

EVALUATION

Premium General-Purpose Ultrasound Scanners, Focusing on the Mindray Resona 7

A Report Excerpted from the Device Evaluation Website | May 2021

Also Includes Ratings and Purchasing Advice for:

Canon Medical Systems Aplio i800 Philips Healthcare Epiq Elite Samsung RS85 Prestige Siemens Healthcare Solutions Acuson Sequoia Siemens Healthineers Acuson S3000 HELX Evolution with Touch Control Toshiba America Medical Systems Aplio 500



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EVALUATION

Premium General-Purpose Ultrasound Scanners, Focusing on the Mindray Resona 7

A Report Excerpted from the Device Evaluation Website | May 2021

This report focuses on our Evaluation of the Mindray Resona 7 premium general-purpose ultrasound scanner. For perspective, it also includes our findings for the other products we evaluated: the Canon Medical Systems Aplio i800, Philips Healthcare Epiq Elite, Samsung RS85 Prestige, Siemens Healthcare Solutions Acuson Sequoia, Siemens Healthineers Acuson S3000 HELX Evolution with Touch Control, and Toshiba America Medical Systems Aplio 500.

A summary of our findings is presented below and on the next 5 pages. Our detailed Evaluation results for the Resona 7 begin on page 9.

RATINGS: PREMIUM GENERAL-PURPOSE ULTRASOUND SCANNERS

| Model | Where Marketed | Rating | Performance | Safety | Workflow | Patient Experience | Interop- erability | Cyber- security | Maintenance | User Experience | Cost of Ownership (Estimated) over Seven Years |
|---|-------------------|--------|-------------|--------|-----------|-----------------------|-----------------------|-----------------------|-------------|--------------------|--|
| Mindray Resona 7 Last updated 6/2019 | Worldwide | ★★★★☆ | Excellent | Good | Good | Not evaluated | Good | Good | Good | Good | Good; \$137,000 |
| Canon Aplio i800 Last updated 11/2019 | Worldwide | ★★★★☆ | Excellent | Good | Excellent | Not evaluated | Good | Good | Good | Good | Good; \$220,000 |
| Philips Epiq Elite Last updated 12/2020 | Worldwide | ★★★★☆ | Excellent | Good | Good | Not evaluated | Good | Good | Good | Good | Good; \$190,000 |
| Samsung RS85 Prestige Last updated 12/2020 | Worldwide | *** | Excellent | Good | Fair | Not evaluated | Good | Good | Good | Excellent | Good; \$210,000 |
| Siemens Acuson S3000 HELX Evolution with Touch Control Last updated 6/2017 | Worldwide | **** | Excellent | Good | Excellent | Not evaluated | Good | Not evalu- ated | Good | Good | Good; \$220,000 |
| Siemens Acuson Sequoia Last updated 12/2020 | Worldwide | ★★★★☆ | Excellent | Good | Good | Not evaluated | Good | Good | Good | Excellent | Good; \$200,000 |
| Toshiba Aplio 500 Last updated 11/2016 | Worldwide | ★★★★☆ | Excellent | Good | Good | Not evaluated | Good | Not evalu- ated | Good | Good | Good; \$152,000 |

MINDRAY RESONA 7

Rating



Findings

The Resona 7 is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner, as well as improve workflow.

Our rating is based on the following findings:

Performance—Excellent. The Resona 7 met our required B-mode and Doppler performance criteria. The scanner demonstrated advantages in its optional advanced technologies of strain and shear-wave elastography, fusion imaging and needle navigation, and contrast-enhanced ultrasound imaging.

Safety—Good. The Resona 7 met our safety criteria, including fulfilling all recommendations in the Industry Standards for the Prevention of Work-Related Musculoskeletal Disorders in Sonography, published by the Society of Diagnostic Medical Sonography.

Workflow-Good. The Resona 7 met our required workflow criteria and demonstrated advantages in being able to simultaneously display in real time conventional B-mode and contrast-enhanced ultrasound data, and for having multiple ways to import data for fusion imaging.

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The Resona 7 met our required interoperability criteria. The scanner can communicate via Ethernet with a hospital information system (HIS) and picture archiving and communication system (PACS). Wi-Fi is available as an option.

Cybersecurity—Good. The scanner met our required cybersecu-

Maintenance—Good. The vendor does not specify the frequency of inspection and preventive maintenance procedures, allowing facilities to set their own frequency.

User Experience—Good. Surveyed users confirmed the findings of our tests.

Cost of Ownership—Good; \$137,000 (estimated) over seven years

CANON MEDICAL SYSTEMS APLIO 1800

Rating



Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

The Aplio i800 is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. We evaluated the device for both general-purpose (GP) applications and obstetric and gynecologic (OB/GYN) applications. A number of options are available that have the potential to enhance the clinical performance of the scanner, as well as improve workflow. Our ratings are based on the following findings:

Performance—Excellent (GP applications); Good (OB/GYN applications). The Aplio i800's advantages include the optional advanced technologies of strain and shear-wave elastography, fusion imaging, contrast-enhanced ultrasound imaging, excellent B-mode axial resolution, and strain imaging for fetal echocardiography studies.

Safety—Good (GP and OB/GYN). The scanner met our required safety criteria, including those pertaining to the Industry Standards for the Prevention of Work-Related Musculoskeletal Disorders in Sonography, published by the Society of Diagnostic Medical Sonography.

Workflow-Excellent (GP); Good (OB/GYN). The scanner met our required workflow criteria, and has advantages related to automated gynecologic data acquisition, measurement, and calculation capabilities, as well as other features that enhance its usability for both conventional and advanced GP applications.

Patient Experience—Not evaluated. Patient experience is not a purchasing factor for these devices.

Interoperability—Good (GP and OB/GYN). The Aplio i800 met our required interoperability criteria. The scanner can communicate via Ethernet with a hospital information system (HIS) and picture archiving and communication system (PACS). Wi-Fi is available as an option.

Cybersecurity—Good (GP and OB/GYN). The scanner met our required cybersecurity criteria.

Maintenance—Good (GP and OB/GYN). The vendor recommends annual inspection and preventive maintenance. Several maintenance options are available.

User Experience—Good (GP and OB/GYN). Surveyed users confirmed the findings of our Evaluation.

Cost of Ownership—Good (GP and OB/GYN). Estimated at \$220,000 for GP applications and \$230,000 for OB/GYN applications over seven years. Note that these calculations are based on prices for the United States, a major market for the product.

Considerations for Challenging Environments

No significant challenges or concerns. The Aplio i800 is designed to be used in a controlled hospital environment by trained operators. Hospitals have biomedical engineers to perform preventive maintenance, and service contracts that include OEM service are common.

PHILIPS HEALTHCARE EPIQ ELITE

Rating



Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

The Epiq Elite is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner, as well as improve workflow.

The Epiq Elite is a very good choice for general-purpose ultrasound applications and, when configured with the required options, may be used for advanced applications that include strain and shearwave elastography, contrast-enhanced imaging, fusion imaging, needle navigation, and 3D and 4D (i.e., real-time 3D) imaging. The scanner supports desirable workflow enhancements such as automated image optimization features, as well as Wi-Fi connectivity.

Our rating is based on the following findings:

Performance—Excellent. The Epiq Elite met ECRI's required performance criteria, including supporting advanced modes such as elastography, contrast-enhanced imaging, 3D/4D, fusion imaging, and needle navigation. The scanner offers the vendor's Micro Flow Imaging HD (MFI HD) advanced blood flow detection mode.

Safety—Good. The scanner met our required safety criteria.

Workflow-Good. The Epiq Elite demonstrated workflow advantages in having a battery-operated standby mode and Auto Color, which is an automated image optimization feature for color Doppler imaging (CDI).

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The scanner met our required interoperability criteria.

Cybersecurity—Good. The manufacturer has completed ECRI's cybersecurity questionnaire, which allows us to identify the cybersecurity capabilities of the scanner. We judged the responses to be satisfactory.

Maintenance—Good. The scanner met our required maintenance criteria.

User Experience—Good. Surveyed users confirmed the findings of our tests.

Cost of Ownership-Good; \$190,000 (estimated) over seven years for an installation including four two-dimensional (2D) transducers commonly used for general-purpose applications. This calculation is based on prices for the United States, a major market for the product.

Considerations for Challenging Environments

These scanners are typically used in hospital radiology departments and vascular laboratories by ultrasound imaging professionals. There are no significant concerns for use of this product in challenging environments. However, users should be aware that there are limits for use of the device in extremely humid, cold, or hot environments. Also, as with any ultrasound scanner, parts and servicing in remote areas may involve delays and increased shipment costs.

SAMSUNG RS85 PRESTIGE

Rating



Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

The Samsung RS85 Prestige is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner, as well as improve workflow.

The RS85 Prestige is a good choice for general-purpose applications and, when configured with the required options, may be used for advanced applications that include strain and shear-wave elastography, contrast-enhanced imaging, fusion imaging, needle navigation, and 3D and 4D (i.e., real-time 3D) imaging. The scanner supports desirable workflow enhancements such as automated Doppler optimization features and Wi-Fi connectivity.

Our rating is based on the following findings:

Performance—Excellent. The RS85 Prestige met ECRI's required performance criteria, including supporting advanced modes such as elastography, contrast-enhanced imaging, 3D/4D, fusion imaging, and needle navigation. The scanner offers up to 43 cm (16.9 in) of B-mode penetration and offers the vendor's MV-Flow advanced blood flow detection mode.

Safety—Good. The scanner met our required safety criteria.

Workflow-Fair. The RS85 Prestige offers automated data acquisition features for general-purpose applications, but lacks an effective automated B-mode image optimization feature.

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The scanner met our required interoperability criteria.

Cybersecurity—Good. The manufacturer has completed ECRI's cybersecurity questionnaire, which allows us to identify the cybersecurity capabilities of the scanner. We judged the responses to be satisfactory.

Maintenance—Good. The scanner met our required maintenance criteria.

User Experience—Excellent. Surveyed users confirmed the findings of our tests.

Cost of Ownership—Good; \$210,000 (estimated) over seven years for an installation including four 2D transducers commonly used for general-purpose applications. This calculation is based on prices for the United States, a major market for the product. The RS85 Prestige has a five-year warranty standard.

Considerations for Challenging Environments

These scanners are typically used in hospital radiology departments and vascular laboratories by ultrasound imaging professionals. There are no significant concerns for use of this product in challenging environments. However, users should be aware that there are limits for use of the device in extremely humid, cold, or hot environments. Also, as with any ultrasound scanner, parts and servicing in remote areas may involve delays and increased shipment costs.

SIEMENS HEALTHCARE SOLUTIONS **ACUSON SEQUOIA**

Rating



Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

The Sequoia is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner, as well as improve workflow.

The Sequoia is a very good choice for general-purpose applications and, when configured with the required options, may be

used for advanced applications that include strain and shear-wave elastography, contrast-enhanced imaging, fusion imaging, and needle navigation. The scanner supports desirable workflow enhancements such as automated image optimization features and Wi-Fi connectivity.

Our rating is based on the following findings:

Performance—Excellent. The scanner met ECRI's required performance criteria, including supporting advanced modes such as elastography, contrast-enhanced imaging, fusion imaging, and needle navigation. 3D and 4D (i.e., real-time 3D) imaging is supported on the endocavity probe. The scanner also offers up to 40 cm (15.7 in) B-mode penetration when using the DAX transducer, as well as the vendor's S-Flow advanced blood flow detection mode.

Safety—Good. The scanner met our required safety criteria.

Workflow—Good. The scanner offers a hibernation mode.

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The scanner met our required interoperability criteria.

Cybersecurity—Good. The manufacturer has completed ECRI's cybersecurity questionnaire, which allows us to identify the cybersecurity capabilities of the scanner. We judged the responses to be satisfactory.

Maintenance—**Good.** The scanner met our required maintenance criteria.

User Experience—Excellent. Surveyed users confirmed the findings of our tests.

Cost of Ownership—Good; \$200,000 (estimated) over seven years for an installation including four 2D transducers commonly used for general-purpose applications. This calculation is based on prices for the United States, a major market for the product.

Considerations for Challenging Environments

These scanners are typically used in hospital radiology departments and vascular laboratories by ultrasound imaging professionals. There are no significant concerns for use of this product in challenging environments. However, users should be aware that there are limits for use of the device in extremely humid, cold, or hot environments. Also, as with any ultrasound scanner, parts and servicing in remote areas may involve delays and increased shipment costs.

SIEMENS HEALTHINEERS ACUSON S3000 HELX EVOLUTION WITH TOUCH CONTROL

Rating



Findings

The Acuson S3000 HELX Evolution with Touch Control is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner as well as improve workflow.

Our rating is based on the following findings:

Performance—Excellent. The Acuson S3000 met all of our required B-mode and Doppler performance criteria. The scanner offers advantages in its optional advanced technologies of strain and shear-wave elastography, fusion imaging and needle navigation, contrast-enhanced ultrasound imaging, and 3D and 4D imaging.

Safety—Good. The scanner met all of our safety criteria, including fulfilling all recommendations in the Industry Standards for the Prevention of Work-Related Musculoskeletal Disorders in Sonography, published by the Society of Diagnostic Medical Sonography, as well as ECRI's established security criteria.

Workflow—Excellent. The scanner met our workflow criteria and demonstrated several advantages that enhance its use for both conventional and advanced applications.

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The scanner can communicate via Ethernet with a hospital information system (HIS) and picture archiving and communication system (PACS). Wi-Fi is available as an option.

Maintenance—Good. The scanner requires inspection and preventive maintenance once every 24 months.

User Experience—Good. Surveyed users confirmed our findings. **Cost of Ownership—Good.** Based on ECRI's SELECTplus database of scanners in this category, the typical cost of the Acuson S3000 HELX Evolution with Touch Control is higher than average.

TOSHIBA AMERICA MEDICAL SYSTEMS APLIO 500

Rating



Findings

The Aplio 500 is a premium general-purpose ultrasound scanner that offers B-mode, M-mode, and Doppler capabilities and supports a wide range of transducers for general imaging applications. A number of options are available that have the potential to enhance the clinical performance of the scanner as well as improve workflow. Our rating is based on the following findings:

Performance—Excellent. The Aplio 500 met all of our required B-mode and Doppler performance criteria. The scanner received advantages based on its optional advanced technologies of strain and shear-wave elastography, fusion imaging and needle navigation, contrast-enhanced ultrasound imaging, and 3D and 4D imaging.

Safety—Good. The Aplio 500 met all of our safety criteria, including fulfilling all recommendations in the Industry Standards for the Prevention of Work-Related Musculoskeletal Disorders in Sonography and ECRI's established security criteria.

Workflow—Good. The Aplio 500 demonstrated several workflow advantages that enhance the use of the scanner for both conventional and advanced applications; however, we found the complex user interface to be a major disadvantage.

Patient Experience—Not evaluated. The patient experience is not a purchasing factor for these devices.

Interoperability—Good. The Aplio 500 can communicate via Ethernet with a hospital information system (HIS) and picture archiving and communication system (PACS). Wi-Fi is available as an option.

Maintenance—Good. The Aplio 500 requires inspection and preventive maintenance once per year.

User Experience—Good. Surveyed users confirmed the findings of our tests.

Cost of Ownership—Good. Based on ECRI's SELECTplus database of scanners in this category, the typical cost of the Aplio 500 is lower than average.

RATING



The Resona 7 is a very good choice for general-purpose applications and, when configured with the required options, may be used for advanced applications that include strain and shear-wave elastography, fusion imaging, contrast-enhanced imaging, needle navigation, and 3D and 4D (i.e., real-time 3D) imaging. The scanner met our required criteria, including those for safety and cybersecurity, and incorporates desirable workflow enhancements such as simultaneous display of conventional B-mode and contrast-enhanced ultrasound (CEUS) images and the ability to fuse ultrasound images with imported data. The scanner offers wired and optional Wi-Fi connectivity.

DEVICE DETAILS

- Name: Resona 7
- Date evaluated: June 2019
- Manufacturer: Mindray Medical International Ltd. [455416]
- Healthcare Product Comparison System (HPCS) comparison chart: Scanning Systems, Ultrasonic, General-Purpose (HPCS is available to members of Health Devices Gold and SELECTplus.)
- Software version evaluated: 2.51

DEVICE DESCRIPTION

- 1. The Mindray Resona 7 is a general-purpose (GP) ultrasound scanner that can be configured for specific applications.
 - a) These scanners are typically used to perform ultrasound examinations of the abdomen, pelvis, and superficial structures such as the thyroid gland, testes, and breast.
 - b) They are also used for ultrasound guidance during interventional procedures such as needle biopsies and fluid drainages.
- 2. The major device components and software features include:
 - a) A console
 - (1) The console contains a computer that controls the ultrasound signal generator, receiver, and processor. The console also contains a 1 TB hard drive and a 120 GB solid-state drive for onboard data storage, and has data input and output ports.

(2) The console dimensions (W \times D \times H) are 54.4 \times 94.5 \times [136 to 167] cm (21.4 × 37.2 × [53.5 to 65.7] in). It weighs 135 kg (297 lb) and has 12.5 cm (5 in) double casters that all have swivel locks and brakes that the user can engage and disengage, both independently and with a central foot control located on the front of the scanner. On the front of the console above the transducer ports there is a USB port, a microphone input, and a patient physiologic data input port. A DVD+RW drive is on the left side of the console, and a data input/output panel is on the rear that includes three USB ports, one HDMI output, one network port, one VGA output, one S-Video output, and L/R audio output ports.

b) A control panel user interface

- (1) The control panel is used to enter patient data, select transducers, select presets and imaging modes, adjust image quality, obtain measurements, annotate images, and perform calculations. The scanner supports the vendor's ZONE Sonography Technology (ZST) and various modes and features, including: M-mode, anatomical M-mode, pulsed-wave (PW) Doppler, continuous-wave (CW) Doppler, Color Doppler Imaging (CDI), power Doppler imaging (PDI), tissue Doppler imaging (TDI) and PW-tissue Doppler, V Flow, tissue harmonic imaging (THI), Dynamic Pixel Focusing (DPF), Sound Speed Compensation (SSC), Total Recall Imaging (TRI), UWN+ (Ultra-Wideband Non-linear Plus) contrast imaging, contrast imaging quantification and analysis (QA), Sound Touch Elastography (STE), iBeam Spatial Compound Imaging, iClear Speckle Suppression Imaging, iTouch Auto Image Optimization, iNeedle Needle Visualization Enhancement, extended field of view, HD Scope, and iWorks exam protocols.
- (2) The control panel is a "floating" (i.e., position-adjustable) design, with electronic up/down and side-to-side position controls; the scanner must be powered on to use these controls. There is a 30.7 cm (12.1 in) high-resolution color LCD touchscreen that tilts to allow optimal viewing, OWERTY hard keyboard, trackball, hard controls, and softkeys that change function based on the mode of operation. There is one audio speaker on each side of the control panel. A handle is used to position the

- control panel during exams and for transport. Integrated into the control panel are transducer holders, a gel-bottle holder, and transducer cable hooks.
- c) A 54.6 cm (21.5 in) high-resolution, flat-panel LED video display used to view ultrasound images and other data. The display has a wide viewing angle and is attached to the scanner on an articulated arm to allow users to position it separately from the console panel for optimal use during exams. The display can be folded down and locked during transport.
- d) Four transducer ports, used to connect the scanner's pinless transducer connectors to the scanner. The ports are located on the lower front of the console. There is also an inactive port that can hold a probe connector. A blue light in the probe connector indicates the active probe.
- 3. Typical locations where the Resona 7 is used include:
 - a) Hospital radiology department
 - b) Freestanding imaging facility
 - c) Private physician office
- 4. Optional hardware and software. Because the Resona 7 is a GP scanner that can be configured for general, cardiac, vascular, obstetrics and gynecology (OB/GYN), and shared service applications, there are a large number of hardware and software options available. Listed below are the typical options used on a scanner for GP applications:
 - a) Hardware
 - (1) Application-specific transducers—see the table Transducers Supported by the Resona 7 on the next page.
 - (2) Integrated DVR to digitally record images and video clips to removable media

- (3) Gel-bottle warmer to maintain scanning gel at a user-selectable temperature of 34°C, 37°C, or 40°C (93.2°F, 98.6°F, or 104°F) for patient comfort
- (4) ECG module to input patient physiologic data such as ECG into the scanner for correlation with imaging data
- (5) Footswitch with programmable functionality to allow foot activation of commonly used controls such as freeze and print during examinations. Two-switch and threeswitch models are available.
- (6) One-dimensional and two-dimensional bar-code readers, which allow patient bar-code data to be imported into the scanner for efficient data entry. The use of a bar-code reader also reduces data-entry error compared with manual entry.
- (7) Integrated wireless adapter for a Wi-Fi connection
- b) Software
 - (1) Natural Touch Elastography (strain elastography)
 - (2) STE Sound Touch Elastography (shearwave elastography)
 - (3) STQ Sound Touch Elastography (quantitative analysis for STE)
 - (4) Contrast imaging
 - (5) Contrast imaging quantitative analysis (QA) package
 - (6) iFusion
 - (7) Needle Navigation Guiding
 - (8) iNeedle enhanced needle-visualization mode
 - (9) iScape View real-time panoramic imaging
 - (10) Application-specific quantification and analysis software packages including obstetric and gynecologic

TRANSDUCERS SUPPORTED BY THE RESONA 7

The following data was provided by the vendor.

| Model ID and Type | Frequency Range (MHz) | Applications | Biopsy Attachment | Elastography Type | Contrast-Enhanced Imaging | Fusion Imaging |
|--------------------------------------|--------------------------|--|----------------------|-----------------------|------------------------------|-------------------|
| SC6-1U* Convex linear array (CLA) | 1.0-6.0 | Abdomen, obstetric and gynecologic (OB/GYN), vascular | Yes | Shear wave | Yes | Yes |
| SC8-2U* CLA | 1.8-8.2 | Abdomen, OB/GYN, pediatric | _ | _ | Yes | Yes |
| C4-1U CLA | 1.0-4.5 | Abdomen, OB/GYN, vascular | Yes | _ | Yes | Yes |
| C6-2GU CLA | 1.2-6.0 | Abdomen, OB/GYN, pediatric | Yes | Shear wave | Yes | _ |
| C11-3U CLA | 2.6-12.8 | Neonatal head, pediatric | Yes | _ | _ | _ |
| L14-5WU Flat linear array (FLA) | 4.0-14.0 | Musculoskeletal (MSK), nerve, pediatric, small parts, vascular | _ | Strain, shear wave | Yes | Yes |
| L14-6WU FLA | 4.0-14.0 | MSK, nerve, pediatric, small parts, vascular | _ | Strain | _ | _ |
| L20-5U FLA | 7.6-20.0 | MSK, nerve, small parts, vascular | _ | Strain | _ | _ |
| L9-3U FLA | 1.8-9.8 | Abdomen, MSK, nerve, obstetric, pediatric, small parts, vascular | Yes | Strain, shear wave | Yes | _ |
| L11-3U FLA | 3.0-10.0 | Abdomen, obstetric, pediatric, small parts, MSK, nerve, vascular | Yes | Strain, shear wave | Yes | Yes |
| L16-4HU FLA | 3.5-16.0 | Intraoperative, MSK, nerve, pediatric, small parts, vascular | _ | Strain | _ | _ |
| P10-4U Sector | 3.0-11.4 | Pediatric abdomen, pediatric cardiac, neonatal | _ | _ | _ | _ |
| P7-3U Sector | 2.3-8.0 | Abdomen, cardiac, pediatric | _ | _ | _ | _ |
| V11-3HU Endocavity CLA | 3.0-11.0 | OB/GYN, urology | Yes | _ | Yes | _ |
| D8-2U Volume CLA | 1.8-8.2 | Adult abdomen, OB/GYN | Yes | _ | Yes | _ |
| DE10-3U Volume endocavity CLA | 2.0-9.0 | OB/GYN, urology | Yes | _ | Yes | _ |

^{*} Single-crystal probe technology.

SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. For more details, see the ECRI's Testing section of our Evaluation Background on premium GP scanners.

Performance—Excellent

The Resona 7 met ECRI's required performance criteria and offers several major and minor performance advantages, as listed below.

Major Advantages

- 1. Elastography:
 - a) The Resona 7 has Natural Touch Elastography (strain elastography) and Sound Touch Elastography (STE; shear-wave elastography) capabilities on a variety of probes; see the transducer table above for more details. STE correctly and reproducibly demonstrated the relative stiffness of the 10 kPa, 40 kPa, and 60 kPa targets in the phantom. Strain imaging correctly and reproducibly demonstrated the relative stiffness of the 10 kPa and 60 kPa targets, but did not demonstrate the 40 kPa target. The scanner has software to quantify elastography data.
 - b) Elastography provides tissue stiffness data that enhances the diagnostic capabilities of the modality. Read more about elastography in our article Advances in Diagnostic Ultrasound: Elastography.
- 2. Fusion imaging and needle navigation:
 - a) We reviewed product labeling and other information regarding the scanner's iFusion and Needle Navigation Guiding capabilities.
 - b) Fusion imaging allows users to simultaneously view previously acquired ultrasound, CT, MRI, or PET/CT data during a real-time ultrasound exam. Fusion imaging is used for a variety of clinical applications, including to guide sonographic localization of a target lesion or area for diagnosis and for ultrasound-guided interventional procedures. Needle Navigation Guiding is used alone or in combination with iFusion to guide interventional procedures. Read more in our article Advances in Diagnostic Ultrasound: Fusion Ultrasound Imaging.

3. Contrast-enhanced ultrasound imaging:

- a) The Resona 7 supports the vendor's UWN+ (Ultra-Wideband Non-linear Plus) CEUS software that can be used on several 2D and volume probes; see the transducer table for more details. When used with the ultrasound contrast agent Lumason (Bracco Diagnostics, Princeton, NJ), contrast enhancement was demonstrated qualitatively within the Doppler flow phantom, and the degree of signal enhancement met our quantitative criteria. The scanner offers optional contrast quantification software to enhance diagnoses and workflow.
- b) CEUS improves the ability to assess blood flow and tissue perfusion. It also improves the ability to characterize focal liver tumors and can be used for other applications. For additional information regarding ultrasound contrast agents, see our article Advances in Diagnostic Ultrasound: Contrast-Enhanced Ultrasound Imaging.

Minor Advantages

- 1. Three-dimensional and four-dimensional imaging:
 - a) The scanner's 3D and 4D capabilities, which we qualitatively assessed using dedicated volume phantoms, were easy to use and offered rapid data acquisition rates.
 - b) Three- and four-dimensional imaging can enhance the ability to assess both normal and abnormal structures and can enhance the diagnostic capabilities of the scanner.
- 2. Needle-enhancement mode:
 - a) iNeedle is available on flat linear-array transducers. Our tests on the L14-5WU probe confirmed the effectiveness of this mode to increase the conspicuity of needles in a soft-tissue phantom. User-adjustable controls include needle angle, magnification, gain, and single or dual image display.
 - b) Needle enhancement is used to improve a clinician's ability to identify and localize needles and other devices (e.g., radio-frequency ablation probes) during ultrasound-guided interventions. This feature has the potential to reduce the user-dependence of performing ultrasound-guided procedures, and to improve accuracy of needle placement.

Safety—Good

The Resona 7 met our required safety criteria.

Workflow-Good

The Resona 7 met our required workflow criteria, and demonstrated advantages for features that enhance the use of the scanner for both conventional and advanced applications, as listed below.

Major Advantages

- 1. Dual display of conventional B-mode and CEUS modes and individually adjustable controls:
 - a) A dual display can be used to simultaneously view conventional B-mode and contrast-enhanced images in real time.
 There are individual user-adjustable controls for CEUS and conventional B-mode.
 - b) Contrast enhancement can obscure anatomical details that can be visualized on the conventional B-mode image. Having simultaneous display of the conventional B-mode and CEUS data can reduce problems associated with this phenomenon. Individual user-adjustable controls allow users to optimize the image quality of each mode.
- 2. Data import for fusion imaging:
 - a) Data can be imported in Digital Imaging and Communications in Medicine (DICOM) format, from a DVD or from a picture archiving and communication system (PACS) via an Ethernet connection.
 - b) Having multiple ways to import data provides flexibility and enhances workflow.

Minor Advantages

- 1. Auto-optimization control for PW Doppler (optional):
 - a) The optional iTouch one-button auto-optimization control improves suboptimal PW Doppler spectral data by adjusting the pulse repetition frequency—which is a key parameter that impacts blood flow detection—and the baseline position to optimize the display of data. Additionally, the Smart Track feature automatically adjusts the PW Doppler sample volume size and position.
 - b) Effective PW Doppler auto-optimization features reduce the user-dependence of obtaining diagnostically acceptable Dop-

pler data and facilitate examination processes by reducing the number of parameters that must be adjusted manually. This feature also has the potential to reduce work-related musculoskeletal disorders (WRMSDs) because fewer user keystrokes are required to optimize data.

- 2. Auto-optimization for CDI and PDI:
 - a) The optional Smart Track control improves suboptimal CDI or PDI data by adjusting the color region of interest (ROI) position and angle. This feature is available on flat linear-array transducers.
 - b) Effective CDI and PDI auto-optimization features reduce the user-dependence of obtaining diagnostically acceptable data and facilitate examination processes by reducing the number of parameters that must be adjusted manually. This feature also has the potential to reduce WRMSDs because it requires fewer user keystrokes to optimize images.

Notable Finding

The Resona 7's iTouch feature is described in the user manual as a control to optimize the B-mode image based on tissue characteristics. However, it does not actually change the imaging parameters based on tissue characteristics; instead, the iTouch control simply sets the B-mode gain and TGC levels at a user-selected default value.

Patient Experience—Not Evaluated

Patient experience is not a purchasing factor for these devices.

Interoperability—Good

The Resona 7 met our interoperability criteria, including the ability to communicate via Ethernet with a hospital information system (HIS) and PACS. Wi-Fi is available as an option.

Cybersecurity—Good

The Resona 7 met our required cybersecurity criteria.

Maintenance—Good

The vendor does not specify the frequency of inspection and preventive maintenance procedures, allowing facilities to set their own frequency.

User Experience—Good

Surveyed users confirmed the findings of our Evaluation and did not report having many maintenance problems. Specific features of the scanner that users commented about include:

- Doppler sensitivity—Users frequently indicated that CDI and PW Doppler provided high sensitivity to blood flow.
- 2. User interface is easy to learn and use.
- 3. Automated B-mode optimization—The iTouch feature does not perform as well as the auto-optimization controls on other scanners they have used.

- 4. Contrast-enhanced ultrasound imaging—The Resona 7 performed very well for CEUS studies.
- 5. Vendor support is very good for both clinical applications and technical issues.

Cost of Ownership—Good; \$137,000 (Estimated) over Seven Years

ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MINDRAY RESONA 7

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's SELECTplus and PriceGuide databases, respectively.

Note that we updated our Cost of Ownership calculation methods in 2019, so some figures in this table may not compare directly with cost figures for products evaluated in prior years.

| Factor | Typical Cost | Assumptions |
|---|-----------------|--|
| Purchase Costs | | |
| Capital cost | \$73,000 | Based on average quoted price in ECRI's SELECTplus database. This cost does not include software that may be required for advanced imaging capabilities such as elastography, CEUS, or 3D/4D imaging, or for automated data acquisition and analysis features. |
| Typical accessories | \$34,000 | Four 2D transducers @ \$8,500 each. |
| Warranty | \$0 | Five-year warranty that covers accidental probe damage is standard. |
| Clinical staff training | \$0 | Included. |
| Biomedical staff training | \$0 | None required. |
| Infrastructure modifications | \$0 | Assumes facility has an existing exam room and network. |
| Total purchase cost | \$107,000 | _ |
| Annual Operational Costs | | |
| Consumables | \$580/yr | Assumes 60 patients per week (3,100 per year). Acoustic gel from third party (four 5 L containers per case, enough for 340 imaging studies); nine cases per year @ \$64 per case. |
| Expected part replacement—averaged throughout life of device | \$0 | None. |
| Service | \$13,000/yr | Annual warranty that covers accidental probe damage after the initial five-year warranty. |
| Annual license fee | \$0 | None required. |
| Average annual operational cost | \$4,300 | \$580/yr for years 1-5 (warranty period), \$13,580/yr for years 6-7. |
| Estimated Total Cost of Ownership (for an estimated life of seven years) | \$137,000 | Total purchase cost + (annual operational cost × estimated life) |

DISCUSSION OF KEY MANUFACTURER CLAIMS

| Mindray Claim | Category | ECRI Perspective |
|---|-------------|--|
| Acquisition and software processing of large ZONES of acoustic data creates individual ultrasound image frames 10 times faster than conventional line-by-line beam forming methods. | Performance | ECRI does not agree. The frame rates of the probes tested were not significantly faster than those of other devices we evaluated. |
| Total Recall Imaging (TRI) allows the user to retrospectively modify numerous imaging parameters and optimize clinical information. It eliminates the need for repeat scanning and improves patient throughput. | Workflow | ECRI agrees, but the benefit is not likely significant. Other devices we evaluated also allow retrospective modification of imaging parameters. |

RECALLS AND HAZARDS

A review of *Health Devices Alerts* records from May 2016 through May 2019 did not identify any alerts related to the Resona 7.

SERVICE AND MAINTENANCE

The following information is provided largely verbatim from the manufacturer.

Warranty

Standard warranty terms: 5 years parts and labor

Inspection and Preventive Maintenance (IPM)

- 1. IPM frequency: The Resona 7 does not require regular preventative maintenance.
- 2. Downtime for IPM: N/A

In-House/Third-Party Service

- 1. Manufacturer supports user repair: Yes
- 2. Training is optional; typical cost is \$3,000/person
- 3. Availability of service manual: Yes
- 4. Dedicated test equipment and/or software required: No
- 5. Availability of manufacturer assistance: Yes, technical support toll free

OEM Maintenance

- 1. Standard OEM service options: N/A
- 2. Remote monitoring: No
- 3. Software upgrade and update policy:
 - a) 5 years of software upgrades/updates included with the purchase of the system. Adding new functionality may not be free. Software update is free.
 - b) An update would be correcting a known bug or improving image quality on existing transducers or technology. Upgrades are included as long as they are software related. Any hardware that has to be changed or added would be chargeable to the customer.

OTHER PURCHASE OPTIONS

None specified.

About ECRI ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit ecri.org and follow @ECRI_Org.

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