



JUL 18 2014

K141639  
Page 1 of 4

GE Healthcare  
510(k) Premarket Notification Submission

**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 18, 2014

Submitter: GE Healthcare  
9900 Innovation Dr  
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn  
Regulatory Affairs Manager  
GE Healthcare  
T:(414)721-4214  
F:(414)918-8275

Secondary Contact Person: Chan Sook Kim  
Regulatory Affairs Leader  
GE Healthcare  
T: +82 31 740 6307

Device: Trade Name: Voluson S6, Voluson S8 Ultrasound System

Common/Usual Name: Voluson S6, Voluson S8

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN  
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO  
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K120741 Voluson S6, Voluson S8 Diagnostic Ultrasound System  
K132913 Voluson E Series  
K122387 Voluson P6/P8  
K121063 Vivid S5/S6

Device Description: The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronic-array transducers. It has the same general appearance, dimensions and weight as the unmodified device, it is a Track 3 general-purpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology and vascular applications.



## GE Healthcare

510(k) Premarket Notification Submission

Intended Use: The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Technology: The Voluson S6, Voluson S8 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence: Comparison to Predicate Device(s): The Voluson S6/S8 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Voluson S6/S8 and predicate Voluson S6/S8 systems have the same clinical intended use
- The Voluson S6/S8 and predicate Voluson S6/S8 systems have the same imaging modes.
- The Voluson S6/S8 and predicate Voluson S6/S8 systems transducers are identical except for the 12S-RS (same as predicate Vivid S5/S6 K121063), RAB2-6-RS (same as predicate Voluson P6/P8 K122387) and RAB6-RS (Equivalent to RAB6-D on predicate Voluson E Series K132913).
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The Voluson S6/S8 and predicate Voluson S6/S8 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- New software features added to Voluson S6/S8: HDLive, Sono IT, SonoBiometry and Sono L&D are the same features cleared on predicate Voluson E Series(K132913).
- The Voluson S6/S8 and predicate systems have been



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510(k) Premarket Notification Submission

designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. Voluson S6, Voluson S8 and its applications comply with voluntary standards;

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)



GE Healthcare  
510(k) Premarket Notification Submission

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson S6, Voluson S8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson S6, Voluson S8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 18, 2014

GE Healthcare  
% Mr. Bryan Behn  
Regulatory Affairs Manager  
9900 Innovation Drive  
WAUWATOSA WI 53226

Re: K141639  
Trade/Device Name: Voluson S6, Voluson S8 Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: June 18, 2014  
Received: June 19, 2014

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson S6, Voluson S8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number		
RAB4-8-RS	4C-RS	E8C-RS
C1-5-RS	12L-RS	AB2-7-RS
RIC5-9W-RS	RAB2-5-RS	8C-RS
M1.6-15-RS	3Sc-RS	9L-RS
P2D	12S-RS	RAB2-6-RS
RAB6-RS		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)

K141639

Device Name

Voluson S6/Voluson S8 Diagnostic Ultrasound System

Indications for Use (Describe)

The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Type of Use (Select one or both, as applicable)

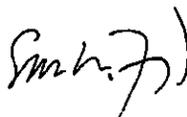
Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

#### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson S6/S8 Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetus / Obstetrics <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[ 5,6,9]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[ 5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[ 5,6,9]
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	[ 5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6,9]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[6]</sup>	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate.
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with RAB4-8-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[ 5,6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[ 5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[ 5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[ 5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate.
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 4C-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes: [1] Abdominal includes renal, GYN/Pelvic  
 [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients  
 [3] Cardiac is Adult and Pediatric  
 [4] 3D/4D Imaging Mode  
 [6] Includes imaging of guidance of biopsy (2D/3D/4D)  
 [7] Includes infertility monitoring of follicle development  
 [8] Includes urology/prostate  
 [9] Elastography imaging- Elasticity  
 [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with E8C-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	[6]
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B:M, B:Color M, B:PWD, B:Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson S6/S8 with C1-5-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Lapuroscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

[\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 12L-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / (Obstetrics) <sup>1)</sup>											
Abdominal <sup>1)</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	[6,9]
Small Organ <sup>2)</sup>	P	P	P		P	P	P	P	P	P	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>3)</sup>											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6,9]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>4)</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with AB2-7-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes: [1] Abdominal includes renal, GYN/Pelvic  
 [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients  
 [3] Cardiac is Adult and Pediatric  
 [5] 3D/4D Imaging Mode.  
 [6] Includes imaging of guidance of biopsy (2D/3D/4D)  
 [7] Includes infertility monitoring of follicle development.  
 [8] Includes urology:prostate.  
 [9] Elastography imaging- Elasticity  
 [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson S6/S8 with RIC5-9W-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes <sup>1</sup>	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[ 5.6.9]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[ 5.6.9]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	[ 5.6.9]
Transvaginal	P	P	P		P	P	P	P	P	P	[ 5.6.9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes: [1] Abdominal includes renal, GYN/Pelvic  
 [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients  
 [3] Cardiac is Adult and Pediatric.  
 [4] 3D/4D Imaging Mode.  
 [5] Includes imaging of guidance of biopsy (2D/3D/4D).  
 [6] Includes infertility monitoring of follicle development.  
 [7] Includes urology/prostate.  
 [8] Elastography imaging- Elasticity  
 [9] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with RAB2-5-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	(5,6)
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	(5,6)
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	(5,6)
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric
  - [4] 3D-4D Imaging Mode.
  - [5] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [6] Includes infertility monitoring of follicle development.
  - [7] Includes urology/prostate.
  - [8] Elastography imaging- Elasticity
  - [9] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**GE Healthcare**  
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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 8C-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	(9)
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P		P	P	P	P	P	P	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	(9)
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	(9)
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate.
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with ML6-15-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>											
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	(6,9)
Pediatric	P	P	P		P	P	P	P	P	P	(6,9)
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	(6,9)
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	(6,9)
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	(6,9)
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	(6,9)
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication. P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate.
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 3Sc-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes <sup>*</sup>	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[6]
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA

Notes [1] Abdominal includes renal, GYN-Pelvic

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (2D/3D/4D)

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

[\*] Combined modes are B/M, B-Color M, B/PWD, B-Color/PWD, B/PWD

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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 9L-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Puls	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	(9)
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	(9)
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [4] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development
  - [8] Includes urology/prostate
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B:M, B:Color M, B:PWD, B:Color:PWD, B:PWD

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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic					P						
Cardiac <sup>[3]</sup>					P						
Peripheral Vascular					P						
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric
  - [4] 3D/4D Imaging Mode.
  - [5] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [6] Includes infertility monitoring of follicle development.
  - [7] Includes urology/prostate
  - [8] Elastography imaging- Elasticity
  - [9] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with 12S-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Puls	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P'	P'	P'	P'	P'	P'	P'	P'	P'	P'	[6]
Small Organ <sup>[2]</sup>	N	N	N	N	N	N	N	N	N	N	[6]
Neonatal Cephalic	P'	P'	P'	P'	P'	P'	P'	P'	P'	P'	[6]
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	[6]
Cardiac <sup>[3]</sup>	P'	P'	P'	P'	P'	P'	P'	P'	P'	P'	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P' = previously cleared by FDA, P'' = previously cleared by FDA (K121063)

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [4] 3D/4D Imaging Mode.
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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GE Healthcare  
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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with RAB2-6-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>	P*	P*	P*		P*	P*	P*	P*	P*	P*	(5,6)
Abdominal <sup>[1]</sup>	P*	P*	P*		P*	P*	P*	P*	P*	P*	(5,6)
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P*	P*	P*		P*	P*	P*	P*	P*	P*	(5,6)
Musculo-skeletal Superficial											
Other											
<i>Exam Type/ Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; P\* = previously cleared by FDA (K122387)

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic
  - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
  - [3] Cardiac is Adult and Pediatric.
  - [5] 3D/4D Imaging Mode
  - [6] Includes imaging of guidance of biopsy (2D/3D/4D).
  - [7] Includes infertility monitoring of follicle development.
  - [8] Includes urology/prostate
  - [9] Elastography imaging- Elasticity
  - [\*] Combined modes are B-M, B-Color M, B-PWD, B-Color/PWD, B/PWD

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**GE Healthcare**  
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**Diagnostic Ultrasound Indications for Use Form**

**GE Voluson S6/S8 with RAB6-RS Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[2]</sup>	N	N	N		N	N	N	N	N	N	(5,6)
Abdominal <sup>[1]</sup>	N	N	N		N	N	N	N	N	N	(5,6)
Pediatric	N	N	N		N	N	N	N	N	N	(5,6)
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	(5,6)
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[4]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes: [1] Abdominal includes renal, GYN/Pelvic  
 [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients  
 [3] Cardiac is Adult and Pediatric.  
 [5] 3D/4D Imaging Mode.  
 [6] Includes imaging of guidance of biopsy (2D/3D/4D)  
 [7] Includes infertility monitoring of follicle development.  
 [8] Includes urology/prostate  
 [9] Elastography imaging- Elasticity  
 [\*] Combined modes are B:M, B:Color M, B:PWD, B:Color:PWD, B/PWD

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