

### Specificație Tehnică Completată

**Modelul: Voluson Expert22; PN: H48711KA; Producător: GE Healthcare Austria GmbH & Co OG; Țara: Austria.**

| Ultrasonograf General, OB-GYN, performanță înaltă - 1 buc                 |                                                                                |                                                                                                                                     |                                                                                                                                                                                                            |
|---------------------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Specificarea tehnică deplină solicitată de către autoritatea contractantă |                                                                                |                                                                                                                                     | Specificarea tehnică deplină propusă de către autoritatea contractantă                                                                                                                                     |
| PROBE PORTURI                                                             |                                                                                | ≥4                                                                                                                                  | DA 4 porturi pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                        |
| Sonde TIP, MHz                                                            | Linear tip matricială / XD Clear/ Single cristal sau altă tehnologie analogică | cu valoarea minima nu mai mare de 4 Mhz - si cu valoarea maxima nu mai mică de 8 Mhz, banda activă sau câmpul de vedere minim 40 mm | DA tip matricială modelul <b>ML6-15-D</b> cu valoarea minima de 4 Mhz - si cu valoarea maxima de <b>13 Mhz</b> , banda activă sau câmpul de vedere <b>50 mm</b> , pag. 3 din Voluson Expert 22 PROBE GUIDE |
|                                                                           | Convex tip matricială / XD Clear/ Single cristal sau altă tehnologie analogică | cu valoarea minima nu mai mare de 3 Mhz - si cu valoarea maxima nu mai mică de 6 Mhz, banda activă sau câmpul de vedere minim 70 °  | DA tip XDclear modelul <b>C2-9-D</b> cu valoarea minima de 3 Mhz - si cu valoarea maxima de <b>9 Mhz</b> , banda activă sau câmpul de vedere <b>100 °</b> , pag. 2 din Voluson Expert 22 PROBE GUIDE       |
|                                                                           | Endovaginal 4D                                                                 | cu valoarea minima nu mai mare de 4 Mhz - si cu valoarea maxima nu mai mică de 9 Mhz, banda activă sau câmpul de vedere minim 135 ° | DA modelul <b>RIC5-9-D</b> cu valoarea minima de 4 Mhz - si cu valoarea maxima de 9 Mhz, banda activă sau câmpul de vedere <b>189°</b> , pag. 2 din Voluson Expert 22 PROBE GUIDE                          |
|                                                                           | Volum 4D                                                                       | cu valoarea minima nu mai mare de 2 Mhz - si cu valoarea maxima nu mai mică de 7 Mhz, banda activă sau câmpul de vedere minim 70 °  | DA modelul <b>RM7C</b> cu valoarea minima de 2 Mhz - si cu valoarea maxima de <b>8 Mhz</b> , banda activă sau câmpul de vedere <b>90°</b> , pag. 2 din Voluson Expert 22 PROBE GUIDE                       |
| Dispozitivul va fi setat pentru lucru cu sondele livrate                  |                                                                                | da                                                                                                                                  | DA Confirmam acest lucru                                                                                                                                                                                   |
| NIVELE DE GRI                                                             |                                                                                | ≥256                                                                                                                                | DA sint prezente 256 de nivele gri pag. 6 din Voluson Expert 22 Datasheet.                                                                                                                                 |
| PREPROCESARE, canale digitale                                             |                                                                                | ≥8 000 000 / 500 (canale fizice)                                                                                                    | Da sint prezente 1.800.989.313 de canale digitale pag. 6 din Voluson Expert 22 Datasheet.                                                                                                                  |

Anexa 1.

|                                                               |                                                                  |         |                                                                                                                                                       |
|---------------------------------------------------------------|------------------------------------------------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sumarul gamei dinamice</b>                                 |                                                                  | ≥350dB  | Da sint prezente 418 dB gama dinamica pag. 6 din Voluson Expert 22 Datasheet.                                                                         |
| <b>Adîncimea de scanare</b>                                   | <b>minima</b>                                                    | ≤ 1 cm  | DA 0-1 cm minima adîncimea de scanarea pag. 6 din Voluson Expert 22 Datasheet.                                                                        |
|                                                               | <b>maxima</b>                                                    | ≥ 50 cm | DA 0-50 cm maxima adîncimea de scanarea pag. 6 din Voluson Expert 22 Datasheet.                                                                       |
| <b>Posibilitate de rotare a imaginii minim pînă la</b>        |                                                                  | ≥ 180 ° | DA 180 ° pag. 6 din Voluson Expert 22 Datasheet.                                                                                                      |
| <b>Posibilitatea de oglindire a imaginii Stînga / Dreapta</b> |                                                                  | da      | DA se poate oglindi imaginea Stînga/Dreapta pag. 6 din Voluson Expert 22 Datasheet.                                                                   |
| <b>POSTPROCESARE</b>                                          |                                                                  | da      | DA permite postprocesarea pagina 13-20/444 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 |
| <b>IMAGINE MODURI</b>                                         | <b>M-mod</b>                                                     | da      | DA M-Mode pag. 3 din Voluson Expert 22 Datasheet                                                                                                      |
|                                                               | <b>M-mod și 2-D/B-Mode</b>                                       | da      | DA prezent pag. 3 din Voluson Expert 22 Datasheet                                                                                                     |
|                                                               | <b>3-D (automatic)</b>                                           | da      | DA prezent pag. 3 din Voluson Expert 22 Datasheet                                                                                                     |
|                                                               | <b>4-D (live 3-D)</b>                                            | da      | DA prezent pag. 3 din Voluson Expert 22 Datasheet                                                                                                     |
|                                                               | <b>Harmonic imaging</b>                                          | da      | DA este inclus Coded Harmonic Imaging pag. 4 din Voluson Expert 22 Datasheet                                                                          |
|                                                               | <b>STIC</b>                                                      | da      | DA este inclus STIC pag. 4, 10 din Voluson Expert 22 Datasheet                                                                                        |
|                                                               | <b>STIC in regim Dopler color</b>                                | da      | <b>DA</b> pag. 4, 10 din Voluson Expert 22 Datasheet – STIC- CFM                                                                                      |
|                                                               | <b>STIC in regim Dopler tisular</b>                              | da      | <b>DA</b> pag. 10 din Voluson Expert 22 Datasheet – STIC -TD                                                                                          |
|                                                               | <b>Elastografie tip compresivă activă pentru sonda liniră și</b> | da      | Da este disponibil modul Elastografie de tip Compresiva pag. 5 din Voluson Expert 22 Datasheet.                                                       |

Anexa 1.

|                 |                                                                  |                  |                                                                                                                                                                                                                              |
|-----------------|------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 | endocavitară cu care va fi livrat dispozitivul                   |                  |                                                                                                                                                                                                                              |
| DOPPLER         | Tip                                                              | CW, PW, CFM, TD. | DA CW Doppler pag. 5 din Voluson Expert 22 Datasheet,<br>PW, Color Doppler Mode, TD pag. 3 din Voluson Expert 22 Datasheet                                                                                                   |
|                 | Afișare frecvență                                                | da               | DA pag. 5 din Voluson Expert 22 Datasheet                                                                                                                                                                                    |
|                 | Afișare viteză                                                   | da               | DA pag. 5 din Voluson Expert 22 Datasheet – <i>Color Scale: Khz, cm/s, m/s</i>                                                                                                                                               |
|                 | Power Doppler                                                    | da               | DA PW pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                                                 |
|                 | HRPF                                                             | da               | DA HRPF pag. 5 din Voluson Expert 22 Datasheet – <i>PRF including HPRF</i>                                                                                                                                                   |
|                 | Duplex                                                           | da               | DA Duplex pag. 3, 10 din Voluson Expert 22 Datasheet                                                                                                                                                                         |
|                 | Triplex                                                          | da               | DA Triplex pag. 3, 10 din Voluson Expert 22 Datasheet                                                                                                                                                                        |
| FUNCTİONALITĂȚI | Măsurători digitale                                              | da               | DA sînt masurări de tip digitale pag. 6 din Voluson Expert 22 Datasheet – <i>Measure setup.</i>                                                                                                                              |
|                 | Configurarea Masurartorilor conform necesitatilor utilizatorului | da               | DA este posibilitate de setare a masuratorilor in dependeta de necesitatiile utilizatorului. pag. 6 din Voluson Expert 22 Datasheet - <i>Measure setup.</i>                                                                  |
|                 | Diapazon dimamic selectabil                                      | da               | DA este selcetabil/reglabil diapazonul dinamic pag. 6 din Voluson Expert 22 Datasheet - <i>Up to 418 dB Dynamic Range</i> sau pag. 7 din Voluson Expert 22 Datasheet - <i>Dynamic Contrast 1 – 12 in 0.5 step increments</i> |
|                 | Focalizare de transmisie ajustabilă                              | da               | DA este ajustabil focalizare de transmisie pag. 6 din Voluson Expert 22 Datasheet - <i>Transmission Focus: 1-5 Focus Points</i>                                                                                              |

Anexa 1.

|                                                                                                                                                                                                                         |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                         |    | <i>selectable (probe and application dependent)</i><br><i>Focal Zone position, up to 10 positions selectable</i>                                                                                                                                                                                                                                                                                                                                                     |
| <b>Măsurători pe reluarea video</b>                                                                                                                                                                                     | da | DA este posibil masurare pe reluare video – pag. 6 din Voluson Expert 22 Datasheet - <i>Mwasre setup&gt; Post assign measurements</i>                                                                                                                                                                                                                                                                                                                                |
| <b>Raport sau formarea protocolului final de către ecograf. Cu posibilitatea de schimbare conform necesităților utilizatorului final.</b>                                                                               | da | DA este inclus formarea rapoartelor de către ecograf pag. 4 din din Voluson Expert 22 Datasheet - <i>Measurement, Calculations and Worksheets/Report</i> sau pagina 10-33 / 333 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                                                                                                                           |
| <b>Regim 4D (3D live) si 3D avansat cu posibilitate de schimbare a mapilor de culori, prezenta tehnologie de formare a culori nature a fatului.</b>                                                                     | da | DA este prezent regimul 4D (3D live) ) si 3D avansat cu posibilitate de schimbare a mapilor de culori, prezenta tehnologie de formare a culori nature a fatului.- <b>vezi capitolul 8 3D and 4D mdoe</b><br>Pag. 8-40/238 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10– <i>paragraful 8.7 Additionla tools</i><br>Exemplu din Voluson Expert 22 Customer Presentation pag. 15, 16<br>Si imagini fig. 1 |
| <b>Regim de postprocesare pentru imaginile 4D (3D live) si 3D cu posibilitate de taiere a sectiunilor care nu sunt necesare, schimbare unghiului de vizualizarea, adincimeii pe toate axelor de formare a imaginii.</b> | da | DA este prezent tehnologia MagicCut pag. 8-50/248 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                                                                                                                                                                                                                                                         |



Anexa 1.

|                                                                                                                                                                                                                                                                                                                                                                                             |    |                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Formare a tabelului folicular cu clasificare după diametru in regim automat. La necesitate se va putea adauga voliculi care nu a fost inclusi in tabel.                                                                                                                                                                                                                                     | da | DA este present tabelul falocular cu posibilitate de redactare pag. 8-60 /258 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 – <i>Paragraful SonoAV follicle</i>   |
| Regim non-doppler de diagnostic. Este obligator prezenta acestui tip de tehnologie care va fi disponibil pentru toate sondele cu care va fi livrat dispozitivul. In caz că se va prezenta o tehnologie analogica sa fie posibil de efectuat studiul arborelui vascular la rinichi la mama si fat ( trimestru 3), Cap fat trimestru 2,3, ficat mama si fat. La fel pentru vasele periferice. | da | DA este disponibil tehnologia B-Flow care este tehnologie non dopler pag. 11 din Voluson Expert 22 Datasheet Este compatibil cu toate sondele infara de 6S-D, M5Sc-D si L8-18i-D. Cu restul cele lalate sonde este compatibil. |
| Regim specilizat pentru vizualizarea scheletului fatului in trimestru 3. (Prezența imaginii pentru modelul de dispozitiv propus)                                                                                                                                                                                                                                                            | da | DA mai mult ca atit este preset si pentru trimestul 2 18 saptamini fig. 2 Pentru trimestru 2-3 est present regimul Skeleton/X-ray, OmniView pag. 18 din Exemplu din Volusov Expert 22 Customer Presentation                    |
| Prezența tehnologie de marire a imaginii fara a micsora rezolutia, contrastul si claritatea zonei care este marite.                                                                                                                                                                                                                                                                         | da | DA HD Zoom metoda de activarre este descrisa pag. 4-8/90 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                            |
| Sistema automatizat de ajustare a imaginii pentru regim 2D/ B-mode                                                                                                                                                                                                                                                                                                                          | da | DA Automatic optimization pag. 4-8/90 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                               |

Anexa 1.

|                                                                                            |    |                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                            |    | Si pag. 4 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                                                                   |
| <b>Ajustarea fregventelor de lucru automat de catre dispozitiv</b>                         | da | DA fregventa de lucru este ajustat in citeva pas astfel incit ecograful lucreaza nu pe o fregventa fixa dar intr-o gama de fregventa pag. 7 din Voluson Expert 22 Datasheet<br><i>Frequency Range 1 to 18 MHz depending on the probe, adjustable in 3 fundamental steps (penetration, normal, resolution) and up to 5 Harmonic steps (Augment, low, mid, high, UltraHD)</i> |
| <b>Tehnologia Omniview sau analogic</b>                                                    | da | DA este prezenta tehnologia OmniView pag. 2, 4, 10 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                          |
| <b>Regim de formare panoramica a imaginiei pentru sonda linira</b>                         | da | DA tehnologia Virtual Convex pag. 4 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                                         |
| <b>Masuratori automatizate in regim de dopler pulsativ (PW)</b>                            | da | DA este present regimul automat de masurare pag. 6, 12 din Voluson Expert 22 Datasheet - <i>Auto Sequence measurements</i><br><i>PW Doppler Mode:</i><br>•Auto & Manual Trace:<br>- PS (Peak Systole)<br>- ED (End Diastole)<br>- MD (Mid. Diastole)<br>- S/D (Ratio)<br>- TAmx<br>- HR<br>- PI (Pulsatility Index)<br>- RI (Resistance Index)                              |
| <b>Vizulizare de rezolutie inalta in 1 trimestru pentru masurarea translucenței nucale</b> | da | DA este functia SonoNT pag. 4 din Voluson Expert 22 Datasheet si fig 4 imaginea cu care prezetina massurarae                                                                                                                                                                                                                                                                |

Anexa 1.

|                                       |                             |                   |                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------|-----------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PAN/ZOOM</b>                       | <b>imagine în timp real</b> | da                | DA este prezent PAN ZOOM pag. 4-8/90 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 este active si pe imaginea in timp real si imaginea inghetata                                                                                                                            |
|                                       | <b>imagine înghețată</b>    | da                | DA este prezent PAN ZOOM pag. 4-8/90 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 este active si pe imaginea in timp real si imaginea inghetata                                                                                                                            |
| <b>STOCARE IMAGINI</b>                | <b>Capacitate</b>           | ≥ 500GB           | DA 2 TB tip HDD + 64 GB SSD pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                       |
|                                       | <b>Cine</b>                 | 500GB/85000 cadre | DA – ca volum maxim care este deticat stocare cine secventilor pina la slavare este de 1024 GB apg. 6 din Voluson Expert 22 Datasheet, ca cadre/frame maxime care pot fi pastrate Sint peste 85.000 cadre – modul de deductive pentru 1 min sau 60 sec – 3.000 Frame/sec * 60 sec = 180.000 frame Pag. 7 din Voluson Expert 22 Datasheet |
| <b>DICOM 3.0</b>                      |                             | da                | DA pag. 4 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                                |
| <b>Porturie pentru intrari iesiri</b> | <b>USB 2.0 /3.0</b>         | min. 2 buc        | DA USB 3.0 prezent 5 unitai pag. 18 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                      |
|                                       | <b>HDMI/VGA</b>             | da                | DA este present HDMI VGA pag. 18 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                         |
|                                       | <b>LAN/NET RJ45</b>         | da                | DA este present NET(Network ) RJ 45 pag. 18 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                              |
| <b>PACHETE DE ANALIZĂ</b>             | <b>Obstetric</b>            | da                | DA Obstetrica pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                     |
|                                       | <b>Ginecologie</b>          | da                | DA Ginecologie pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                                                                                                                                                    |

Anexa 1.

|                         |                                                                                             |           |                                                                                                                                                                  |
|-------------------------|---------------------------------------------------------------------------------------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                         | <b>Abdomen</b>                                                                              | da        | DA Abdomen pag. 3 din Voluson Expert 22 Datasheet                                                                                                                |
|                         | <b>Small Parts/ Parti moi</b>                                                               | da        | DA Small parts si Sin pag. 3 Voluson Expert 22 Datasheet                                                                                                         |
|                         | <b>Vascular</b>                                                                             | da        | DA Vascular pag. 3 Voluson Expert 22 Datasheet                                                                                                                   |
|                         | <b>Pediatric</b>                                                                            | da        | DA Pediatric pag. 3 Voluson Expert 22 Datasheet                                                                                                                  |
|                         | <b>Cardiologie</b>                                                                          | da        | DA Cardiologie pag. 3 din Voluson Expert 22 Datasheet                                                                                                            |
|                         | <b>Transrectal</b>                                                                          | da        | DA Transrectal pag. 3 din Voluson Expert 22 Datasheet                                                                                                            |
|                         | <b>Muscoscheletal (MSK)</b>                                                                 | da        | DA Muscoscheletal pag. 3 din Voluson Expert 22 Datasheet                                                                                                         |
|                         | <b>Omniview sau anlogic</b>                                                                 | da        | DA este inclus OmniView pag. 4 din Voluson Expert 22 Datasheet                                                                                                   |
|                         | <b>Elastografie tip compresivă</b>                                                          | da        | DA este inclus Elastografia pag. 5 din Voluson Expert 22 Datasheet                                                                                               |
| <b>MONITOR</b>          | <b>Diagonala</b>                                                                            | ≥ 23"     | DA 23.8 inch pag. 3 din Voluson Expert 22 Datasheet                                                                                                              |
|                         | <b>Rezolutia minimă</b>                                                                     | 1920x1080 | DA 1920x1080 pixel din Voluson Expert 22 Datasheet                                                                                                               |
|                         | <b>Brat articulată cu posibilitate de ajustare pe inaltime și articulare dreapta stinga</b> | da        | DA este prezent brat articulată pag. 2-17/35, 3-14/78 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 |
| <b>DIVIZARE MONITOR</b> | <b>Prezenta obligatoriu a monitorului de control</b>                                        | da        | DA pag. 3-3/67 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                        |
|                         | <b>Tehnologie Touch screen</b>                                                              | da        | DA Touch screen pag. 3 Voluson Expert 22 Datasheet                                                                                                               |
|                         | <b>Diagonala</b>                                                                            | ≥ 10"     | DA 15.6 inch pag. 3 Voluson Expert 22 Datasheet                                                                                                                  |

Anexa 1.

|                                               |                                                                                        |    |                                                                                                                                                                                                                                                              |
|-----------------------------------------------|----------------------------------------------------------------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Tastieră</b>                               | <b>Integrata digitală / pe consola sau glisantă</b>                                    | da | Da este digitala OSD Keyboard Layout pag. 13-18/442 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                                               |
| <b>Iluminare consola</b>                      |                                                                                        | da | DA pag. 3-11/75 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                                                                                   |
| <b>Butoane programabile pentru utilizator</b> |                                                                                        | da | Da sint prezente butoane programabile pag. 3-5/69 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 - <i>Configurable keys (programmable)</i>                                                       |
| <b>Consola de lucru</b>                       | <b>Ajusare înălțime</b>                                                                | da | DA este prezen ajustarea pe inaltime pag. 3 din Voluson Expert 22 Datasheet - Height (minimum) 113 cm (44.3 in) Height (maximum) 177 cm (68.3 in) Control cu motor electric                                                                                  |
|                                               | <b>Ajustare stinga si dreapta fara miscarea totala a dispozitivului fata de podea.</b> | da | DA se ajusteaza doar consola de sus fara a fi necesar rotire complete a ecografului pag. 13-4/428 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 – <i>Swivel left-right: +/- 38° from center</i> |
| <b>Prezenta rotilor</b>                       | <b>minim</b>                                                                           | 4  | DA sin prezente 4 roti diametru 15 cm pag. 3 din Voluson Expert 22 Datasheet                                                                                                                                                                                 |
|                                               | <b>Frîne minim</b>                                                                     | 2  | DA 4 fine - frina central pentru 4 roti concomitant, frina de directive.                                                                                                                                                                                     |
| <b>Termoprinter alb/negru integrat</b>        |                                                                                        | da | Da inclus termoprinter pag. 3-3/67, 12-5/413 din din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10                                                                                                  |

Anexa 1.

|                                     |      |                                                                                                                                                               |
|-------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Compatibil cu printer extern</b> | da   | Da inclus printer color extern pag. 3-12-5/413 din din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10 |
| <b>GEL USG</b>                      | ≥5 L | DA va fi livrat cu gel USG 5 L si cu buteli mai mica de 200 ml pentru a folosi gelul comod.                                                                   |

Anexa 1.

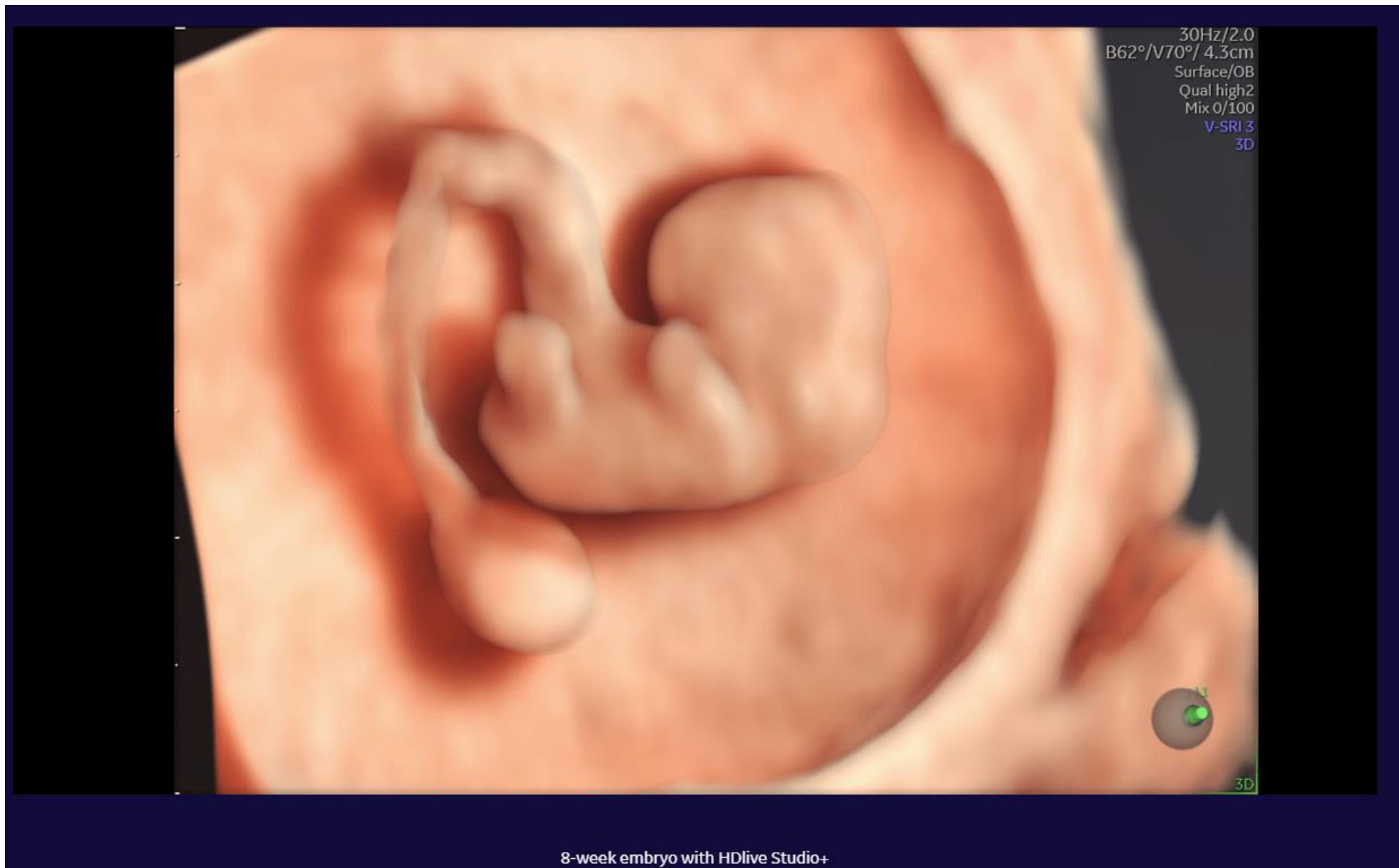
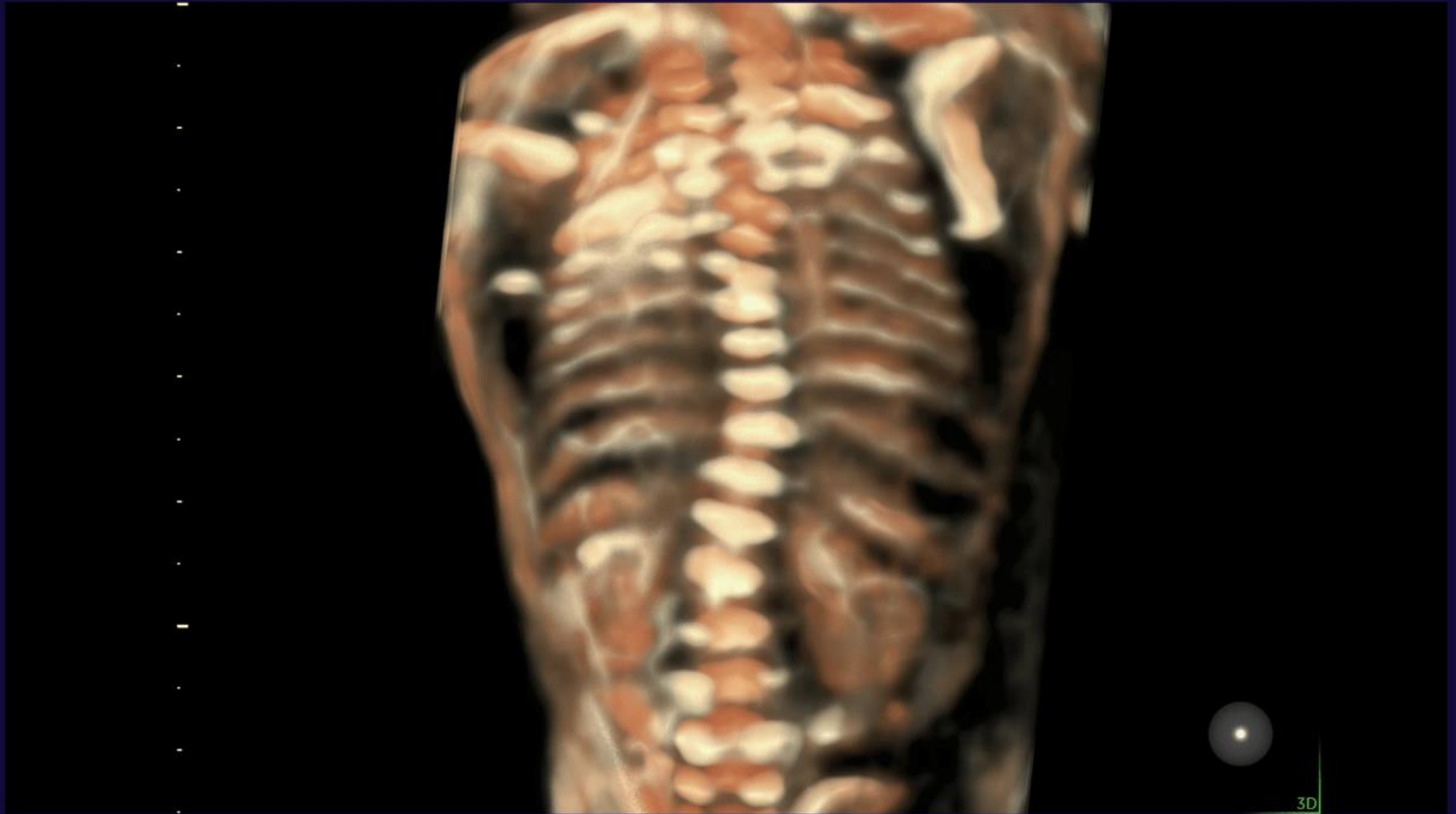


Fig. 1 - Sursa - <https://www.gehealthcare.com/products/ultrasound/voluson/voluson-expert22/imaging-capabilities>

Anexa 1.



18-week fetus with scoliosis

Fig. 2 - Sursa - <https://www.gehealthcare.com/products/ultrasound/voluson/voluson-expert22/imaging-capabilities>



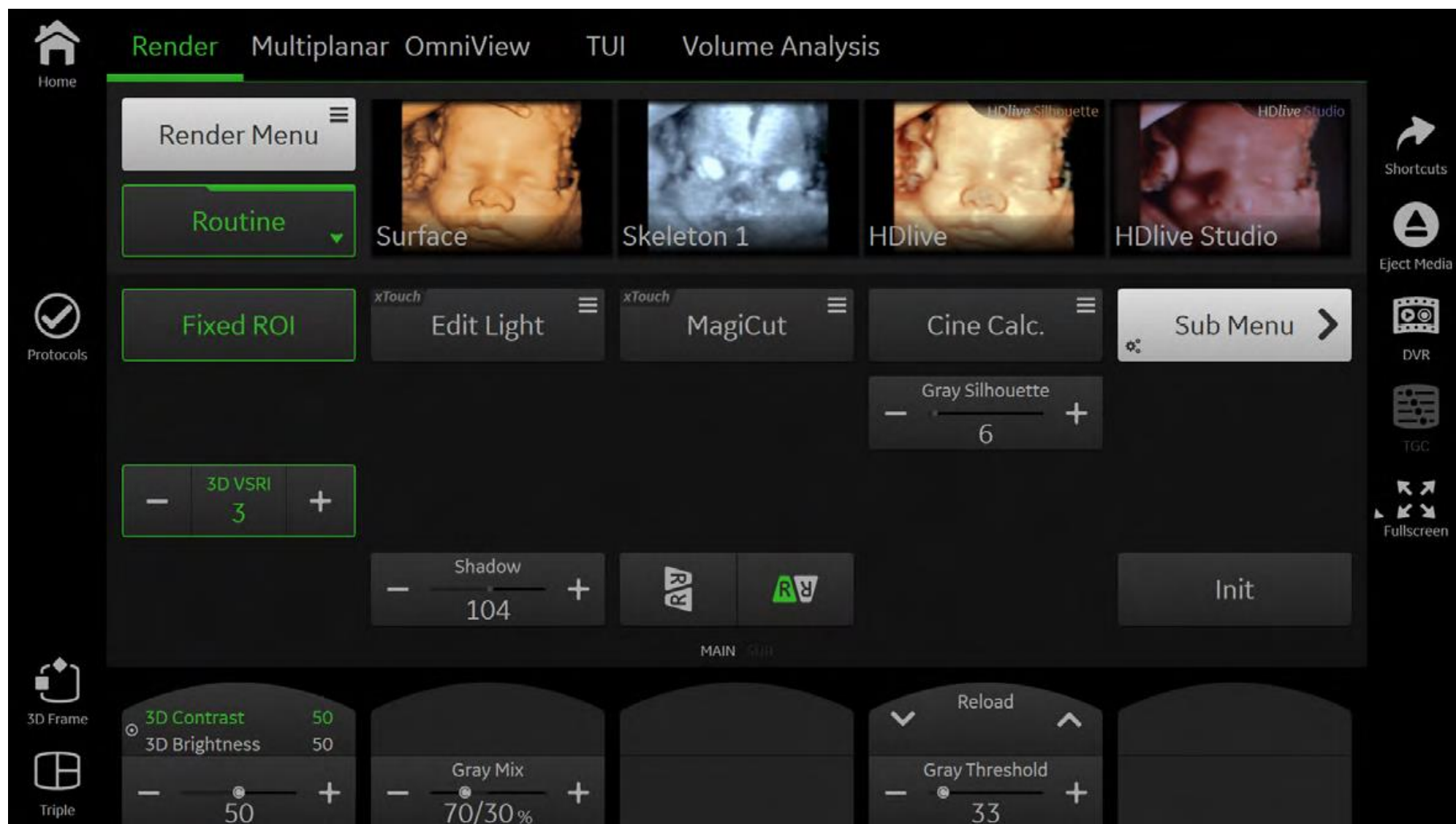


Fig. 3 sursa- pag. 8-23/221 din Voluson™ Expert 18 / Voluson™ Expert 20 / Voluson™ Expert 22 Instructions for Use H48711HM Revision 10

Anexa 1.

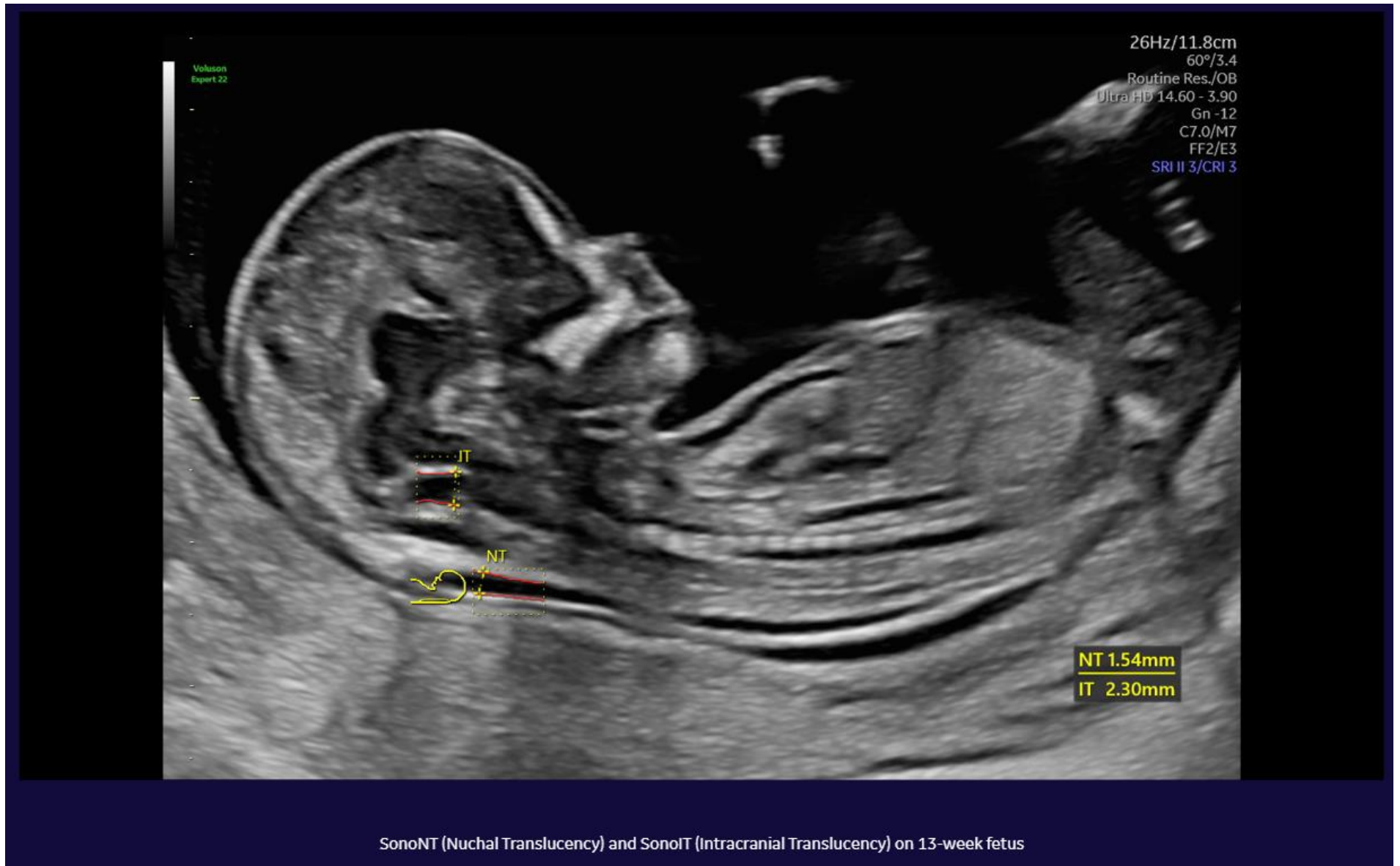


Fig.4 - sursa <https://www.gehealthcare.com/products/ultrasound/voluson/voluson-expert22/early-detection>

# Voluson Expert 22

PROBE GUIDE



**Voluson™**

A Healthier Future for Women

[gehealthcare.com](http://gehealthcare.com)



|                                                                                                           | Description                                                                       | Applications                                            | FOV                 | Bandwidth  |
|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------------------------------|---------------------|------------|
| ABDOMINAL – 2D                                                                                            |                                                                                   |                                                         |                     |            |
| <br>C1-6-D H40472LT      | XDclear™ Wide Band Convex Probe                                                   | Abdomen, Obstetrics, Gynecology, Fetal Echo             | 113°                | 2 – 5 MHz  |
| <br>C2-9-D H40462LN      | XDclear Wide Band Convex Probe                                                    | Abdomen, Obstetrics, Gynecology, Pediatrics, Fetal Echo | 100°                | 3 – 9 MHz  |
| ABDOMINAL – REAL-TIME 4D                                                                                  |                                                                                   |                                                         |                     |            |
| <br>eM6C G3 H48711KW     | Wide Band Convex Volume Probe with Active Full Electronic Matrix Array Technology | Abdomen, Obstetrics, Gynecology, Fetal Echo             | 85°, V 85° x 90°    | 2 – 7 MHz  |
| <br>RM7C H44901AR       | XDclear Wide Band Convex Volume Probe with Active Matrix Array Technology         | Abdomen, Obstetrics, Gynecology, Pediatrics, Fetal Echo | 90°, V 90° x 85°    | 2 – 8 MHz  |
| <br>RAB6-D H48681MG    | Wide Band Convex Ultra-light Volume Probe                                         | Abdomen, Obstetrics, Gynecology, Pediatrics             | 90°, V 90° x 85°    | 2 – 8 MHz  |
| ENDOCAVITY – 2D                                                                                           |                                                                                   |                                                         |                     |            |
| <br>IC 5-9-D H40442LK  | Wide Band Micro Convex Endocavitary Probe                                         | Obstetrics, Gynecology, Transrectal                     | 189°                | 4 – 9 MHz  |
| ENDOCAVITY – REAL-TIME 4D                                                                                 |                                                                                   |                                                         |                     |            |
| <br>RIC5-9-D H48651MS  | Wide Band Micro Convex Endocavitary Volume Probe                                  | Obstetrics, Gynecology, Transrectal                     | 189°, V 189° x 120° | 4 – 9 MHz  |
| <br>RIC6-12-D H48651NA | Wide Band Micro Convex Endocavitary Volume Probe                                  | Obstetrics, Gynecology, Transrectal                     | 190°, V 190° x 120° | 5 – 13 MHz |



|                                                                                                            | Description                                                | Applications                                                              | FOV                    | Bandwidth     |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------------------------------------|------------------------|---------------|
| LINEAR – 2D                                                                                                |                                                            |                                                                           |                        |               |
| <br>9L-D H40442LM         | Wide Band Linear Probe                                     | Small Parts, Peripheral Vascular, Pediatrics, Obstetrics, Musculoskeletal | 44 mm                  | 3 – 8 MHz     |
| <br>11L-D H40432LN        | Wide Band Linear Probe                                     | Small Parts, Breast Peripheral Vascular, Pediatrics, Musculoskeletal      | 38 mm                  | 4 – 10 MHz    |
| <br>ML6-15-D H40452LG     | Wide Band Linear Probe with Active Matrix Array Technology | Small Parts, Breast Peripheral Vascular, Pediatrics, Musculoskeletal      | 50 mm                  | 4 – 13 MHz    |
| <br>L8-18I-D H40452LL    | Wide Band Linear Probe                                     | Small Parts, Musculoskeletal, Pediatrics                                  | 25 mm                  | 5 – 14 MHz    |
| LINEAR – REAL-TIME 4D                                                                                      |                                                            |                                                                           |                        |               |
| <br>RSP6-16-D H48651MR* | Wide Band Linear Volume Probe                              | Small Parts, Breast, Peripheral Vascular, Pediatrics, Musculoskeletal     | 38 mm<br>V 38 mm x 29° | 6 – 18 MHz    |
| PHASED ARRAY – 2D                                                                                          |                                                            |                                                                           |                        |               |
| <br>6S-D H45021RR       | Wide Band Phased Array Probe                               | Small Parts, Cardiology, Pediatrics                                       | 90°                    | 2 – 7 MHz     |
| <br>M5Sc-D H44901AE     | XDclear Wide Band Phased Array Probe                       | Abdominal, Cardiology, Obstetrics, Fetal Echo, Pediatrics, Cephalic       | 90°                    | 1.5 – 4.5 MHz |

\*Not available in all countries.



© GE, 2022

GE Healthcare reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE Healthcare representative for the most current information. GE, the GE Monogram, Voluson, and XDclear are trademarks of GE. GE Healthcare, a division of GE. GE Medical Systems, Inc., doing business as GE Healthcare.

April 2022  
JB18567XX

# Voluson Expert 22

You Set the Limits



**Voluson™**

A Healthier Future for Women

[gehealthcare.com](http://gehealthcare.com)



# You Set the Limits

You set out to make a difference. You became a leader.  
Medicine is who you are. Women's health—your life, your legacy.

Your eye is focused on 'right now', but you are envisioning 'what's next',  
Finding answers to questions that have yet to be asked.  
And the more you know. The more you want to know.

That's why we created the Voluson Expert 22 – to help you:

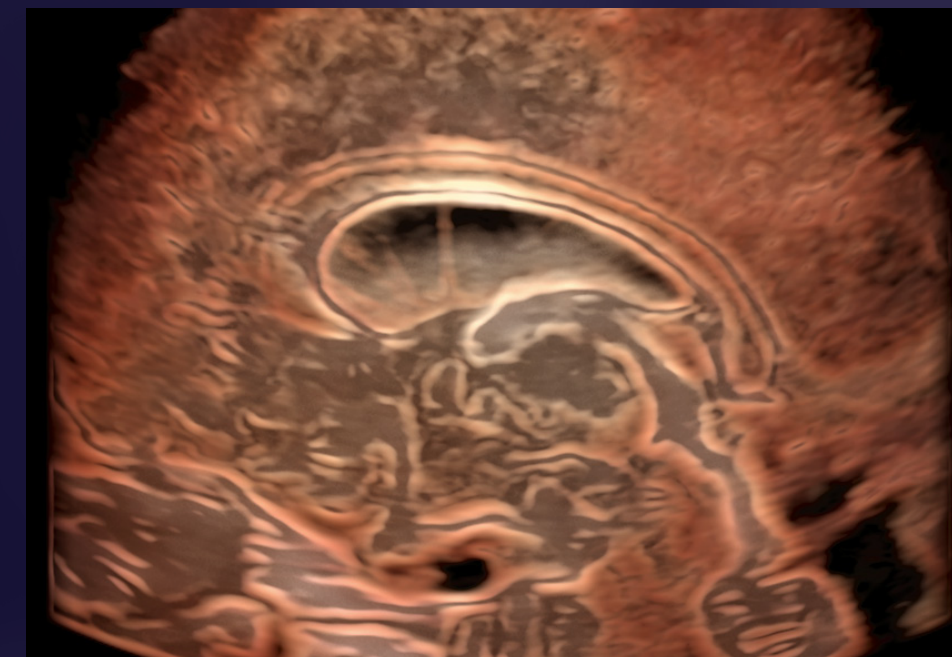
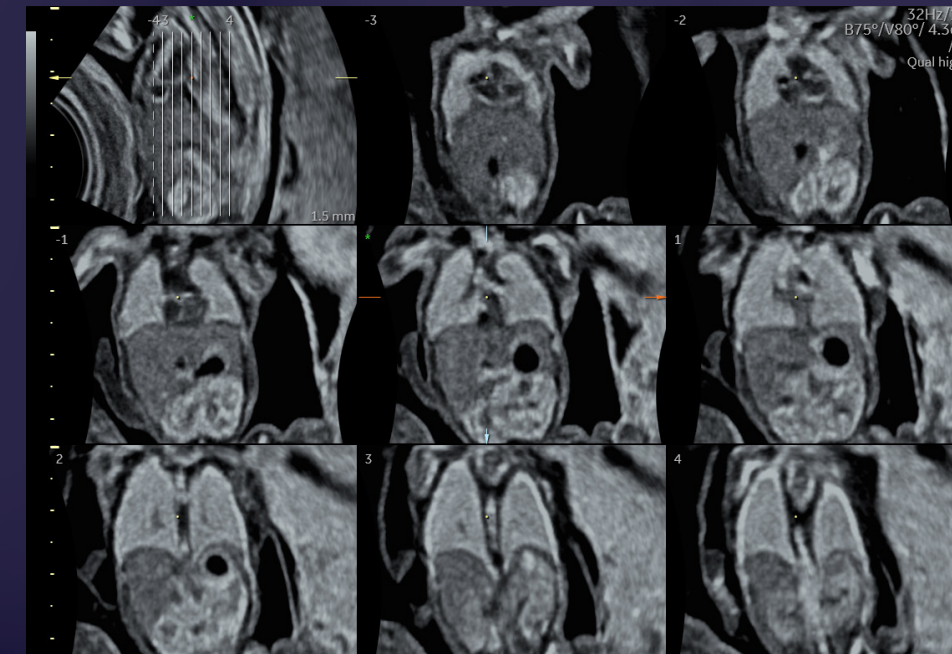
REVEAL THE INVISIBLE  
DETECT THE UNDETECTABLE  
ACHIEVE THE UNACHIEVABLE  
EXPECT THE UNEXPECTED

It's a milestone in the making.  
Not the end of a path, but the continuation of a journey.

Because, like you, we don't just hope for  
a healthier future for women.

We insist on creating it.

Voluson Expert 22







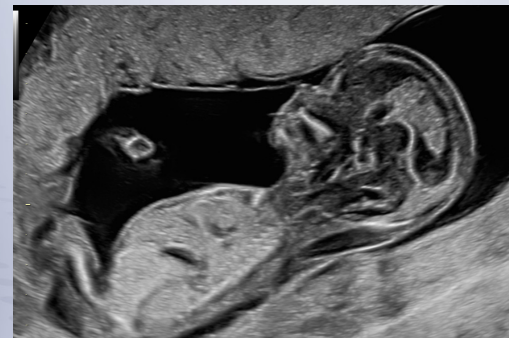
# REVEAL THE INVISIBLE

Detailed imaging is essential and the Voluson Expert 22 is ready to show you more than you ever thought possible. We are taking innovation further, making it easier to collect more information at record speeds for even faster, sharper, and clearer imaging. The Voluson Expert 22 will help you see critical details required for a confident diagnosis.

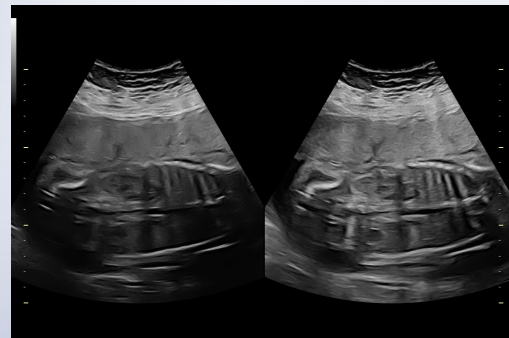
How do you find a needle in a haystack? Build a powerful engine with the most progressive and adaptive capabilities yet. The **Lyric Architecture** unlocks new imaging and processing power to achieve high resolution, detailed images – independent of body habitus and other difficult scanning conditions.

- Generates new levels of penetration, resolution, and frame rates to reveal fine anatomy in 2D/3D/4D with ease
- Delivers uniformity throughout the image with increased spatial and contrast resolution
- Works in harmony with our unique probe technology offering advanced imaging options
- Opens doors to unique Voluson imaging capabilities

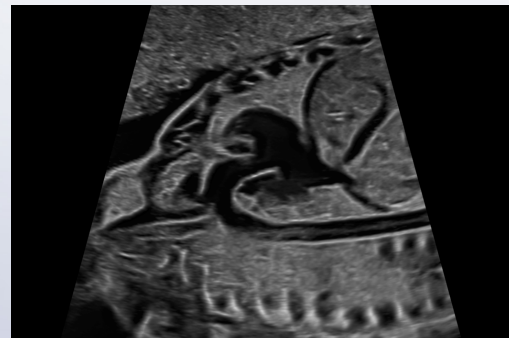
The Lyric Architecture allows you to set new standards in image quality for years to come.



Obtain super fine details with **UltraHD** – providing increased axial and lateral resolution.

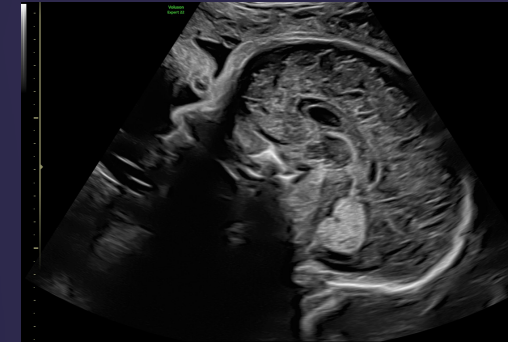


Utilize **Augment** to reduce noise and increase penetration for a robust, cleaner image even in difficult to scan situations like high BMI.



Utilize **Radiant** for greater definition and clarity. Change the levels to enhance the 3D-like elevation effect for greater border visibility and sharpness.

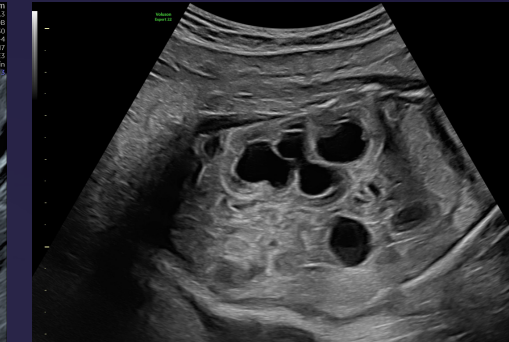
Uncover answers by elevating your 2D imaging with exceptional spatial and contrast resolution for distinct border and tissue differentiation.



Excellent detail resolution of 23-week corpus callosum with UltraHD and Radiant



16-week fetal diaphragm



32-week dilated kidney shown with UltraHD

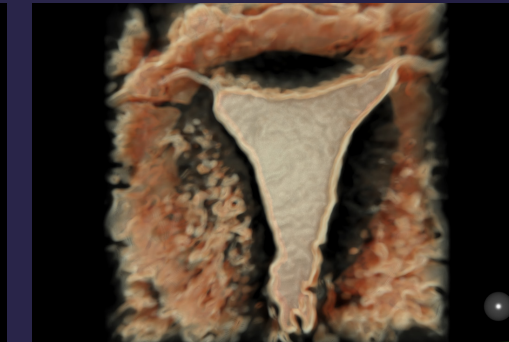
Visualizing anatomy from another view can be the difference between delaying or making a confident diagnosis. Discover the next generation of 3D/4D imaging.



8-week embryo with HDlive™ Studio+

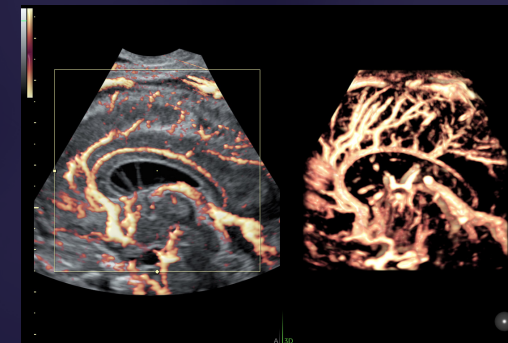


27-week fetal abdomen with HDlive Studio+

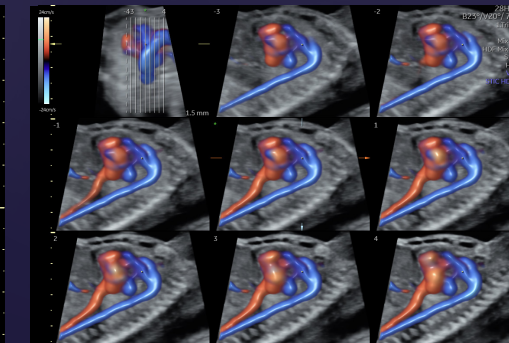


HyFoSy\* highlighted with HDlive Studio+

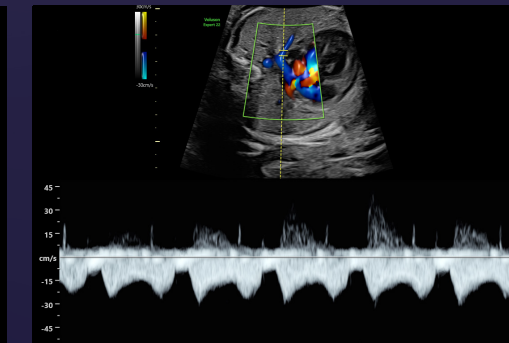
Make blood flow assessment faster and easier with advanced Voluson technologies. Increased resolution and sensitivity in color and pulsed wave Doppler for unprecedented clarity.



Corpus callosum of 25-week fetus highlighted with Slowflow3D



Ductal arch STIC volume with HDlive Flow in TUI format



Pulsed wave Doppler of 27-week pulmonary vein

\*HyFoSy not available in all regions



# DETECT THE UNDETECTABLE

Complex cases come with enough uncertainty. That is why the Voluson Expert 22 delivers extraordinary image quality and unique tools to help you focus on early detection and intervention.

## EARLY PREGNANCY

Improving detection rates of chromosomal and structural anomalies in the earliest stages of development is critical for better decision making. With small anatomy, exposing anomalies requires clear, high-resolution imaging and simplified assessment tools. With features like **UltraHD**, **Radiant**, **SonoNT** and **HDlive Studio+**, you can feel confident seeing even the tiniest detail.

## FETAL HEART

Identifying fetal cardiac abnormalities earlier means you can intervene sooner, plan for delivery, and potentially improve outcomes. The Voluson Expert 22 provides a full suite of progressive tools to help distinguish the tiniest structures with stunning clarity to detect patient answers faster.

- Detection – Assess and uncover structural anomalies with *fetalHS* and **Radiant**
- Diagnosis – Find answers to challenging exams using **Radiantflow™**, **eM6C eSTIC & Bi-Plane**
- Monitoring – Use *fetalHQ* to determine size, shape, and contractility

## PELVIC HEALTH

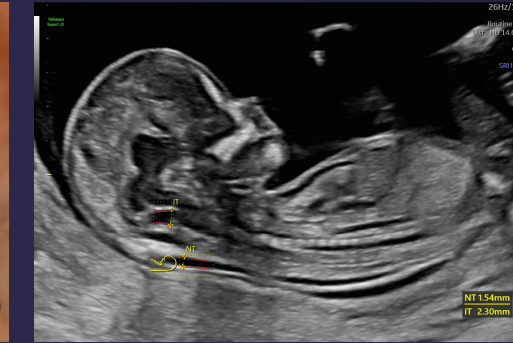
Symptoms such as pelvic pain, post-menopausal bleeding, genitourinary dysfunction, and infertility can be confusing and concerning for your patients. Exceptional imaging and advanced analysis tools like **Uterine Trace** and **SonoPelvicFloor** can provide clinical insights into gynecological health.



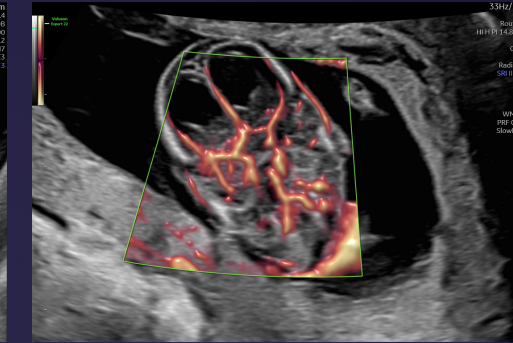
Examine developing structures earlier to uncover anomalies with high resolution probe & imaging technologies.



HDlive Studio+ 8-week pregnancy image acquired with RIC6-12 probe

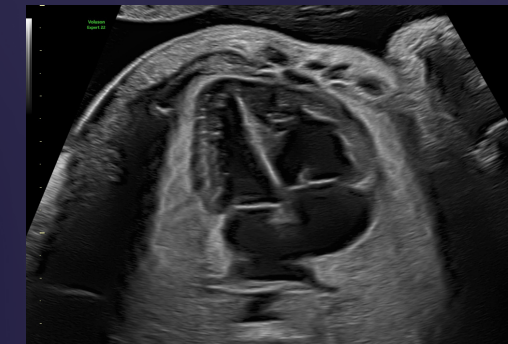


Consistently assess the nuchal and intracranial translucency with SonoNT and SonoIT automation

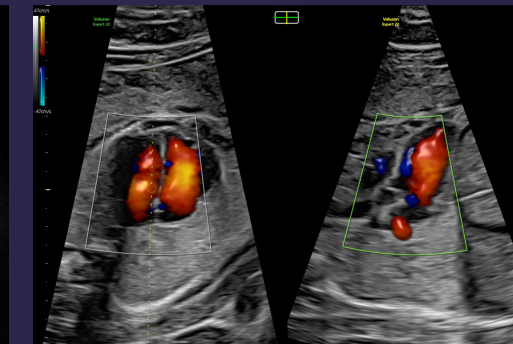


13-week fetal brain with SlowflowHD

Increase detection, diagnose confidently, and effectively monitor the fetal heart.



28-week 4-chamber heart with Radiant applied for clear borders

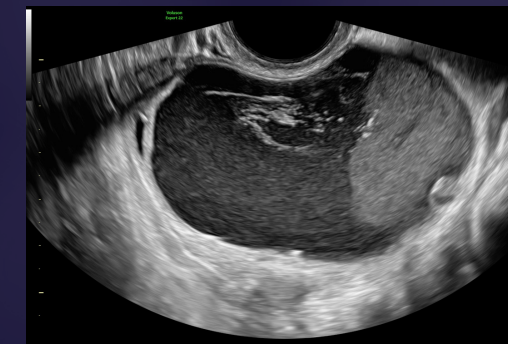


Two perpendicular views of the fetal heart displayed with Bi-Plane from eM6C probe

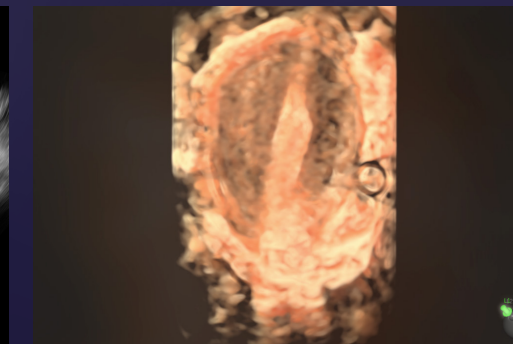


*fetalHQ* showing contractility of the fetal heart

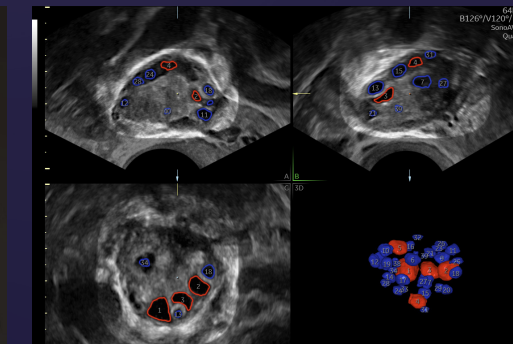
Simplify reproductive health with advanced analysis tools and easy 3D technologies.



High-definition ovarian mass image



Unicornuate uterus rendered with HDlive Studio+

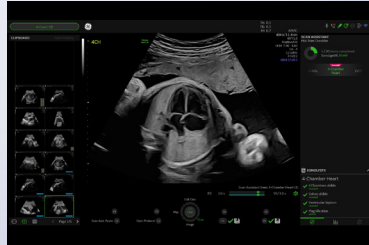


Antral follicle count with SonoAVCantral<sup>2.0</sup>



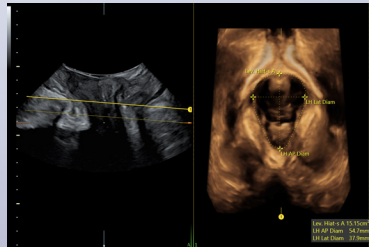
# ACHIEVE THE UNACHIEVABLE

Modern, yet familiar, the Voluson Expert 22 is our most intuitive and customizable ultra-premium ultrasound. Designed with a new generation of artificial intelligence and automation tools, it helps increase exam speed and accuracy to streamline your day. Just think of the potential.



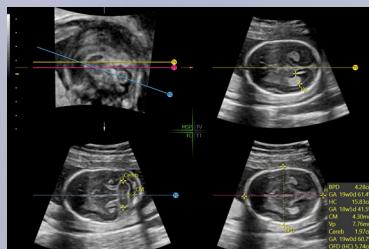
## SonoLyst

SonoLyst is your virtual on-board expert, utilizing the power of AI to identify fetal anatomy seen on standard views while enhancing efficiency by adding annotations and measurements. For quality assurance, SonoLyst can also be used to compare the image or view acquired to standard criteria, ensuring exam quality and consistency.



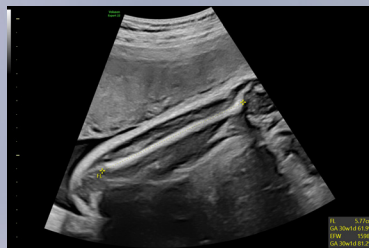
## SonoPelvicFloor

Analysis of the pelvic floor anatomy can be complicated. Through AI, SonoPelvicFloor simplifies the exam process by automating plane alignment and measurements while offering workflow guidance to improve efficiency while eliminating uncertainty.



## SonoCNS

AI driven SonoCNS supports consistent measurements and helps drive workflow efficiency by helping align and display recommended views and measurements of the fetal brain from a 3D volume.



## SonoBiometry

Repetitive tasks are a daily challenge especially in fetal development assessment. SonoBiometry helps reduce keystrokes and improve exam time by automatic caliper placement and fetal measurements of bi-parietal diameter (BPD), head circumference (HC), abdominal circumference (AC), femur length (FL), humerus length (HL), cerebellum, cisterna magna, and lateral ventricle.\*

\*As compared to manual measurements



Modern yet familiar user interface incorporating Voluson's simple and seamless workflow.



The 23.8" high-definition ultrasound (HDU) display offers 3 image sizes including unique full screen imaging that allows you to work comfortably and see finer details with ease.



Personalize the user interface for your unique preferences and select system colors to suit your mood with more than 4000 color combinations.



Work smarter using Respond probe activation which automatically initializes probes and presets when removed from the probe holder.

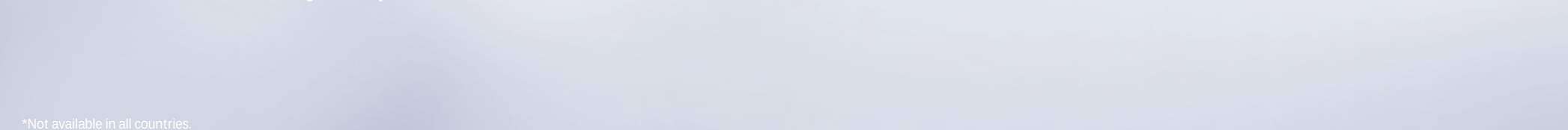
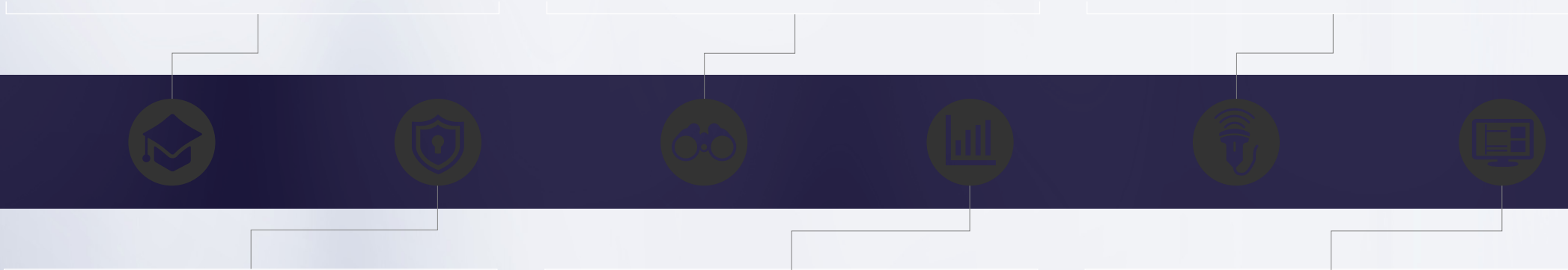


Conveniently located probe ports for easy access.



# EXPECT THE UNEXPECTED

Leverage our entire ecosystem of support for peace of mind – now and in the future. Combined with a flexible service program, GE Healthcare partners with you to monitor and maintain your Voluson ultrasound systems, ensure quality and compliance, and train and inspire your staff. Experience more. More services. More support. More future-focused solutions. Finally, a partnership that won't leave you wanting more.



\*Not available in all countries.





© GE, 2022

GE Healthcare reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE Healthcare representative for the most current information. GE, the GE Monogram, Voluson, Radiantflow, HDlive, InSite and ViewPoint are trademarks of GE. SonoLyst incorporates the AI technology of Intelligent Ultrasound. Tricefy™ is a registered trademark of Trice Imaging, Inc. Windows is a registered trademarks of Microsoft Corporation. GE Healthcare, a division of GE. GE Medical Systems, Inc., doing business as GE Healthcare.

March 2022  
JB18769XX





## **EU DECLARATION OF CONFORMITY**

Following the provisions of the medical devices regulation 2017/745.

We:

### **Manufacturer**

**GE Healthcare Austria GmbH & Co OG**

**Tiefenbach 15**

**4871 Zipf**

**Austria**

Single Registration Number (SRN): **AT-MF-000001461**

Declare under our sole responsibility that the device:

### **Voluson Expert 22**

Basic UDI-DI: 8406821BUG00148HD

Identification number (MD Number): 5805692

Intended Purpose:

The **Voluson Expert 22** is a general purpose ultrasound system intended for ultrasound image acquisition for diagnostic purposes incl. measurements on acquired image.

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

Class: **Ila**

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis) and Rule 11 (Software) of Annex VIII of Council Regulation EU 2017/745]

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

Zipf, 09-JUN-2022

  
Roland Kuntscher  
Regulatory Affairs Specialist





This conformity is based on the following elements:

- Technical Documentation reference: DOC2548733, of the product to which this declaration relates.
- EC certificate Number: **G10 075707 0078**
  - Conformity assessment procedure followed: Annex IX excluding Chapter II
  - Delivered by **TÜV SÜD Product Service GmbH** (Notified Body **0123**) , Ridlerstraße 65,80339 Munich, Germany

This EC declaration of conformity supersedes the previous declaration dated 05-MAY-2022

SIGNATURE:

Date of issue:

09-JUN-2022

Place of issue:

Zipf/Austria

Name:

Roland Kuntscher

Function:

Regulatory Affairs Specialist

Signature:



---

**ADDENDUM TO THE EC DECLARATION OF CONFORMITY**

| <b>Product Description</b>                                                                          | <b>Catalog Designation</b>                                                                |
|-----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <i>Device, accessory description covered by this DoC and its associated technical documentation</i> | <i>Catalog number used by customer to order the device and/or accessories</i>             |
| Software Version: EC400                                                                             | See Appendix A – List of Compatibility - Accessories and Options covered with this EC-DoC |
| Significance Letter: I                                                                              |                                                                                           |
| Serial Number: From F160101 onwards + F60070 to F60099                                              | See Appendix B – List of Compatibility used with Console Voluson Expert 22                |

Zipf, 09-JUN-2022



Roland Kuntscher  
Regulatory Affairs Specialist



## Appendix A: List of Compatibility -Accessories and Options covered by this EC-DoC

| Console Voluson Expert 22 EC400 (=Ref #)                     | Medical Device Number / Sales Number         |
|--------------------------------------------------------------|----------------------------------------------|
| Voluson Expert 22                                            | 5805692 (MD Number) / H48711KA (Cat. Number) |
| Update new VExpert SW                                        | H48711NX (Cat. Number)                       |
| <b>Real Times 4D Probes</b>                                  |                                              |
| RAB6-D Volume Abdominal Probe                                | H48681MG                                     |
| RIC5-9-D 5-9 MHZ 4D ENDOCAVITY PROBE                         | H48651MS                                     |
| RIC6-12-D 6-12MHz 4D ENDOCAVITY PROBE                        | H48651NA                                     |
| RSP6-16-D; 6-16 MHz Realtime 4D broadband linear array probe | H48651MR                                     |
| RM7C 4D Abdominal probe                                      | 5790293                                      |
| eM6C G3 Volume Abdominal Probe                               | 5835134                                      |
| RIC10-D 4D ENDOCAVITY PROBE                                  | 5845346                                      |
| <b>Software Options Individual</b>                           |                                              |
| Advanced VCI- Volume Contrast Imaging                        | H48681FP                                     |
| Advanced STIC                                                | H48681GD                                     |
| VCI-2D                                                       | N/A                                          |
| CODED CONTRAST IMAGING-CONTRAST MEDIA                        | H48681FT                                     |
| SonoAVC - Sono Automated Volume Count                        | H48681FX                                     |
| SonoVCADlabor                                                | H48681FY                                     |
| Elastography                                                 | H48681GB                                     |
| Shear Wave Elastography                                      | H48711EE                                     |
| 4DView 18 PC Software                                        | H48701YF                                     |
| V-SRI                                                        | H48711CY                                     |
| E4D Advanced features                                        | H48691YA                                     |
| CW-Software Option                                           | H48691NZ                                     |
| Tricify Uplink                                               | H48701NB                                     |
| IOTA (LR2, Simple Rules, Adnex)                              | N/A                                          |
| Fetal HQ                                                     | H48701WN                                     |
| Fetal HQ2                                                    | H48711PT                                     |
| Sono CNS                                                     | N/A                                          |
| Advanced Security Features                                   | H48701WM                                     |
| Premium Security Feature                                     | H48701WT                                     |
| Voluson Remote Updates                                       | H48711KH                                     |
| SonoLyst                                                     | H48711NZ                                     |
| SonoLyst live                                                | N/A                                          |
| SonoPelvic Floor                                             | H48711PA                                     |
| Fetal HS                                                     | N/A                                          |
| Adapt                                                        | N/A                                          |
| eDelivery                                                    | H48711NW                                     |
| AVURI Device Management (Permanent Access)                   | H48711PC                                     |
| Data Streaming                                               | N/A                                          |
| <b>Hardware Options</b>                                      |                                              |
| ECG Digital Module USB                                       | H48711KX                                     |
| ECG Digital Module USB (Canada)                              | H48711KY                                     |
| MDM400 monitor (OLED)                                        | N/A                                          |

Zipf, 09-JUN-2022

Roland Kuntscher  
Regulatory Affairs Specialist



**Appendix B: List of Compatibility used with Consoles Voluson Expert 22**

Note: For this products GE Healthcare Austria GmbH & Co OG is not manufacturer

| <b>2D SMALL PARTS PROBES, LINEAR ARRAY</b>                      |                         |
|-----------------------------------------------------------------|-------------------------|
| 11L-D linear array probe, small parts                           | H40432LN <sup>[1]</sup> |
| 12L-RS Multi Biopsy Guide- CIVCO Part # 742-335                 | H40432LC <sup>[2]</sup> |
| 9L-D linear array probe, small parts & vascular                 | H40442LM <sup>[1]</sup> |
| Biopsy for 9L – CIVCO Part # 742-333                            | H4906BK <sup>[2]</sup>  |
| ML6-15-D Active Matrix Phased Array Linear Probe                | H40452LG <sup>[1]</sup> |
| ML6-15D Biopsy Starter Kit, Multi-Angle - CIVCO Part # 742-352  | H40432LJ <sup>[2]</sup> |
| L8-18i-D linear array probe, small parts                        | H40452LL <sup>[1]</sup> |
| <b>2D ENDOCAVITY PROBES, MICRO-CURVED ARRAY</b>                 |                         |
| IC5-9-D endocavity probe                                        | H40442LK <sup>[1]</sup> |
| Biopsy for IC5-9H, reusable                                     | H40412LN <sup>[1]</sup> |
| Biopsy for IC5-9H, disposable (20) - CIVCO Part # 742-270       | E8385MJ <sup>[2]</sup>  |
| <b>2D ABDOMINAL PROBES, CURVED ARRAY</b>                        |                         |
| C2-9-D Curved Array Probe                                       | H40462LN <sup>[1]</sup> |
| C2-9-D Biopsy Guide                                             | H4913BA <sup>[2]</sup>  |
| C1-6-D Curved Array Probe                                       | H40472LT <sup>[1]</sup> |
| C1-6-D Biopsy Guide                                             | H4913BB <sup>[2]</sup>  |
| <b>2D PHASED ARRAY PROBES</b>                                   |                         |
| 6S-D Phased Array Probe                                         | H45021RR <sup>[3]</sup> |
| M5Sc-D Phased Array Probe                                       | H44901AE <sup>[3]</sup> |
| M5Sc-D Biopsy Kit                                               | H45561FC <sup>[2]</sup> |
| <b>Real Times 4D Probes Biopsy Guides</b>                       |                         |
| RSP Biopsy Starter Kit - CIVCO Part # 742-327                   | H46701AD <sup>[2]</sup> |
| RIC Biopsy PEC 63 - Reusable CIVCO                              | H46721R <sup>[2]</sup>  |
| RIC Biopsy Starter Kit - Disposable CIVCO                       | H48681GF <sup>[2]</sup> |
| RAB6 Biopsy Starter Kit (RAB UltraLight) - CIVCO Part # 742-421 | H48681ML <sup>[2]</sup> |

Notes: [1] EC-Declaration of Conformity by GE Healthcare Japan Corporation  
[2] EC-Declaration of Conformity by CIVCO Medical Solutions, USA  
[3] EC-Declaration of Conformity by GE Parallel Design, SAS France

Zipf, 09-JUN-2022

End of document

Roland Kuntscher  
Regulatory Affairs Specialist





## 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. 01**

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

**SRN Manufacturer:** AT-MF-000001461

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.  
For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 075707 0078 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10 075707 0078 Rev. 01)

**Report No.:** 713202497  
**Preceding Certificate No.:** G10 075707 0078 Rev. 00  
**Valid from:** 2021-07-16  
**Valid until:** 2025-05-13  
**Date of Initial Issuance:** 2020-05-14

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2021-07-16





## 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. 01**

**Classification:** IIa  
**Device Group:** Z11040182 - ULTRASOUND SCANNERS - SOFTWARE  
**Intended Purpose:** -

**Classification:** IIa  
**Device Group:** Z1104 - ECHOGRAPHIC INSTRUMENTS  
**Intended Purpose:** -

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

|                          |      |            |           |
|--------------------------|------|------------|-----------|
| <b>Revision History:</b> | Rev. | Dated      | Report    |
|                          | 00   | 2020-05-14 | 713175299 |



# Certificate

No. Q5 075707 0058 Rev. 02

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

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

**Certification Mark:**



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

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

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

**Report No.:** 713202497

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

**Date,** 2021-11-11

Christoph Dicks  
Head of Certification/Notified Body



Введите текст для поиска...

| Nr          | Denumire      | Den.comerc. | Model                                             | Nr. catalog | Tara    | Prodicatorul                       | Reprezentant    | Ordin              | Data       | Cod vamal |
|-------------|---------------|-------------|---------------------------------------------------|-------------|---------|------------------------------------|-----------------|--------------------|------------|-----------|
|             |               |             | Voluson E                                         |             |         |                                    |                 |                    |            |           |
| DM000392790 | ULTRASONOGRAF |             | VOLUSON EXPERT 22                                 | H48711KA    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | Rg04-000290        | 05-12-2022 |           |
| DM000124878 | ULTRASONOGRAF |             | Voluson E6 BT13.5, E6 EC250                       | H48681XB    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-163 | 19-06-2018 |           |
| DM000129793 | ULTRASONOGRAF |             | Voluson E6 BT15 Console without CW-Doppler, EC300 | H48691RL    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-167 | 25-06-2018 |           |
| DM000124879 | ULTRASONOGRAF |             | Voluson E6 BT13.5 CW, E6 EC250                    | H48691YG    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-163 | 19-06-2018 |           |
| DM000227346 | ULTRASONOGRAF |             | Voluson E10 BT20 OLED                             | H48711FC    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | Rg04-000199        | 13-08-2019 |           |
| DM000227345 | ULTRASONOGRAF |             | Voluson E10 BT20                                  | H48711FB    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | Rg04-000199        | 13-08-2019 |           |
| DM000129915 | ULTRASONOGRAF |             | Voluson E8 Expert BT13 220V Korea, EC200          | H48681WE    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-167 | 25-06-2018 |           |
| DM000129893 | ULTRASONOGRAF |             | Voluson E8 BT13 115V USA, EC200                   | H48681TT    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-167 | 25-06-2018 |           |
| DM000129615 | Ultrasonograf |             | VOLUSON E10 BT17, SOFTWARE VERSION EC320          | H48701GT    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-167 | 25-06-2018 |           |
| DM000129913 | ULTRASONOGRAF |             | Voluson E8Expert BT13 115V USA, EC200             | H48681WC    | Austria | GE HEALTHCARE AUSTRIA GMBH & CO OG | INTERMED S.R.L. | A07.PS-01.Rg04-167 | 25-06-2018 |           |

Страница 1 из 5 (Всего элементов: 43)

✓

Содержит([Model], 'Voluson E')

Очистить