrated within the Vivid iq cart and provides approximately three additional scanning hours¹

Operating System

Windows® 10

^{*}Vivid iq Premium is a configuration of the Vivid iq ultrasound system with software version v204.

¹ Depending on operation modes used and battery status.

Console Design

- Laptop style
- · ECG port
- · Integrated solid state drive
- Multiple USB ports (front/back)
- Integrated speakers for premium sound
- CPU Intel duo core
- DC power input
- USB interface (5)
- HDMI interface
- ECG
- LAN 10/100/1000 base

Cart Dimension

• Height: 835 - 1115 mm (32.9" - 43.9")

• Width: 524.9 mm (20.7")

• Depth: 552.3 mm (21.7")

• Weight: 41 kg (90 lbs.)

Cart Design

- Three USB ports including one isolated USB interface
- Six probe holders
- · Four probe cable hooks
- Charge box (optional) to charge up to three batteries and to scan more than 180 min with four fully charged batteries
- Multi-probe box (optional) three RS, one DLP to support 6VT-D

User Interface

Operator Panel

- Innovative track pad design a new track pad provides new ergonomic gestures, including two-finger swipe to control Depth and Gain and Click to Set, allowing the user's arm to stay rested for a significant time during the exam
- Ergonomic simplified hard key layout with ergonomic design around the track pad
- Interactive back-lighting of application-specific push buttons – adjustable back-light intensity

- Easy-to-learn user interface with intelligent touch keyboard
- Image manager on the touch screen for quick review of image clipboard contents and easy export of images and loops to remote archives or media

Touch Screen

- Full touch ability including tap, double-tap, swipe, and pinch gestures, for fast and highly responsive user experience
- 15.6" ultra-high-resolution, wide screen format, color, multi-touch LCD screen
- On-screen touch keyboard with support for characters in 14 languages
- Interactive user-configurable short-cut software menu
- Application-specific operator and sidebar touch menu controls operated by finger tapping and swiping
- Overall gain, depth and zoom control bar on the touch for easy adjustment
- · Touch-screen control of TGC sliders

Display Monitor

- 15.6" wide screen full High-Definition (HD) flicker-free LCD display with full touch ability
- 16.7 million simultaneous colors available
- Ergonomic FlexFit design with adjustable typing angle and flexible view angle
- · Resolution: 1920 x 1080 pixels, full HD
- Fold down and lock mechanism for transportation
- Screen can be adjusted in different angles for scanning mode, typing mode and closing, allowing to optimize the viewing angle in each position
- · Backlight adjustable
- Selectable big image size to use more screen area for the ultrasound image for better visibility from a distance
- Adaptive video formats and resolution

System Overview

Applications (probe dependent)

- Cardiac
- · Transesophageal
- · Intracardiac and intraluminal
- · Intraoperative
- · Peripheral vascular
- Fetal/OB
- Abdominal adults
- · Pediatric
- · Small organ
- · Neonatal cephalic
- · Adult cephalic
- · Musculoskeletal conventional
- · Musculoskeletal superficial
- Transcranial
- Transrectal
- Transvaginal

Operating Modes

- 2D tissue
- · 2D color flow
- · 2D angio flow
- · Color M-mode
- · Tissue velocity M-mode
- · Continuous wave Doppler
- · Tissue M-mode
- Pulsed wave Doppler
- · Anatomical M-mode
- · Curved anatomical M-mode
- · Tissue velocity imaging
- · Tissue tracking
- · Tissue synchronization imaging
- · Strain imaging
- · Strain rate imaging
- · Tissue velocity Doppler
- · Blood flow imaging
- B-flow
- · 2D stress
- Automated Function Imaging (AFI) 3.0 (optional)
- AFI LA

- AFIRV
- Auto EF 3.0
- · Al auto measure 2D
- Al auto measure spectrum recognition
- Virtual convex
- · Virtual apex
- Bi-plane
- Tri-plane
- · Coded phase inversion
- · Compound imaging
- Extended field-of-view (LOGIQ[™] View)
- 4D full-volume scanning single-beat and multi-beat
- · Scan coach

Scanning Methods

- · Electronic sector
- · Electronic volume
- · Electronic convex
- · Electronic linear
- CW pencil

Transducer Types

- · Sector phased array
- Convex array
- Linear array
- · Single crystal matrix array
- · 2D matrix array

Peripheral Options

- DVDRW
- · Color video printer
- B/W video printer with optional inverted background printing, allowing for environmentally sensitive ink saving
- USB memory stick
- · One TB USB hard drive
- · HDMI cable
- Video converter providing electrically isolated video signals for external monitors
 - digital Full HD 1920 x 1080
 - analogue VGA 800 x 600

- Three-pedal configurable footswitch
- · Rolling bag
- Ergonomic wrist rest

Accessories (options)

- Interface cable for external ECG
- ECG adapter for DIN-type pediatrics electrode leads

Display Modes

- Live and stored display format: full size and split screen, both with thumbnails, for still and cine
- Instant-review screen displays 12 simultaneous loops/images for a quick study review
- Selectable display configuration of duplex and triplex modes: side-byside or top-bottom during live, digital replay and clipboard image recall
- · Single-, dual- and quad-screen view
- · Simultaneous capability
 - 2D+PW
 - 2D+CW (with 6VT-D probe)
 - 2D + CFM/TVI + PW
 - 2D + CFM + CW (with 6VT-D probe)
 - 2D + CFM/Angio/TVI/SRI/TT/SI/TSI
 - 2D + M/AMM/CAMM
 - 2D + CFM/Angio/TVI/SRI/TT/SI/TSI + M/AMM/CAMM
 - Real-time duplex or triplex mode (with 6VT-D probe)
 - Compound + M/CFM/PW
 - 2D + bi-plane (with 6VT-D probe)
 - 2D + bi-plane + CFM/AMM/CAMM (with 6VT-D probe)
 - 2D + tri-plane (with 6VT-D probe)
 - 2D + tri-plane + CFM/AMM/CAMM (with 6VT-D probe)
 - 2D + color split screen (simultaneous mode)
- · Selectable alternating modes
 - 2D or compound + PW
 - 2D + CW
 - 2D or compound + CFM/PW
 - 2D + CFM + CW
- Multi-image (split/quad screen)
 - Live and/or frozen
 - Independent cine playback

- · Timeline display
 - Independent 2D (or compound) + PW/CW/M display
 - A choice of display formats with various sizes of 2D + PW/CW/M
- · Top/bottom selectable format
- · Side/side selectable format

Display Annotation

- · Patient name
- Patient ID
- · Age, sex and birth date
- · Hospital name
- Date format: three types selectable MM/DD/YYYY, DD/MM/YYYY, YYYY/MM/DD
- Time format: two types selectable 24 hours, 12 hours
- · Gestational age from LMP/EDD/GA
- · Probe name
- Probe orientation
- · Depth scale marker
- Focal zone markers
- · Image depth
- Zoom depth
- B-mode
 - Gain
 - Imaging frequency
 - Frame averaging
 - Dynamic range
 - Gray map
- M-mode
 - Gain
 - Frequency
 - Time scale
 - Dynamic range
- · Doppler mode
 - Gain
 - Angle
 - Sample volume size and position
 - Wall filter (low velocity reject)
 - Velocity and/or frequency scale
 - Spectrum inversion
- · Time scale
 - PRF
 - Doppler frequency

- Color flow Doppler mode
 - Frame rate
 - Sample volume size
 - Color scale
 - Power
 - Color baseline
 - Color threshold marker
 - Color gain
 - Frame averaging
- Spectrum inversion
- · Acoustic frame rate
- CINE gauge, image number/frame number
- Bodymarks: multiple human anatomical structures
- · Application/preset 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
- · Power output in dB
- · Biopsy guide line and zone
- · Heart rate
- · TrackPad-driven annotation arrows
- · Active mode display
- · Stress protocol parameters
- Parameter annotation follow ASE standard
- · Free text with word library
- Scan plane position indicator and probe temperature are displayed with all TEE probes
- · Image orientation marker

General System Parameters

System Setup

- Pre-programmable M&A and annotation categories
- Different user presets per probe/application may be stored for quick access
- User programmable preset capability with administrator preset protection

- Factory default preset data, protected against modification
- QuickApps: Factory and user programmable sub-preset feature that keeps 2D and geometry settings while allowing different color flow or contrast parameters
- User Interface languages: English, LA Spanish, French, German, Italian, Portuguese (European and Brazilian), Russian, Swedish, Norwegian, Danish, Dutch, Finnish
- · User-defined annotations
- · Body patterns
- Customized comment home position

Comprehensive User Manual Available on Board

User manual and service manual are included on USB media with each system and can be downloaded from the Internet. A printed user manual is provided.

Memory/Image Memory

- 500 MB of cine memory
- Selectable cine sequence for cine review
- Measurements/calculations and annotations on cine playback
- · Scrolling timeline memory
- · Dual-image cine display
- · Quad-image cine display
- CINE indicator and cine image number display
- · CINE review loop
- · CINE review speed

Image Storage

- On-board database of patient information from past exams
- User-selectable ECG and time gated acquisition available on touch panel during live scanning
- User-selectable prospective or retrospective capture in config

- · Storage formats:
 - DICOM®-compressed or uncompressed, single/multi-frame, with/without raw data, storage via clipboard and/or seamlessly directly to destination device
 - Transfer/"Save As" JPEG, MPEG, AVI formats
- Storage devices (optional):
 - USB memory stick: 32 GB
 - CD-RW storage: 700 MB (DVD option required)
 - DVD storage: -RW (4.7 GB)
 - Hard drive image storage: one TB
- Compare previous images with current exam
- · Reload of archived data sets

Connectivity and DICOM (optional)

- · Ethernet network connection
- Wireless network connection
- DICOM 3.0
- Verify
- Print
- Store
- · Modality worklist
- · Storage commitment
- Modality Performed Procedure Step (MPPS)
- · Media exchange
- · DICOM spooler
- DICOM query/retrieve
- Structured reporting compatible with adult cardiac, pediatric, vascular and abdominal
- · Media store of structured reporting
- InSite™ ExC capability for remote service/access
- · Support of two patients' IDs in DICOM
- Separate DICOM SR and image storage destinations
- Adaptive DICOM SR supported for Cardiac
- Simultaneous transfer of DICOM to multiple destinations
- Streaming (option) sends the image information as digital video stream over Ethernet in real-time to clients

Patient Archive

EchoPAC™/Patient Archive

- Data format fully compatible with offline EchoPAC review/reporting stations of same or newer vintage
- Instant access to ultrasound raw data provided by the system
- · Advanced post-processing analysis
- Three user levels help organizing data security requirements
- E-signoff compatibility, with clear indications in patient management screens and report screen that a report was signed off, and by whom and at what time. The signed off report and exam cannot be changed. The "Diagnosing Physician" field is automatically assigned to the user that did the sign-off

Image and Data Management

- Exceptional workflow with instant access data management
- DICOM 3.0 support see DICOM conformance statement for details
- Support for transfer of the proprietary raw data files within the DICOM standard, configurable per mode
- 2D, CFM or TVI data at maximum frame rate may be reviewed by scrolling or by running cine loops (can contain more than 1000 images for imaging modes)
- Image clipboard for stamp-size storage and review of stored images and loops
- Built-in patient archive with images/loops, patient information, measurements and reports
- DICOM-SR Standard structured reporting mechanism
- Structured findings report tools support efficient text entries with direct editing of findings text, usability improvements, new configuration options and conclusion section
- User can enter normal values which are then compared to actual measurements
- Configurable HTML-based report function

- Report templates can be customized on board
- ASE-based default text modules (English), user-customizable
- Internal archive data can be exported to removable image storage through DICOM media
- Internal hard disk for storing programs, application defaults, ultrasound images and patient archive
- All data storage is based on ultrasound raw data, allowing to change gain, baseline, color maps, sweep speeds, etc., for recalled images and loops
- DICOM media read/write images on DICOM format
- DICOM viewer embedded on media (optional and selectable in Config)
- Alphanumeric data can be exported in XML format
- JPEG export ("Save As") for still frames
- AVI and MPEG export ("Save As") for cineloops
- Ability to transfer Systole Only for Stress echo loops to PACS

CartoSound®Interface (optional)

- The system can interface with the Carto®3 EP navigation system and the SOUNDSTAR® ultrasound catheters manufactured by Biosense Webster
- The interface allows the Vivid iq system to send images to the Carto 3 EP system
- The Vivid iq is able to send ultrasound scaling parameters to the Carto 3 EP system via a peer-to-peer LAN connection

Tricefy® Cloud Service

- · Can serve as long-term archive
- Can be used to share examinations with colleagues for information or collaboration
- Can be used to share images with patients

Self-contained DICOM Viewer (optional)

- Exams can be transferred to CD/DVD or USB media with an integrated "EZ DICOM CD viewer™"
- Self-contained "EZ DICOM CD viewer™" allows review of exams from media on a standard PC without installing anything on the host

Insite[™] Express Connection (ExC)

Enables Remote Service and Training

- Easy, flexible and secure connectivity configuration. The "Contact GE" on-screen button directly generates a real-time service request to the GE online engineering or application specialist. It takes a snapshot (e.g., error logs, setup files) of the system at the time of the service request to enable analysis of problem before customer contact
- Virtual Console Observation (VCO)
 enables the customer to allow
 desktop screens to be viewed and
 controlled remotely over the encrypted
 tunnel to enable real-time training,
 device configuration and clinical
 application support
- Operation of Insite Express Connection is dependent on the infrastructure being available – check with your local GE service representative
- File transfer via Secure File Transfer Protocol (SFTP) enables the customer (biomed or clinician) to directly transfer system information (e.g., system logs, images, parametric data) to GE product engineering teams (no patient data transferred)
- Software reload provides remote application reconstruction and recovery capabilities in the event of system corruption

Smart Service Interface (SSI) (optional)

 A suite of GE proprietary service tools, designed for expert healthcare technology management professionals who want to streamline troubleshooting and diagnostics on their GE Vivid systems

- Provides an intelligent visual dashboard with drill-down capability to rapidly assess equipment status and health
- Can drive productivity by quickly isolating specific issues and decreasing overall system downtime
- SSI is available for licensed qualified users; please contact your local sales representative for more information

Scanning Parameters

- Digital beamformer with up to 974,026 effective channels
- Minimum field-of-view range (depth):
 1 cm (probe dependent)
- Maximum field-of-view range (depth): 33 cm (probe dependent)
- Width range: 10° 168° (probe dependent)
- Continuous dynamic receive focus/continuous dynamic receive aperture
- Composite dynamic range up to 415 dB
- · Adjustable dynamic range
- · Image reverse: right/left
- Image rotation of 0,° 180°
- Touch user-interface inversion for right-hand scanning users

Tissue Imaging

General

- Variable transmit frequencies for resolution/penetration optimization
- Display zoom with zoom area control
- High-Resolution (HR) zoom concentrates all image acquisition power into selected Region of Interest (ROI)
- Variable contour filtering for edge enhancement
- Selectable grayscale parameters: gain, reject, DDP, clarity, dynamic range and compress – can be adjusted in live, digital replay and image clipboard recall (probe dependent)
- Automatically calculated TGC curves reduce operator interaction
- · Automatically calculated lateral gain

2D Mode

- · Sector tilt and width control
- Frame rate in excess of 1000 fps, depending on probe, settings and applications
- Coded octave imaging with coded phase inversion – 3rd generation harmonic tissue imaging providing improved lateral and contrast resolution over conventional fundamental imaging. Features help reduce noise, improve wall definition, and axial resolution, making it well suited for a wide variety of patient groups
- Automatic tissue optimization single keystroke optimizes immediately automatically and dynamically different grayscale settings with the goal of signal independent uniform gain and contrast distribution
- UD clarity and UD speckle reduce imaging – an advanced image processing technique to remove speckle in real-time examining the relative difference between neighboring pixel values and determining whether the grayscale variations have a sharp difference, follow a trend, or are random in nature
- Multiple-angle compound imaging –
 multiple co-planar images from different angles combined into a single
 image in real-time to help enhance
 border definition and contrast
 resolution, as well as reduce angular
 dependence of border or edge as
 compared to no-compound imaging
- LOGIQ View: Provides the ability to construct and view a static 2D image with wider field-of-view of a given transducer. This allows viewing and measurements of anatomy that is larger than what would fit in a single image
- Virtual convex provides a wider field-of-view with linear probes, effective at certain imaging views where a wide far field may be preferred
- Virtual apex provides a wider field-of-view with phased array probes, effective at certain imaging views where a wide near field may be preferred

- L/R and up/down invert, in live, digital replay or image clipboard recall
- Digital replay for retrospective review or automatic looping of images, allowing for adjustment of parameters such as gain, reject, anatomical M-mode, persistence and replay speed
- Data dependent processing performs temporal processing which helps reduce random noise but leaves motion of significant tissue structures largely unaffected – can be adjusted even in digital replay
- · 256 shades of gray
- Colorized 2D-mode, user-selectable in real-time, digital replay

Multi-dimensional Mode (with 6VT-D probe)

- Bi-plane scanning: two independent simultaneous scan planes where one of them can be rotated and tilted freely
- Tri-plane: three independent simultaneous scan planes that can be rotated freely
- Both bi-plane and tri-plane scanning is possible in all color Doppler modes

M-mode

- TrackPad steers M-mode line available with all imaging probes – max steering angle is probe dependent
- Simultaneous real-time 2D- and M-mode
- M-mode PRF 1 kHz image data acquired is combined to give high-quality recording regardless of display scroll speed
- Digital replay for retrospective review of spectral data
- Several top-bottom formats, side-byside format and time-motion-only format – can be adjusted in live or digital replay
- Selectable horizontal scroll speed:
 1, 2, 3, 4, 6, 8, 12, 16 seconds
 across display
- Horizontal scroll can be adjusted in live or digital replay

Anatomical M-mode

- M-mode cursor can be adjusted at any plane
- Curved anatomical M-mode free (curved) drawing of M-mode generated from the cursor independent from the axial plane
- Can be activated from live, digital replay or image clipboard recall
- Anatomical color and tissue velocity M-mode
- M&A capability

Color Doppler Imaging

General

- Steerable color Doppler available with all imaging probes – max steering angle is probe dependent
- TrackPad-controlled ROI
- Touchscreen-controlled ROI
- Removal of color map from the tissue during digital replay
- Digital replay for retrospective review of color or color M-mode data allowing for adjustment of parameters such as encoding principle, color priority and color gain even on stored data
- PRF settings user-selectable
- Advanced regression wall filter gives efficient suppression of wall clutter
- For each encoding principle, multiple color maps can be selected in live and digital replay – variance maps available
- More than 65,000 simultaneous colors processed, providing a smooth display two-dimensional color maps containing a multitude of color hues
- Simultaneous display of grayscale
 2D and 2D with color flow
- Color invert user-selectable in live and digital replay
- Variable color baseline user-selectable in live and digital replay
- Multi-variate color priority function gives delineation of disturbed flows even across bright areas of the 2D-mode image

 Color Doppler frequency can be changed independently from 2D

Color Flow Imaging

- TruSpeed imaging allows either ultrahigh frame rate or increased lateral resolution as compared to previous generation GE products
- Frame rate in excess of 700 (it is 400 on 12S-RS) fps, depending on probe and settings
- · Variable ROI size in width and depth
- User-selectable radial and lateral averaging to help reduce statistical uncertainty in the color velocity and variance estimates
- Data Dependent Processing (DDP)
 performs temporal processing and
 display smoothing to help reduce loss
 of transient events of hemodynamic
 significance
- Digital replay for retrospective review or automatic looping of color images, allowing for adjustment of parameters such as DDP, encoding principle, baseline shift, color maps, color priority and color gain even on frozen/recalled data
- Application-dependent, multi-variate motion discriminator helps reduce flash artifacts
- Dedicated coronary flow application
- Multiple-angle compound imaging in 2D mode is maintained while in color Doppler mode

Multi-Dimensional Color Doppler Imaging (with 6VT-D probe)

 Bi-plane and tri-plane scanning with all color Doppler and tissue velocity modes

Color Angio

 Angle-independent mode for visualization of small vessels with increased sensitivity compared to standard color flow of previous GE products

Color M-mode

Variable ROI length and position – user-selectable

- User-selectable radial averaging to help reduce statistical uncertainty in the color velocity and variance estimates
- Selectable horizontal scroll speed:

 2, 3, 4, 6, 8, 12, 16 seconds
 across display can be adjusted during live, digital replay or image clipboard recall
- Real-time 2D image while in color M-mode
- Same controls and functions available as in standard 2D color Doppler

Anatomical Color M-mode

- GE-patented, any plane color M-mode display derived from color Doppler cine loop
- Also applicable to tissue velocity Imaging
- · M&A capability

B-flow

- B-flow is a digital imaging technique that provides real-time visualization of vascular hemodynamics by directly visualizing blood reflectors and presenting this information in a grayscale display
- Use of GE-patented techniques to boost blood echoes, and to help preferentially suppress non-moving tissue signals
- B-flow is available for most vascular and shared service applications

Blood Flow Imaging

- Combines color Doppler with grayscale speckle imaging
- Helps improve delineation of blood flow without bleeding into tissue or vessel wall

Blood Flow Angio Imaging

Combines angio with grayscale speckle imaging

Tissue Velocity Imaging Tissue Velocity Imaging Mode

 Myocardial Doppler imaging with color overlay on tissue image

- Tissue Doppler data can be acquired in background during regular
 2D imaging
- The velocity of myocardial segments after entire heart cycle can be displayed in one single image
- Tissue color overlay can be removed to show just the 2D image, still retaining the tissue velocity information
- Quantitative profiles for TVI, tissue tracking, strain and strain rate can be derived
- Time markers for valve events derived from any TM mode help simplify understanding of signals in velocity traces or curved anatomical M-mode

Tissue Tracking Mode

- Real-time display of the time integral of TVI for quantitative display of myocardial systolic displacement
- Myocardial displacement is calculated and displayed as a color-coded overlay on the grayscale and M-mode image – different colors represent different displacement ranges

Tissue Synchronization Imaging Mode

(option, enabled by Advanced QScan)

- Parametric imaging which gives information about synchronicity of myocardial motion
- Myocardial segments colored according to time to peak velocity, green for early and red for late peak
- Waveform trace available to obtain quantitative time to peak measurement from TSI Image
- Available in live scanning, as well as an offline calculation derived from tissue Doppler data
- Additional features in combination with multi-dimensional imaging option
- Simultaneous acquisition of tri-plane TSI images covering all standard segments in apical views (with 6VT-D probe)
- Efficient segment specific TSI time measurements
- Immediate bulls-eye report

- Automatic calculated TSI synchrony indexes
- TSI surface mapping
- · LV synchronization report template
- · CRT programming protocol

Strain/Strain Rate Mode (option, enabled by Advanced QScan)

- Tissue deformation (strain) and rate of deformation (strain rate) are calculated and displayed as real-time, color-coded overlay on the 2D image
- Cine compound calculates and displays cineloops generated from a temporal averaging of multiple consecutive heart cycles
- Anatomical M-mode and curved anatomical M-mode displays (SI and SRI)

Spectral Doppler

General

- · Operates in PW, HPRF and CW modes
- TrackPad steerable Doppler available with all imaging probes – max steering angle is probe dependent
- Selectable Doppler frequency for enhanced optimization
- High-quality, real-time duplex or triplex operation in all Doppler modes, CW and PW, and for all velocity settings
- Frame rate control for optimized use of acquisition power between spectrum, 2D and color Doppler modes in duplex or triplex modes
- Very fast and flexible spectrum analysis with an equivalent DFT rate of 0.2 ms
- Automatic Spectrum Optimization (ASO) provides a single press, automatic, real-time optimization of PW or CW spectrum scale, and baseline display
- Dynamic gain compensation for display of flows with varying signal strengths over the cardiac cycle to help improve ease of use
- Dynamic reject gives consistent suppression of background – user-selectable in real-time, digital replay or image clipboard recall

- Digital replay for retrospective review of spectral Doppler data
- Several top-bottom formats, side-by-side format and timemotion-only format – can be adjusted in live or digital replay
- Selectable horizontal scroll speed: 1, 2, 3, 4, 6, 8, 12, 16 seconds across display – can be adjusted in live or digital replay
- Adjustable spectral Doppler display parameters: gain, reject, compress, color maps – can be adjusted in live or digital replay
- User-adjustable baseline shift in live, digital replay and image clipboard recall
- · Adjustable velocity scale
- Wall filters with range 10-2000 Hz (velocity scale dependent)
- Angle correction with automatic adjustment of velocity scale – in live, digital replay and image clipboard recall
- Auto Doppler angle
- Stereo speakers mounted in the front panel
- Display annotations of frequency, mode, scales, Nyquist limit, wall filter setting, angle correction, acoustic power indices
- Compound in duplex

PW/HPRF Doppler

- Automatic HPRF Doppler maintains its sensitivity even for shallow depths and with the highest PRF's
- Digital velocity tracking Doppler employs processing in range and time for high-quality spectral displays
- Adjustable sample volume size of 1-16 mm (probe dependent)
- Maximum sample volume depth 30 cm

CW Doppler

- Highly sensitive steerable CW available with all phased array probes
- · Tissue velocity Doppler

Contrast Imaging (optional)

LVO Contrast (accessed through QuickApps)² – Enables contrast applications intended for imaging of the left ventricle:

LV contrast (3Sc-RS probe) enhances delineation of the LV border in combination with ultrasound contrast agents. The new implementation of GE's Coded Phase Inversion (CPI) provides high-resolution detection of contrast in the LV cavity and excellent suppression of myocardial tissue signals.

Physiological Traces

- · Integrated three-lead ECG module
- · Automatic QRS complex detection
- · External ECG lead input
- Internally generated respiratory trace using ECG leads
- · ECG lead selection
- · Adjustable ECG QRS markers

Automatic Optimization

- Dynamic optimization of B-mode image to improve contrast resolution, TGC and grayscale (soft or sharp, user-selectable)
- Auto-spectral optimize dynamic adjustments of baseline, and PRF (on live image) and angle correction

Measurement and Analysis (M&A)

- Personalized measurement protocols allow individual set and order of M&A items
- Measurements can be labeled seamlessly by using protocols or post assignments
- Measurements assignable to protocol capability
- Parameter annotation follow ASE standard
- Seamless data storage and report creation
- User-assignable parameters
- Comprehensive set of adult and pediatric cardiac measurements and calculations to help assess dimensions, flow properties and other functional parameters of the heart

- Comprehensive set of shared service measurements and calculations covering vascular, abdominal, obstetrics and other application areas
- Configuration package to set up a customized set and sequence of measurements to use, defining user-defined measurements and changing settings for the factorydefined measurements
- Stress echo support allowing wall motion scoring and automatic stress level labeling of measurements
- Support for measuring on DICOM images
- Al-based Cardiac Auto 2D Measurement (option) enables automated quantification of the most common distance measurements performed on parasternal LAX 2D images, with minimum user guidance
- Al-based Spectrum Recognition (option) enables automated recognition of the most common Doppler spectra and automatically starts the Auto Doppler measurement (where available), or opens the applicable manual measurement
- Cardiac Auto Doppler automatically provides Doppler measurement results for the most common parameters with minimal user guidance
- Automatic Doppler trace functionality for use in non-cardiac applications in both live and replay

- Worksheet for review, edit and deletion of performed measurements
- Reporting support allowing a configurable set of measurements to be shown in the exam report
- DICOM SR export of measurement data

Intima Media Thickness (IMT) Measurements

- Automatic measurements (patent pending) of carotid artery Intima-Media Thickness (IMT) on any acquired frame
- On-board IMT package facilitates non-interrupted workflow – fully integrated with M&A, worksheet, archiving and reporting functions
- Algorithm provides robust, quick, reliable measurements which can be stored to the on-board archive for review and reporting
- IMT measurement can be made from frozen images or images retrieved from archive
- IMT package supports measurements of different regions of the intima in the carotid vessel (e.g., Lt./Rt./CCA/ICA etc.)
- Frame for IMT measurement can be selected in relation to the ECG waveform

Z-Scores

 Support for six sets of userselectable Z score publications³ covering the most common pediatric dimension measurements

- 2 Schering developed harmonic imaging for supporting contrast agent imaging.
- 3 C Kampmann, C M Wiethoff, A Wenzel, et. al. Normal Values of M Mode Echocardiographic Measurements of More Than 2000 Healthy Infants and Children in Central Europe. Heart 2000; 83: 667-672.

M Cantinotti, MD; M Scalese, MS; B Murzi, MD; et. al. Echocardiographic Nomograms for Ventricular, Valvular and Arterial Dimensions in Caucasian Children with a Special Focus on Neonates, Infants and Toddlers. <u>Journal of American Society of Echocardiography</u> February 2014; Volume 27, Issue 2; 179-191.e2.

Michael D. Pettersen, MD; Wei Du, PhD; Mary Ellen Skeens, MS; and Richard A. Humes, MD. Regression Equations for Calculation of Z Scores of Cardiac Structures in a Large Cohort of Healthy Infants, Children, and Adolescents: An Echocardiographic Study. <u>Journal of the American Society of Echocardiography</u> 2008; 21(8): 922-34.

Lopez L et. al. Relationship of Echocardiographic Z Scores Adjusted for Body Surface Area to Age, Sex, Race, and Ethnicity. The Pediatric Heart Network Normal Echocardiogram Database. <u>Circ Cardiovasc Imaging</u>. 2017 ov; 10(11). pii: e006979. doi: 10.1161/CIRCIMAGING.117.006979.

BEI Xia, <u>Pediatric Ultrasound Imaging</u>. Beijing: People's Medical Publishing House, 2013 (Second Edition): 173-227.

BEI Xia, <u>Pediatric Ultrasound Imaging</u>. Beijing: People's Medical Publishing House, 2013 (Second Edition): 261-289.

View-X (optional, used with 6VT-D probe)

 Interface between a cath system and the Vivid scanner, such that the cath x-ray image can be shown on the Vivid scanner screen, together with the ultrasound image (picture-in-picture)

Quantitative Analysis Package (Q-Analysis) (optional)

- Traces for velocity or derived parameters (strain rate, strain, displacement) inside defined regions of interest as function of time
- Contrast analysis with traces for grayscale intensity or angio power inside defined regions of interest as function of time
- Curved anatomical M-mode display allowing an M-mode along an arbitrary curve in a 2D image
- Sample-area points may be dynamically anchored to move with the tissue when running the cineloop
- Cine compound displays cineloops generated from a temporal averaging of multiple consecutive heart cycles

Automated Function Imaging (AFI) 3.0 (optional)

- Third generation parametric imaging tool which gives quantitative data for global and segmental strain
- Allows comprehensive assessment at a glance by combining three apical longitudinal views into one comprehensive bulls-eye view
- Integrated into M&A package with specialized report templates
- 2D strain based data moves into clinical practice
- Simplified and flexible workflow with fully automated ROI tracing (if configured), adaptive ROI width and combined display of traces from all segments
- User-selectable endo or full wall global strain values displayed
- Random sequence of analysis of the three views supported

- Ability to exit tool after one or two views completed
- Applicable to transthoracic and TEE 2D data
- · Integrated AutoEF calculation
- Can process raw data and DICOM data acquired with other vendors' ultrasound scanners

Automated Function Imaging for the Right Ventricle (AFI RV) (optional)

- Parametric imaging tool which gives quantitative data for right ventricular longitudinal global strain, free wall strain and segmental strain derived from the apical 4-chamber RV focused view
 - Tricuspid Annular Plane Systolic Excursion (TAPSE) provided
 - Simplified and flexible workflow with 3-point click method for ROI selection, supports editing of both endo- and epicardial borders and adaptive ROI width
 - Combined display of traces from all segments
- User-selectable endo or full wall global strain values displayed

Automated Function Imaging for the Left Atrium (AFI LA) (optional)

- Parametric tool giving quantitative data for LA longitudinal global wall strain, LA volumes and emptying fraction
- Single-plane (4-channel and 2-channel) or bi-plane (4-channel and 2-channel) measurement
 - Simplified and flexible workflow with 3-point click method for ROI selection and adaptive ROI width
- Full wall tracking

Automated Ejection-Fraction Calculation (AutoEF 3.0) (optional)

- Third generation automated EF measurement tool based on 2D speckle tracking algorithm and on Simpson
- Integrated into M&A package with worksheet summary

 Can process raw data and DICOM data acquired with other vendors' Ultrasound scanners

Generic Measurements

- BSA (Body Surface Area)
- MaxPG (Maximum Pressure Gradient)
- MeanPG (Mean Pressure Gradient)
- % Stenosis (Stenosis Ratio)
- PI (Pulsatility Index)
- RI (Resistivity Index)
- HR (Heart Rate) beats/minute
- A/B Ratio (Velocities Ratio)
- TAMAX (Time Averaged Maximum Velocity) – Trace method is Peak or Manual
- TAMIN (Time Averaged Minimum Velocity) – Trace method is Floor
- TAMEAN (Time Averaged Mean Velocity) – Trace method is Mean
- Volume

OB/GYN Application Module

- OB package for fetal growth analysis containing more than 100 biometry tables
- · Dedicated OB/GYN reports
- Fetal graphical growth charts
- · Growth percentiles
- Multi-gestational calculations (up to four)
- · Programmable OB tables
- · Expanded worksheets
- User-selectable fetal growth parameters based on European, American or Asian methods charts
- GYN package for ovary and uterus measurements and reporting

OB Measurements/Calculations

- · Gestational age by:
 - GS (Gestational Sac)
 - CRL (Crown Rump Length)
 - FL (Femur Length)
 - BPD (Bi-Parietal Diameter)
 - AC (Abdominal Circumference)
 - HC (Head Circumference)

- APTD x TTD (Anterior/Posterior Trunk Diameter by Transverse Trunk Diameter)
- LV (Length of Vertebra)
- 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)
- Estimated Fetal Weight (EFW) by:
 - AC, BPD
 - AC, BPD, FL
 - AC, BPD, FL, HC
 - AC, FL
 - AC, FL, HC
 - AC, HC
 - FFBW
- · 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:
 ASUM, ASUM 2001, Berkowitz,
 Bertagnoli, Brenner, Campbell, CFEF,
 Chitty, Eik-Nes, Ericksen, Goldstein,
 Hadlock, Hansmann, Hellman, Hill,
 Hohler, Jeanty, JSUM, Kurtz, Mayden,
 Mercer, Merz, Moore, Nelson, Osaka
 University, Paris, Rempen, Robinson,
 Shepard, Shepard/Warsoff, Tokyo
 University, Tokyo/Shinozuka, Yarkoni
- · Fetal graphical trending
- · Growth percentiles
- Multi-gestational calculations (four)
- Fetal qualitative description (anatomical survey)

- Fetal environmental description (biophysical profile)
- · Programmable OB tables
- Over 20 selectable OB calculations
- · Expanded worksheets

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
- · Summary reports

Abdominal Calculations

- · Splenic index
- Liver volume, mass, cyst
- Pancreas
- CBD
- · GB wall, length
- · Aorta prox, mid, dist
- · Aorta iliac
- Spleen volume
- · Bladder, post void bladder volume
- Renal
- Cortex thickness
- Mesenteric (CA, SMA, IMA)

Vascular Calculations

- RT ECA (Right External Carotid Artery Velocity)
- RT CCA (Right Common Carotid Artery Velocity)
- RT BIFURC (Right Carotid Bifurcation Velocity)
- RT ICA (Right Internal Carotid Artery Velocity)
- RT ICA/CCA (Right Internal Carotid Artery Velocity/Common Carotid Artery Velocity Ratio)

- LT ECA, LT CCA, LT BIFURC, LT ICA, LT ICA/CCA (same as above, for Left Carotid Artery)
- RT BULB (Right Bulbus Artery), RT VERT (Right Vertebral Aretry), RT SUBC (Right Subclavian Artery), RT INN (Right Inn Artery)
- LT BULB, LT VERT, LT SUBC, LT INN
- Stent, pre-stent, post-stent
- A/B Ratio (Velocities Ratio)
- % Stenosis (Stenosis Ratio)
- S/D Ratio (Systolic Velocity/Diastolic Velocities Ratio)
- PI (Pulsatility Index)
- RI (Resistivity Index)
- HR (Heart Rate) beats/minute
- UEV (Upper Extremity Vein velocities):
 IJV, SUBC, Axill V, Bas V, RV, UV, Ves,
 Pseudo, AVF, CephV
- UEA (Upper Extremity Artery velocities): Inn, SUBC, Axill, BA, RA, UA, Pseudo, AVF, Ves
- LEV (Lower Extremity Vein velocities): CFV, Saph FemJunc V, PopV, PTV, ATV, FV, GSV Calf, GSV Thigh, GSV Access, LSV, Saph PopJunc
- LEA (Lower Extremity Artery velocities): EIA, SFA, Pop, PTA, Peron, DPA, ATA, CFA, DFALEA
- MCA (Middle Cerebral Artery), ACA (Anterior Cerebral Artery), PCA (Posterior Cerebral Artery), AcomA (Anterior Communicating Artery), PComA (Posterior Communicating Artery), Basilar (Basilar Artery), Ves

Cardiac Measurements

- %FS (LV Fractional Shortening)
- %IVS Thck (IVS Fractional Shortening)
- %LVPW Thck (LV Posterior Wall Fractional Shortening)
- Ao Arch Diam (Aortic Arch Diameter)
- Ao Asc (Ascending Aortic Diameter)
- Ao Desc Diam (Descending Aortic Diameter)
- Ao Isthmus (Aortic Isthmus)

- · Ao Root Diam (Aortic Root Diameter)
- AR ERO (PISA: Regurgitant Orifice Area)
- AR Flow (PISA: Regurgitant Flow)
- AR PHT (AV Insuf. Pressure Half Time)
- AR Rad (PISA: Radius of Aliased Point)
- AR RF (Regurgitant Fraction over the Aortic Valve)
- AR RV (PISA: Regurgitant Volume Flow)
- · AR Vel (PISA: Aliased Velocity)
- AR Vmax (Aortic Insuf. Peak Velocity)
- AR VTI (Aortic Insuf. Velocity Time Integral)
- ARed max PG (Aortic Insuf. End-Diastole Pressure Gradient)
- ARed Vmax (Aortic Insuf. End-Diastolic Velocity)
- AV Acc Slope (Aortic Valve Flow Acceleration)
- AV Acc Time (Aortic Valve Acceleration Time)
- AV AccT/ET (AV Acceleration to Ejection Time Ratio)
- AV EOA I (VTI) (Aortic Valve Effective Orifice Area Index by Continuity Equation VTI)
- AV EOA I Vmax (Aortic Valve Effective Orifice Area Index by Continuity Equation Peak V)
- AV CO (Cardiac Output by Aortic Flow)
- AV Cusp (Aortic Valve Cusp Separation, 2D)
- AV Dec Time (Aortic Valve Deceleration Time)
- · AV Diam (Aortic Diameter, 2D)
- AV max PG
 (Aortic Valve Peak Pressure Gradient)
- AV mean PG
 (Aortic Valve Mean Pressure Gradient)
- · AV SV (Stroke Volume by Aortic Flow)
- AV Vmax (Aortic Valve Peak Velocity)
- AV Vmean (AV Mean Velocity)
- AV VTI (Aortic Valve Velocity Time Integral)
- AVA (Vmax) (AV Area by Continuity Equation by Peak V)

- AVA (VTI) (AV Area by Continuity Equation VTI)
- AVA Planimetry (Aortic Valve Area)
- AVET (Aortic Valve Ejection Time)
- CO (Teich) (Cardiac Output, M-mode, Teicholtz)
- D-E Excursion (MV Anterior Leaflet Excursion)
- E' Avg (Averaged Early Diastolic Mitral Valve Annular Velocity)
- E' Lat (Early Diastolic Mitral Valve Lateral Annular Velocity)
- E' Sept (Early Diastolic Mitral Valve Septal Annular Velocity)
- E/E' Avg (Mitral Inflow E Velocity to E' Avg Ratio)
- E/E' Lat (Mitral Inflow E Velocity to E' Lat Ratio)
- E/E' Sept
 (Mitral Inflow E Velocity to E' Sept Ratio)
- EDV (Cube) (Left Ventricle Volume, Diastolic, 2D, Cubic)
- EF (A-L A2C) (Ejection Fraction 2CH, Single Plane, Area-Length)
- E-F Slope (Mitral Valve E-F Slope)
- EPSS (E-Point-to-Septum Separation, M-mode)
- ERO (Effective Regurgitant Orifice)
- ESV (Cube) (Left Ventricle Volume, Systolic, 2D, Cubic)
- HR (Heart Rate, 2D, Teicholtz)
- IVC (Inferior Vena Cava)
- IVCT (Isovolumic Contraction Time)
- IVRT (Isovolumic Relaxation Time)
- IVSd (Interventricular Septum Thickness, Diastolic, 2D)
- VSs (Interventricular Septum Thickness, Systolic, 2D)
- LA Diam (Left Atrium Diameter, 2D)
- · LA Major (Left Atrium Major)
- · LA Minor (Left Atrium Minor)
- LA/Ao (LA Diameter to AoRoot Diameter Ratio, 2D)
- LAAd (A2C) (Left Atrium Area, Apical 2C)
- LAEDV (A-L)
 (LA End Diastolic Volume, Area-Length)

- LAEDV Index (A-L) (LA End Diastolic Volume Index, Area-Length)
- LAESV (A-L) (LA End Systolic Volume, Area-Length)
- LAESV Index (A-L) (LA End Systolic Volume Index, Area-Length)
- LAEDV MOD
 (LA End Diastolic Volume MOD)
- LAESV MOD
 (LA End Systolic Volume MOD)
- LIMP (Left Index of Myocardial Performance)
- LVA (s) (Left Ventricular Area, Systolic, 2CH)
- LVAd (A2C) (Left Ventricular Area, Diastolic, 2CH)
- · LVAd (SAX) (LV Area, SAX, Diastolic)
- LVAend (d) (LV Endocardial Area, SAX)
- · LVAepi (d) (LV Epicardial Area, SAX)
- LVAs (A4C) (Left Ventricular Area, Systolic, 4CH)
- · LVAs (SAX) (LV area, SAX, Systolic)
- LVd Mass (LV Mass, Diastolic, 2D)
- LVd Mass (LV Mass, Diastolic, M-mode)
- LVd Mass Index (LV Mass Index, Diastolic, 2D)
- LVEDV (A-L A2C) (LV Volume, Diastolic, 2CH, Area-Length)
- LVESV (A-L A2C) (LV Volume, Systolic, 2CH, Area-Length)
- LVET (Left Ventricle Ejection Time)
- LVIDd (LV Internal Dimension, Diastolic, 2D)
- LVIDs (LV Internal Dimension, Systolic, 2D)
- LVLd (Apical) (Left Ventricular Length, Diastolic, 2D)
- LVLs (Apical) (Left Ventricular Length, Systolic, 2D)
- LVOT Area (Left Ventricle Outflow Tract Area)
- LVOT CO (Cardiac Output by Aortic Flow)
- LVOT Diam (Left Ventricular Outflow Tract Diameter)
- LVOT Max PG (LVOT Peak Pressure Gradient)

- LVOT Mean PG (LVOT Mean Pressure Gradient)
- LVOT SI (Stroke Volume Index by Aortic Flow)
- LVOT SV (Stroke Volume by Aortic Flow)
- LVOT Vmax (LVOT Peak Velocity)
- LVOT Vmean (LVOT Mean Velocity)
- LVOT VTI (LVOT Velocity Time Integral)
- LVPWd (Left Ventricular Posterior Wall Thickness, Diastolic, 2D)
- LVPWs (Left Ventricular Posterior Wall Thickness, Systolic, 2D)
- LVs Mass (LV Mass, Systolic, 2D)
- LVs Mass Index (LV Mass Index, Systolic, 2D)
- LAAd (A2C) (Left Atrium Area, Apical 2C)
- MCO (Mitral Valve Closure to Opening)
- MP Area (Mitral Valve Prosthesis)
- MR Acc Time (MV Regurg. Flow Acceleration)
- MR ERO (PISA: Regurgitant Orifice Area)
- MR Flow (PISA: Regurgitant Flow)
- MR Max PG (Mitral Regurg. Peak Pressure Gradient)
- MR Rad (PISA: Radius of Aliased Point)
- MR RF (Regurgitant Fraction Over the Mitral Valve)
- MR RV (PISA: Regurgitant Volume Flow)
- MR Vel (PISA: Aliased Velocity)
- MR Vmax (Mitral Regurg. Peak Velocity)
- MR Vmean (Mitral Regurg, Mean Velocity)
- MR VTI (Mitral Regurg. Velocity Time Integral)
- MV A Dur (Mitral Valve A-Wave Duration)
- MV A Velocity (MV Velocity Peak A)
- MV Acc Slope (Mitral Valve Flow Acceleration)
- MV Acc Time (Mitral Valve Acceleration Time)
- MV Acc/Dec Time
 (MV: Acc.Time/Decel.Time Ratio)

- MV An Diam (Mitral Valve Annulus Diameter, 2D)
- MV CO (Cardiac Output by Mitral Flow)
- MV Dec Slope (Mitral Valve Flow Deceleration)
- MV Dec Time (Mitral Valve Deceleration Time)
- MV E Velocity (MV Velocity Peak E)
- MV E/A Ratio (Mitral Valve E-Peak to A-Peak Ratio)
- MV Max PG (Mitral Valve Peak Pressure Gradient)
- MV Mean PG (Mitral Valve Mean Pressure Gradient)
- MV PHT (Mitral Valve Pressure Half Time)
- MV Reg Frac (Mitral Valve Regurgitant Fraction)
- MV SI (Stroke Volume Index by Mitral Flow)
- MV SV (Stroke Volume by Mitral Flow)
- MV Time to Peak (Mitral Valve Time to Peak)
- MV Vmax (Mitral Valve Peak Velocity)
- MV Vmean (MV Mean Velocity)
- MV VTI (Mitral Valve Velocity Time Integral)
- · MVA (Mitral Valve Area)
- MVA By PHT (Mitral Valve Area according to PHT)
- MVA by Plan (Mitral Valve Area, 2D)
- MVET (Mitral Valve Ejection Time)
- P Vein A (Pulmonary Vein Velocity Peak A) – Reverse
- P Vein A Dur (Pulmonary Vein A-Wave Duration)
- P Vein D (Pulmonary Vein End-Diastolic Peak Velocity)
- P Vein S (Pulmonary Vein Systolic Peak Velocity)
- PAEDP (Pulmonary Artery Diastolic Pressure)
- PE(d) (Pericard Effusion, M-mode)
- PEs (Pericard Effusion, 2D)
- PR max PG (Pulmonic Insuf. Peak Pressure Gradient)

- PR mean PG (Pulmonic Insuf. Mean Pressure Gradient)
- PR PHT (Pulmonic Insuf. Pressure Half Time)
- PR Vmax (Pulmonic Insuf. Peak Velocity)
- PR VTI (Pulmonic Insuf. Velocity Time Integral)
- PRend Max PG (Pulmonic Insuf. End-Diastole Pressure Gradient)
- PRend Vmax (Pulmonic Insuf. End-Diastolic Velocity)
- Pulmonic Diam (Pulmonary Artery Diameter, 2D)
- PV Acc Slope (Pulmonic Valve Flow Acceleration)
- PV Acc Time (Pulmonic Valve Acceleration Time)
- PV Acc Time/ET Ratio (PV Acceleration to Ejection Time Ratio)
- PV An Diam (Pulmonic Valve Annulus Diameter, 2D)
- PV Ann Area (Pulmonic Valve Area)
- PV CO (Cardiac Output by Pulmonic Flow)
- PV Max PG (Pulmonic Valve Peak Pressure Gradient)
- PV Mean PG (Pulmonic Valve Mean Pressure Gradient)
- PV SV (Stroke Volume by Pulmonic Flow)
- PV Vmax (Pulmonary Artery Peak Velocity)
- PV Vmean (PV Mean Velocity)
- PV VTI (Pulmonic Valve Velocity Time Integral)
- PVA (VTI) (Pulmonary Artery Velocity Time Integral)
- PVein S/D Ratio (Pulmonary Vein SD Ratio)
- PVET (Pulmonic Valve Ejection Time)
- PVPEP (Pulmonic Valve Pre-Ejection Period)
- PVPEP/ET Ratio (PV Pre-Ejection to Ejection Time Ratio)
- Qp/Qs (Pulmonic-to-Systemic Flow Ratio)

- RA Major (Right Atrium Major, 2D)
- RA Minor (Right Atrium Minor, 2D)
- RAA (d) (Right Atrium Area, 2D, Diastole)
- RAA (s) (Right Atrium Area, 2D, Systole)
- RAEDV A2C (Right Atrium End Diastolic Volume, Apical 2 Chamber)
- RAESV A-L (RA End Systole Volume [A-L])
- RALd (Right Atrium Length, Diastole)
- · RALs (RA Length, Systole)
- RIMP (Right Index of Myocardial Performance)
- RJA (A4C) (Regurgitant Jet Area)
- RJA/LAA (Regurgitant Jet Area ratio RJA/LAA)
- · RV Major (Right Ventricle Major)
- RV Minor (Right Ventricle Minor)
- RV S' (Tricuspid Annulus Systolic Excursion Velocity)
- RVAWd (Right Ventricle Wall Thickness, Diastolic, 2D)
- RVAWs (Right Ventricle Wall Thickness, Systolic, 2D)
- RVET (Right Ventricle Ejection Time)
- RVIDd (Right Ventricle Diameter, Diastolic, 2D)
- RVIDs
 (Right Ventricle Diameter, Systolic, 2D)
- RVOT Area (Right Ventricle Outflow Tract Area)
- RVOT Diam
 (RV Output Tract Diameter, 2D)
- RVOT Diam (RV Output Tract Diameter, M-mode)
- RVOT Max PG (RVOT Peak Pressure Gradient)
- RVOT Mean PG (RVOT Mean Pressure Gradient)
- RVOT SI (LV Stroke Volume Index by Pulmonic Flow)
- RVOT SV (Stroke Volume by Pulmonic Flow)
- RVOT Vmax (RVOT Peak Velocity)
- RVOT Vmean (RVOT Mean Velocity)
- RVOT VTI (RVOT Velocity Time Integral)

- RVSP (Right Ventricle Systolic Pressure)
- RVWd (Right Ventricle Wall Thickness, Diastolic, M-mode)
- RVWs (Right Ventricle Wall Thickness, Systolic, M-mode)
- RAA (d) (Right Atrium Area, 2D, Diastole)
- RAA (s) (Right Atrium Area, 2D, Systole)
- SI (A-L A2C) (LV Stroke Index, Single Plane, 2CH, Area-Length)
- SI (A-L A4C) (LV Stroke Index, Single Plane, 4CH, Area-Length)
- SI (Bi-plane) (LV Stroke Index, Bi-plane, MOD)
- SI (bullet) (LV Stroke Index, Bi-plane, Bullet)
- SI (MOD A2C) (LV Stroke Index, Single Plane, 2CH, MOD)
- SI (MOD A4C) (LV Stroke Index, Single Plane, 4CH, MOD)
- SI (Teich) (LV Stroke Index, Teicholtz, 2D)
- SI (Teich) (LV Stroke Index, Teicholtz, M-mode)
- SV (A-L A2C) (LV Stroke Volume, Single Plane, 2CH, Area-Length)
- SV (A-L A4C) (LV Stroke Volume, Single Plane, 4CH, Area-Length)
- SV (Bi-plane) (LV Stroke Volume, Bi-plane, MOD)
- SV (Bullet) (LV Stroke Volume, Bi-plane, Bullet)
- SV (MOD A2C) (LV Stroke Volume, Single-plane, 2CH, MOD) – Simpson
- SV (MOD A4C) (LV Stroke Volume, Single-plane, 4CH, MOD) – Simpson
- SV (Cube) (LV Stroke Volume, 2D, Cubic)
- SV (Cube) (LV Stroke Volume, M-mode, Cubic)
- SV (Teich)
 (LV Stroke Volume, 2D, Teicholtz)
- SV (Teich)
 (LV Stroke Volume, M-mode, Teicholtz)
- Systemic Diam (Systemic Vein Diameter, 2D)
- Systemic Vmax (Systemic Vein Peak Velocity)

- Systemic VTI
 (Systemic Vein Velocity Time Integral)
- TAPSE (Tricuspid Annular Plane Systolic Excursion)
- TCO (Tricuspid Valve Closure to Opening)
- TR Max PG (Tricuspid Regurg. Peak Pressure Gradient)
- TR Mean PG (Tricuspid Regurg. Mean Pressure Gradient)
- TR Vmax (Tricuspid Regurg. Peak Velocity)
- TR Vmean (Tricuspid Regurg. Mean Velocity)
- TR VTI (Tricuspid Regurgitation Velocity Time Integral)
- TV A Dur (Tricuspid Valve A-Wave Duration)
- TV A Velocity (Tricuspid Valve A Velocity)
- TV Acc Time (Tricuspid Valve Time to Peak)
- TV Ann Area (Tricuspid Valve Area)
- TV Ann Diam (Tricuspid Valve Annulus Diameter, 2D)
- TV Area (Tricuspid Valve Area, 2D)
- TV CO (Cardiac Output by Tricuspid Flow)
- TV Dec Slope (Tricuspid Valve Flow Deceleration)
- TV E Velocity (Tricuspid Valve E Velocity)
- TV E/A Ratio (Tricuspid Valve E-Peak to A-Peak Ratio)
- TV Max PG (Tricuspid Valve Peak Pressure Gradient)
- TV Mean PG (Tricuspid Valve Mean Pressure Gradient)
- TV Mean PG (Tricuspid Valve Mean Pressure Gradient)
- TV PHT (Tricuspid Valve Pressure Half Time)
- TV SV (Stroke Volume by Tricuspid Flow)
- TV Vmean (TV Mean Velocity)
- TV VTI (Tricuspid Valve Velocity Time Integral)
- VSD Max PG (VSD Peak Pressure Gradient)
- VSD Vmax (VSD Peak Velocity)

Please refer to the reference manual for the full list of measurements and calculations for all applications.

Annotations

Body Marks

- Body mark icons for location and position of probe
- Option to automatically activate body mark on freeze
- Easy selection of body marks from touch screen
- Easy selection of body marks for dual-screen layout

Text Annotations

- Easy selection of text annotations from touch screen
- Option to automatically activate annotation on freeze

Scan Assist Pro

- Customizable automations that assist the user through each step of the scan
- Facilitates consistency and reduced keystrokes
- Ultrasound image, anatomical picture, step by step training through a predefined protocol
- Supports selection of all modes, all measurements and dual annotations
- Imaging attributes: octave, steer, dual/quad screen, compound, LOGIQ View, zoom, depth, scale and baseline
- On-line or off-line protocol editor
- Image acquisition according to predefined protocol templates
- Various factory protocol templates
- User-configurable protocol templates

Scan Coach (optional)

- A reference and education tool that provides modules depicting basic scanning techniques with animated graphics of probe position, schematic of anatomy and reference clinical image
- Exam protocols can be customized based on local guidelines

Smart Stress Echo (optional) Supported Protocol Examinations

- · 2D pharmacological stress echo
- · 2D bicycle stress echo
- 2D continuous capture stress echo (treadmill stress echo)
- Cardiac resynchronization therapy programming protocols (available with the Advanced QScan option)

Protocol Examinations Features (enabled with Smart Stress option)

- Wall motion scoring: analysis by wall motion in individual myocardial segments
- Show reference: show a reference image from baseline or previous level during acquisition
- Smart stress: automatically set up various scanning parameters (for instance geometry, frequency, gain, etc.) according to same projection on previous level
- Scan mode settings: scan mode may be specified for individual views in the protocol
- Preview of store: show running loops as preview before storing to the examination

Continuous Capture

- Continuously acquire large amounts of 2D image data, and selection of projection views for analysis afterwards
- The entire continuous capture recording may be kept in memory while it is possible to store new images outside the protocol template, or the entire recording can be stored to file
- Selection of projection views on scanner or EchoPAC when the entire recording is stored to file

Wall Motion Scoring

- As part of the measurement and analysis package one can access a wall motion assessment module, providing analysis/scoring of individual myocardial segments
- · For use with all stress modalities

Cardiac Resynchronization Therapy (CRT) Programming Protocols

- CRT protocols require Smart Stress and Advanced OScan
- Tailored acquisition protocol for data needed for programming of AV and VV delays in biventricular pacemakers
- Image acquisition of a set of projection views with various scan mode settings
- Template editor
- · User-configurable protocol templates
- Configure protocol name, number of levels and views, name of level and views and several other protocol settings (smart stress, show reference, scan mode, preview of store, timer handling, etc.)

Safety Conformance

- IEC60601-2-37
- IEC60601-1
- IEC60601-1-2
- IEC60601-1-6
- NEMA UD3
- The European Medical Devices
 Directive (MDD) 93/42/EEC (CE Mark)
- Directive 2011/65/EU on the restriction of use of certain hazardous substances (RoHS)
- EN 62366 Medical Devices
- Directive 2014/53/EU Radio Equipment Directive
- ISO 10993-1 Biological evaluation of medical devices – Part 1 Evaluation and Testing
- The Vivid iq ultrasound unit is a Class I device, with BF (probes) and CF (ECG leads) and Defibrillation-Proof Type (ICE catheters) applied parts according to IEC60601-1
- The Vivid iq ultrasound unit meets the EMC requirements in IEC 60601-1-2:2014 as Group1, Class A specified by CISPR 11

Security

Virus Protection

To reduce virus vulnerability, Vivid iq is configured with a minimal set of open ports and with all network services not actively used by the system closed down. This helps to significantly reduce the risk of a virus attack on Vivid iq.

GE is continuously judging the need for additional actions to reduce vulnerability of equipment; this includes vulnerability scanning of our products and evaluation of new security patches for the 3rd-party technology used. Microsoft* (and other) security patches that address serious issues with Vivid iq will be made available to customers after GE verification of those patches.

Whitelisting

Prevents non-listed applications from running

User Policies

 Secure and advanced user password and login scheme according to user's password requirements

LDAP

 Users can log in to the system by using the same user credentials as used for domain connected computers

Disc Encryption

 Optional encryption of the scanner's E drive containing patient identifiable data

Streaming Server

- Sends the image information as digital video stream over Ethernet in real-time to clients
- Allows simple video transmission over long distances
- Supports 2D data for both, tissue mode and color-flow mode
- Provides raw data images with metadata enabling clients to visualize (render), modify and process the Vivid iq images through their own apps

eDelivery (optional)4

- eDelivery facilitates download of software patches for service purposes (e.g., security patches)
- It is also an enabler for the ability to download apps from the AppStore

App Launchpad⁴

- The app launchpad is a tab available on the archive screen – when selected, various applications ("Apps") can be launched
- Only validated and released apps are supported
- 3rd-party apps can be purchased through an AppStore on a GE website
- Consult with a GE representative for more details

Digital Expert (optional)⁴

 Enables the user to connect remotely to a GE Healthcare Clinical Specialist to receive application related training and help

Probes

3Sc-RS Phased Array Probe

- Applications: Cardiac, pediatric, fetal/obstetrics, transcranial, adult cephalic, abdominal
- Probe presets: Coronary, exercise, LVO contrast (optional, LVO stress, FATE, pediatric, fetal heart, ED-OB1, transcranial Doppler, abdomen, renal, FAST, lung
- Biopsy guide: Multi-angle disposable with a reusable bracket

M5Sc-RS Active Matrix Single Crystal Phased Array Probe

- Applications: Cardiac, pediatric, fetal/obstetrics, transcranial, adult cephalic, abdomen
- Probe presets: Cardiac, exercise, pediatric, FATE, coronary, fetal heart, LVO contrast (optional) LVO stress, abdominal, renal, ED-OB1, transcranial Doppler, contrast low MI, FAST, lung
- Biopsy guide: Multi-angle disposable with a reusable bracket
- 4 eDelivery, App Launchpad and Digital Expert may not be available in all countries and regions. Consult with a GE representative for more details.

6S-RS Phased Array Probe

- Applications: Cardiac, pediatric, abdominal, transcranial, neonatal cephalic, fetal/obstetrics
- Probe presets: Coronary, pediatric, infant, neonates, abdominal, fetal heart, FAST, lung

6VT-D Active Matrix 4D Volume TEE Probe – working in 2D mode and bi-plane/tri-plane mode (option), but 4D mode is not available

- Applications: Cardiac, transesophageal
- Probe presets: Cardiac, coronary, LVO contrast (optional)

6Tc-RS TEE Probe

- Applications: Cardiac, transesophageal
- Probe presets: Cardiac, coronary, LVO contrast (optional)

9T-RS TEE Probe

- Applications: Cardiac, transesophageal
- · Probe preset: Pediatric

9L-RS Linear Array Probe

- Applications: Abdominal, pediatric, peripheral vascular, musculoskeletal conventional/superficial, small organ
- Probe presets: Carotid, LEA, LEV, UEA, UEV, ED-LEV, ED-VA, vertebral, abdomen, musculoskeletal, nerves, ED-MSK, nerves-superficial, nervesaverage, nerves-deep, abdomen, pediatric abdominal, lung
- Biopsy guide: Multi-angle disposable with a reusable bracket

12L-RS Linear Array Probe

- Applications: Abdominal, pediatric, neonatal cephalic, peripheral vascular, musculoskeletal conventional/ superficial, small organ
- Probe presets: Neohead, carotid, LEA, LEV, UEA, UEV, ED-LEV, ED-VA, musculoskeletal, pediatric abdominal, nerves, lung, nerves-superficial, nerves-average, nerves-deep, thyroid, small parts, breast, ED-MSK
- Biopsy guide: Multi-angle disposable with a reusable bracket

ML6-15-RS Linear Array Probe

- Applications: Abdominal, pediatric, neonatal cephalic, peripheral vascular, musculoskeletal conventional/ superficial, small organ
- Probe presets: Abdominal, carotid, ED-LEV, ED-VA, lung, musculoskeletal, nerves-superficial, nerves-average, nerves-deep, ED-MSK
- Biopsy guide: Multi-angle disposable with a reusable bracket

L8-18i-RS Linear Array Probe

- Applications: Intraoperative, peripheral vascular, musculoskeletal conventional/superficial, small organ
- Probe presets: Epicardial, ED-VA, vascular, musculoskeletal superficial, nerves-superficial, small parts

C1-5-RS Curved Array Probe

- Applications: Abdominal, pediatric, fetal/obstetrics, transrectal, musculoskeletal conventional/superficial
- Probe presets: Pediatric abdominal, fetal echo, OB1, OB23, ED-OB1, abdomen, renal, FAST, GYN, prostate, lung, aorta, spine, nerves-deep
- Biopsy guide: Multi-angle disposable with a reusable bracket

8C-RS Curved Array Probe

- Applications: Cardiac, abdominal, pediatric, transcranial, neonatal cephalic, musculoskeletal conventional/superficial, small organ
- Probe presets: Cardiac, pediatric abdominal, neonatal abdominal, neohead, vascular, FAST, lung, spine
- Biopsy guide: Fixed-angle, disposable, or reusable bracke

E8Cs-RS Endo Micro Convex Probe

- Applications: Fetal/obstetrics, transvaginal, abdominal, transrectal
- Probe presets: Fetal echo, OB1, GYN, prostate
- Biopsy guide: Fixed-angle, disposable, or reusable bracket

P2D Pencil Probe

• Probe preset: Cardiac

Catheter Cable ICE Probe Connector

 Allows connecting the AcuNav®ICE catheters to Vividiq

ACUSON® AcuNav 10F IntraCardiac Echo (ICE) Catheter⁵

· Probe presets: ICE

ACUSON AcuNav 8F IntraCardiac Echo (ICE) Catheter⁵

Probe presets: ICE

SOUNDSTAR 3D Ultrasound Catheter based on AcuNav 10F IntraCardiac

Echo (ICE) Catheter⁴⁵

· Probe presets: ICE, carto

SOUNDSTAR eco 10F G Ultrasound Catheter based on AcuNav 10F

IntraCardiac Echo (ICE) Catheter⁵

· Probe presets: ICE, carto

SOUNDSTAR eco 8F G Ultrasound Catheter based on AcuNav 8F

IntraCardiac Echo (ICE) Catheter⁵

· Probe presets: ICE, carto

⁵ Not available in all countries. Please contact Biosense Webster for availability.

| PROBE | FREQUENCY RANGE | CATALOG# |
|-----------------------------------------------------------------------------------|-----------------|-----------------------------------------|
| 3Sc-RS | 1.3 – 4.0 MHz | H45041DL |
| M5Sc-RS | 1.5 – 4.6 MHz | H44901AG |
| 6S-RS | 2.0 – 7.0 MHz | H45021RP |
| 12S-RS | 4.2 – 12.0 MHz | H44901AB |
| 6VT-D | 3.0 – 8.0 MHz | H45581BJ |
| 6Tc-RS | 3.0 – 8.0 MHz | H45551ZE |
| 9T-RS | 3.6 – 10.0 MHz | H45531YM |
| 9L-RS | 2.0 – 10.0 MHz | H40442LL |
| 12L-RS | 4.0 – 13.0 MHz | H40402LY |
| ML6-15-RS | 5.0 – 15.0 MHz | H40462LM |
| L8-18i-RS | 4.5 – 18.0 MHz | H40462LF |
| C1-5-RS | 1.5 – 5.0 MHz | H40462LA |
| 8C-RS | 3.5 – 10.0 MHz | H40402LS |
| E8Cs-RS | 3.5 – 10.0 MHz | H48062AF |
| P2D (Pencil) | 1.9- 2.1 MHz | H45551CA |
| Catheter Cable ICE probe connector | | H48952AR |
| ACUSON AcuNav 10F ⁵ | 4.5 – 11.5 MHz | Distributed by Biosense Webster, Inc |
| ACUSON AcuNav 8F5 | 4.5 – 11.5 MHz | Distributed by Biosense Webster, Inc |
| SOUNDSTAR 3D Ultrasound Catheter based on AcuNav 10F ⁵ | 4.5 – 11.5 MHz | Distributed by Biosense Webster, Inc |
| SOUNDSTAR eco 10F G Ultrasound Catheter based on AcuNav 10F ⁵ | 4.5 – 11.5 MHz | Distributed by Biosense Webster, Inc |
| SOUNDSTAR eco 8F G Ultrasound Catheter based on AcuNav 8F ⁵ | 4.5 – 11.5 MHz | Distributed by Biosense Webster, Inc |

⁵ Not available in all countries. Please contact Biosense Webster for availability.

Product may not be available in all countries and regions. Full product technical specification is available upon request. Contact a GE Healthcare Representative for more information. Please visit www.gehealthcare.com/promotional-locations.

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GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226 U.S.A.

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