

# Ultrasound in the 21<sup>st</sup> Century: Why Carestream Health's Touch Ultrasounds Make Sense

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## Section 1: The value of diagnostic ultrasound

Low in cost and high in diagnostic value with applications that cover nearly every tissue in the human body, medical ultrasound has become one of the most popular imaging exams worldwide – and not just among healthcare professionals. Its lack of ionizing radiation amid gathering public concern about the cancer-causing potential of X-rays, particularly those in CT, makes ultrasound appealing to patients.

With images constructed from the echoes of sound bouncing off tissues and structures, diagnostic ultrasound is as simple as it is elegant. A transducer interfaced with the patient's skin through a thin layer of gel both transmits and receives inaudible sound waves. The amplitude of the echo, its frequency and the elapsed time from transmission to return are translated into images that show body structures and tissue composition.

These echoes indicate the size and shape of structures and whether they are solid or filled with fluid, distinguishing potentially cancerous lesions from cysts. Ultrasound is used today to study the following:

- Heart chambers and their valves
- Internal organs such as the liver, gallbladder, spleen, pancreas, kidneys and bladder
- Thyroid and parathyroid glands
- Scrotum for men
- Breasts for women
- Brain and hips in infants

Sonography is the go-to modality for pregnant patients, particularly when evaluating the uterus, ovaries and fetus.

Interventionally, ultrasound guides needle biopsies, as well as the placement of central lines and needles for regional anesthesia.

**Beyond grayscale images.** To assess blood flow in arteries and veins, Doppler ultrasound uses the frequency shift that occurs when sound waves bounce off a moving object. Those images are used today to uncover blockages and clots, the narrowing of blood vessels and congenital vascular malformations.

In color Doppler, echo measurements are displayed as colors that indicate the speed and direction of blood flow. They are used today to identify narrowed blood vessels, for example, and the tiny “jets” of blood associated with vascular anomalies. Power Doppler is even more sensitive than color Doppler, visualizing blood flow through tiny vessels such as those that feed tumors in the thyroid and scrotum, as well as lesions just below the skin. Spectral Doppler calculates and then graphs the velocity of blood flow according to the distance blood travels over time.

While ultrasound is typically first thought of as the primary screening tool to monitor pregnancy, the device has many uses beyond maternal health. The ultrasound procedures listed as “common” by the FDA (<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm115357.htm>) include:

- Abdominal ultrasound (to visualize abdominal tissues and organs)
- Breast ultrasound (to visualize breast tissue)
- Doppler ultrasound (to visualize blood flow through a blood vessel, organs or other structures)
- Echocardiogram (to view the heart)
- Fetal ultrasound (to view the fetus in pregnancy)
- Ultrasound-guided biopsies (to collect a sample of tissue)
- Ophthalmic ultrasound (to visualize ocular structures)
- Ultrasound-guided needle placement (in blood vessels or other tissues of interest)

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**Increasing popularity.** The popularity of this modality is likely to grow in coming years as practitioners look for ways to reduce costs while improving quality of care. As healthcare becomes more cost-conscious, so too are practitioners becoming more aware of the need to restrict radiation exposure amid growing concerns about the possible cancer-causing effects of X-rays and CT scans.

This new reality, marked by the transition from volume- to value-based reimbursement, promises to help elevate the profile of ultrasound. The potential exists for using ultrasound in place of more expensive, radiation-intense modalities, particularly CT with its history of high radiation exposure.

One clinical study examined the cost and radiation savings achieved by using ultrasound first to evaluate patients suspected of appendicitis. Cost savings in imaging minus the cost of extra surgeries and extra surgical deaths was estimated at \$24.9 million per year for the U.S. population. Patients would avoid 12.4 mSv of radiation in each case ultrasound was used instead of CT. (Parker L, Nazarian LN, Gingold EL, Palit CD, Hoey CL, Frangos AJ. "Cost and radiation savings of partial substitution of ultrasound for CT in appendicitis evaluation: a national projection," *AJR Am J Roentgenol.* 2014 Jan;202(1):124-35. doi: 10.2214/AJR.12.9642)

Ultrasound can help make minimally invasive procedures more effective and less costly. A study comparing surgical biopsies in breast cancer patients and needle biopsies performed with and without ultrasound image guidance found that ultrasound reduced the overall cost of the procedure and yielded more cancer cells. (Masood S, Rosa M, Kraemer DF, Smotherman C, Mohammadi A. "Comparative cost-effectiveness of fine needle aspiration biopsy versus image-guided biopsy, and open surgical biopsy in the evaluation of breast cancer in the era of affordable care act: A changing landscape," *Diagn Cytopathol.* 2015 Feb 26. doi: 10.1002/dc.23270)

A study of Medicare data gathered in 2005 found that ultrasound could have been used in place of MRI in 30.6% of all musculoskeletal (MSK) diagnoses and 45.4% of primary MSK diagnoses. With MRI costs for musculoskeletal imaging of Medicare patients in 2020 estimated to be \$2.0 billion, ultrasound could save hundreds of millions of dollars in that year alone if appropriately substituted for MRI. (Parker L, Nazarian LN, Carrino JA, Morrison WB, Grimaldi G, Frangos AJ, Levin DC, Rao VM. "Musculoskeletal imaging: Medicare use, costs, and potential for cost substitution," *J Am Coll Radiol.* 2008 Mar;5(3):182-8. doi: 10.1016/j.jacr.2007.07.016)

Used in place of CT, color Doppler cut costs by more than 70% when following up patients who had surgery to repair endovascular aneurysms. Yet it was just as effective at spotting endovascular leaks. The authors concluded that using carotid duplex ultrasound as the first choice following endovascular aneurysm repair would have reduced the number of postoperative CTs required in 2010 by 84%, driving per-patient costs down from €117,500 (\$125,543 USD) to €34,915 (\$37,305 USD), saving €82,585 (\$88,238 USD) per patient. (Gray C, Goodman P, Herron CC, Lawler LP, O'Malley MK, O'Donohoe MK, McDonnell CO. "Use of colour duplex ultrasound as a first line surveillance tool following EVAR is associated with a reduction in cost without compromising accuracy," *Eur J Vasc Endovasc Surg.* 2012 Aug;44(2):145-50. doi: 10.1016/j.ejvs.2012.05.008. Epub 2012 Jun 19)

**Overcoming limitations.** The clinical and cost-saving potential of ultrasound might be better realized if the systems were more efficient and easier to use. Carestream Health has done so by combining technological advances and an innovative design in its CARESTREAM Touch Ultrasound System.



Foremost among the strengths of this system is its flexibility. With a console designed for personalization, the Touch system adapts to the user. Sonographers choose to show only the soft keys for the functions they need, assigning them to locations on the console that suit the way sonographers work and programming them to behave the way sonographers want.

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Another strength of the Carestream system is its accessibility. Ultrasound scanners may require sonographers to manually log in and load protocols for applications. Touch users log in with the swipe of a badge, which unlocks the system and automatically configures the console to the sonographer's preferences. Further promoting accessibility is the system's unique architecture, which boots up in 18 seconds versus up to two minutes on conventional systems. Access is further improved by the activation button that resides on the head of each Touch transducer.



Third, Carestream's system takes a technological leap forward, leveraging an etched glass plate bonded to a 19-inch touch-sensitive display that replaces physical keys, knobs, pods and trackballs. This all-glass interface also can be wiped clean in an instant.

**Carestream's Touch Family.** The members of Carestream's new family of scanners are being designed to share core technologies – scan engine, transducers, interface and ergonomic design. All family members will be built around a synthetic aperture architecture that maximizes image parameters to generate excellent resolution at the fastest possible frame rate.

The Touch units are ultra-premium and premium systems intended primarily for use in radiology. This family of scanners is designed to perform mainstream sonography, including general imaging, musculoskeletal, vascular and general ob/gyn exams. Its core technologies will serve as the building blocks for future specialty capabilities, such as Shearwave Elastography, which will be added when its ability to change patient management has been established.

### Section 2: The evolution of ultrasound

Touch is the latest development in a line of ultrasound scanners stretching back to the 1950s. From a cattle watering tank to water baths, water-filled bags to gel-slicked transducers, the clinical and operational performance of ultrasound scanners has improved.

The American public's first look at medical ultrasound in action showed a subject seated in a cattle watering tank. An ultrasonic transducer was mounted on a rotating ring gear taken from a B-29 gun turret. Appearing in the Medicine section of Life Magazine in 1954 with the headline "Sound-Wave Portrait In The Flesh," this device generated intra-abdominal "somagrams."

By the late 1950s, water baths gave way to water-filled bags with built-in transducers. These eventually were replaced by direct contact transducers and gels, which paved the way to the widespread use of medical ultrasound in the 1960s, primarily in ob/gyn.

The first such scans were in A (amplitude) –mode. Ultrasonic waves passed through a single point. Echoes indicated depth. A-mode scanners helped to assess early pregnancy, measure the fetal head and localize the placenta.

They were followed by B-mode scans, which used a linear array transducer to scan a two-dimensional plane. By the middle to the end of the 1960s, B-mode scanners were visualizing the gestational sac, recording extra-uterine pregnancy, even identifying fetal malformations of the heart as well as ovarian tumors.

Rounding out the major types of scans in this era was M- (motion) mode. In this, a succession of ultrasonic pulses recorded dynamic images, for example, of the heart.

By the early 1970s, mixed mode scans were visualizing the fetus (B-mode), while directed ultrasound beams, operating in A- and M-mode, measured the fetal head and heart.

In the mid- to late 1970s, mechanical oscillating transducers captured life-like images of the fetus. Pulsed Doppler scanning accurately measured blood velocity.

As the 1970s drew to a close, diagnostic ultrasound was commonplace. It lacked, however, the computing power being built into CT, PET, SPECT, and MRI scanners. The consensus among manufacturers was that "good enough was good enough" when it came to ultrasound images, and that customers would not pay for machines that delivered much more.

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A start-up, called Acuson, proved them wrong. The company's first product, released in 1983, was the Acuson 128, named for the number of channels in its "computed sonography" architecture. Competition heated up in 1987 with introduction by Advanced Technology Laboratories of the all-digital Ultramark. Diasonics, a major player in ultrasound through much of the preceding decades, rounded out what would be the Big Three of the ultrasound industry with its jump to digital at the close of the 1980s.

Heated competition among these three led to harmonic imaging, the next big leap forward. This new capability took hold in the mid-1990s using low frequency transmissions to image tissues deep in the body. Harmonic imaging was extraordinary for its improved spatial and contrast resolution, reduced background noise, increased dynamic range, and near- and far-field visualization.

As the 20th century gave way to the 21st, mergers and acquisitions transformed the industry. These turned Siemens, GE and Philips into leaders in the ultrasound industry.

### Section 3: Breaking with the past to meet challenges in the future

Over the last decade and a half, the clinical capability of ultrasound has increased remarkably. Yet, the operational aspects of ultrasound scanners have failed to keep pace with technological advances. Their computing architecture remains based on standard central processing units. Consoles are old school, relying on knobs, pods and trackballs like those on consoles for 30 years.

With no installed base to obsolete, Carestream was free to seek higher value from leading edge technologies, building a computing architecture based on graphics processors rather than central processing units (CPU), a touch screen that gets rid of knobs, pods, buttons and trackball, and mechanical innovations that let the sonographer choose the most comfortable and best positions for performing exams.

Graphic processing units (GPU), developed by the gaming industry, bring the functions otherwise performed by various CPU components onto a single GPU board. The development of this fundamentally different scan engine laid the foundation for Carestream's advanced synthetic aperture architecture, which optimizes grayscale and color imaging from Doppler to harmonic imaging and beyond.

The faster processing made possible by GPU technology increases the number of transmit-and-receive foci, potentially increasing image quality while keeping the frame rate high. GPUs have also provided the means to physically connect transducers to the scan engine, reducing noise and further increasing image quality.

Touch transducers are connected on the side of the scanner rather than in the front, allowing operators easy access to the transducers from a seated position. Sonographers using conventional scanners have to get up from their stools and bend over to access them.



A software-driven console allows personalization of the Touch interface. Myriad hard controls are winnowed down to just the soft keys needed for specific procedures and are assigned to locations best suited to the operator. The use of software also paves the way to quick and easy upgrades.

With soft keys built into a flat glass plate, the console can be easily wiped to reduce the potential of cross-contamination to other equipment and patients. This contrasts starkly with conventional consoles comprised of numerous separate keys, knobs, pods and buttons with nooks and crannies that are difficult, if not impossible, to completely clean.

**Migrating innovations to ultrasound.** In its development of Touch, Carestream migrated key innovations from its line of DRX-Revolution Mobile X-ray systems. Among them is the badge-based "Swipe-and-Go" technology, which not only provides quick, secure log-in but automatically configures the Touch console the way the sonographer wants. Much like some cars automatically set the driver's seat, wheel and mirror to suit individual drivers, Touch configures itself to match the preferences of the sonographer in response to the swipe of an identification card across its built-in reader.

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Mechanical engineers who contributed to Carestream's DRX products helped design the Touch cart, developing innovations in the way components rotate, tilt and otherwise shift to suit the sonographer. This flexible positioning of components, determined by an ergonomic study, affords the optimal viewing angle for different exams while promoting comfortable access to the patient.

Making sonographers more comfortable may reduce the incidence or severity of repetitive strain injury. RSI may affect more than 60% of sonographers (Janga D, Akinfenwa O. "Work-related repetitive strain injuries amongst practitioners of obstetric and gynaecological ultrasound worldwide," Arch Gynecol Obstet. 2012 Aug;286(2):353-6. doi: 10.1007/s00404-012-2306-6. Epub 2012 Mar 31). The musculoskeletal discomfort associated with RSI has been tied to the often awkward positions that sonographers, using conventional systems, must assume. (Roll SC, Selhorst L and Evans KD. "Contribution of Positioning to Work-Related Musculoskeletal Discomfort in Diagnostic Medical Sonographers," Work. 2014 Jan 1; 47(2): 253-260.)

**Streamlining the exam process.** The transducer identifies itself and Touch calls up the appropriate imaging presets. Frame rate and image quality are automatically optimized with minimal tweaking by the sonographer. Not only does this reduce setup time, it ensures reproducible results from one patient to the next.

Glass etchings – palpable bumps similar to Braille – on the console's glass plate identify the soft keys, which differ in texture, size and shape. A track pad, like a trackball, serves as home base. High-use soft keys surround it. Like playing the piano while reading sheet music, sonographers' eyes are focused on the clinical imaging looking for certain anatomy, as they aim the transducer and work the soft keys. This is why the etchings are so important. They allow sonographers to maintain their focus on the clinical images as they feel their way around the user interface.



The etched glass cover is physically bonded to the touch-sensitive panel underneath. As a result, the console is impermeable to dust, dirt and liquids, including gels and body fluids.

When scanning, the sonographer can easily tilt, flatten, and slide the console to either side, increasing comfort and possibly reducing the risk of repetitive stress injuries (RSI). The design of the console makes it easy for the sonographer to maintain the best positioning; the console can accommodate as the sonographer stands, sits, or leans into the patient.

The display monitor is right-sized to present a high-resolution image surrounded by enough border for image labeling and the placement of thumbnails. An open handle built into the bottom of the monitor provides a grab point so the monitor, on a smoothly articulating arm, can be pulled and pushed easily into place.



**Voice of the customer.** When developing Touch, Carestream consulted individual users, assembled focus groups of sonographers, and sought advice from ergonomic experts, including collaborators from the Rochester Institute of Technology. Designers asked how to improve efficiency, optimize its value, and simplify interactions with complex devices. The goal was to produce a sleek, compact, easy-to-use and highly maneuverable ultrasound system that produced high quality images.

**Operational advantages.** Swipe-and-Go exemplifies the operational advantages of Touch, as do the intelligent transducers that communicate with the scan engine to set up protocols upon activation. Both save time by automating the pre-scan setup.

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Adding to operational efficiency is the 18-second system boot, which eliminates the need for a battery pack that might otherwise be needed to keep the system operating while being transported from one place to another. This saves up to 20 pounds of excess weight.

**Financial advantages.** At facilities with several Touch scanners, sonographers are cross-trained by default, as the interface will be shared across the family.

Transducers can be shared among machines, making the most of budgets through the purchase of relatively few specialty probes. A customer buying five Touch scanners might buy three core transducers for each, but may purchase only one or two specialty probes, such as an endovaginal probe and endorectal probe, knowing that these can be shared. Similarly, core transducers serve as backups for ones on the various machines.

Service is performed more efficiently because field engineers have fewer parts to replace. Gone are the numerous knobs, keys, pods and computing boards that Carestream field engineers would otherwise have to carry.

These advantages are amplified by Carestream's worldwide service infrastructure, which was established to support the company's other imaging products. In Carestream's single point-of-contact service system, the customer's first contact at Carestream owns the problem and finds the right people to solve it. This may be done over the phone, via a Smart Link remote connection using the Internet, or through an in-person service call.

**In a nutshell.** Touch delivers high image quality, faster and more cost effectively, than conventional systems in ways that are more ergonomic and sonographer friendly. The design of the Touch family offers improved efficiency and ease of use by allowing sonographers to personalize the scanners to their preferences. The soft keys, which replace the knobs, pods, buttons and trackball, can be assigned and their functions defined to match how each sonographer prefers to use the machine. Leveraging software to replace hard keys on the console improves efficiency and ease-of-use to meet increasing challenges to rein in cost. Doing so makes the most of sonographers' skills, increasing image quality and reproducibility, as it accelerates patient throughput.

By using the latest technologies from world-class suppliers, the Touch family capitalizes on ultrasound's use of non-ionizing radiation to deliver low-cost, high-value results that benefit patients, administrators and sonographers.



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