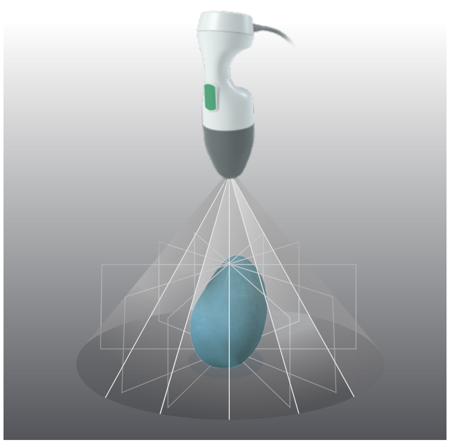
BladderScan
verathon

ImageSense Technology Delivers Trusted Accuracy for Every User

ImageSense® deep learning technology is an advanced implementation of artificial intelligence. The algorithm leverages real-world data to consistently detect and define bladder location, size and shape across all adult and pediatric patient types and anatomies – automatically within seconds. This provides an accuracy of 33% to 100% better than comparable bladder measurement devices.[1]

The ImageSense algorithm is paired with intuitive, simple, user-centric design of the latest generation Verathon® BladderScan® devices to dramatically provide an exceptional ease of use for any user.



VMODE Technology

In less than 5 seconds, VMODE® technology automatically captures 12 B-Mode slices of the bladder and displays the calculated volume results. VMODE automated 3D quantification of bladder volume helps clinicians assess bladder function quickly and confidently.

Figure 1. Conceptual illustration of VMODE technology for automated 3D volume acquisition.

With the innovative ImageSense deep learning based algorithm, Verathon continues to drive bladder volume measurement to unprecedented accuracy levels while simplifying the use of ultrasound technology.

Deep Learning in Bladder Volume Measurement

Artificial intelligence (AI) and machine learning have been in development since the 1950s. Numerous machine learning algorithms have been developed over the years. Verathon was an early adopter of AI in measuring bladder volume. The NeuralHarmonics® technology introduced with the BVI 9400 in 2007 was Verathon's first AI implementation. More recently, an advanced branch of AI and machine learning known as deep learning has developed by leveraging theoretical advances, availability of big data, and recent development of computationally powerful hardware.

Deep learning for computer vision applications, such as medical imaging, models the way the human brain processes light into vision. The human biological neural network inspires developers of artificial neural networks. A key building block of both biological and artificial neural networks is the

Verathon BladderScan Attributes

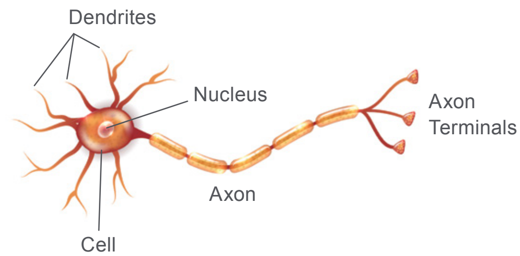
- One-mode scanning for all patient types
- Simple "point and click" use—ImageSense, combined with VMODE automated 3D volume acquisition, requires no manual probe fanning, minimizes user error, and optimizes clinical workflows
- BladderTraq™ live pre-scan aiming includes an onscreen bladder capture feature that highlights and outlines the bladder, helping ensure accurate scans

neuron, as illustrated in Figure 2. State-of-the-art deep learning technologies, such as convolutional neural networks (CNNs), are based on artificial neurons in order to mimic the human brain. Recent generations of BladderScan products leverage the CNN to provide an exceptional approach to bladder volume measurement.

How It Works

When learning to visually recognize an object, we train the biological neural network in our brain. A popular example from the computer vision community is distinguishing an image of a cat from an image of a dog. It is challenging to develop a concise set of rules that unambiguously distinguishes images of cats from images of dogs. However, the human vision system is quite capable of rapidly and reliably distinguishing an image of a cat from an image of a dog. We have learned to detect key features at large scale (e.g., body shape, posture), medium scale (e.g., whiskers, shape of ears, shape of tail), and fine scale (e.g., edges). We combine the detected features at multiple scales to arrive at a decision (i.e., an image is a cat or dog). Furthermore, we are able to ignore irrelevant features, such as ambient brightness or the background of a particular scene.

Biological Neuron



Artificial Neuron

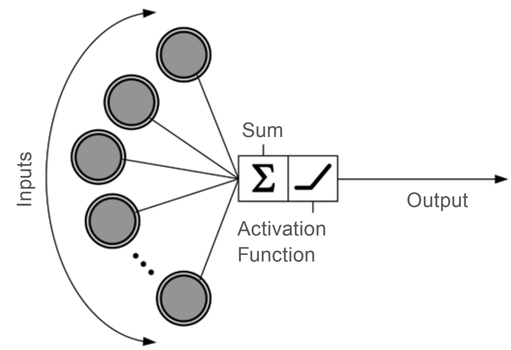


Figure 2. Conceptual illustration of a biological neuron and artificial neuron.

The biological neural network of the human visual system is a hierarchical structure that detects features at a range of scales through multiple stages. Learning to recognize a bladder in a set of ultrasound images and measure its volume follows a similar learning process. To do so, we create an artificial neural network that includes multiple layers of interconnected neurons. See Figure 3 for a conceptual illustration of an artificial neural network.

Artificial Neural Networks

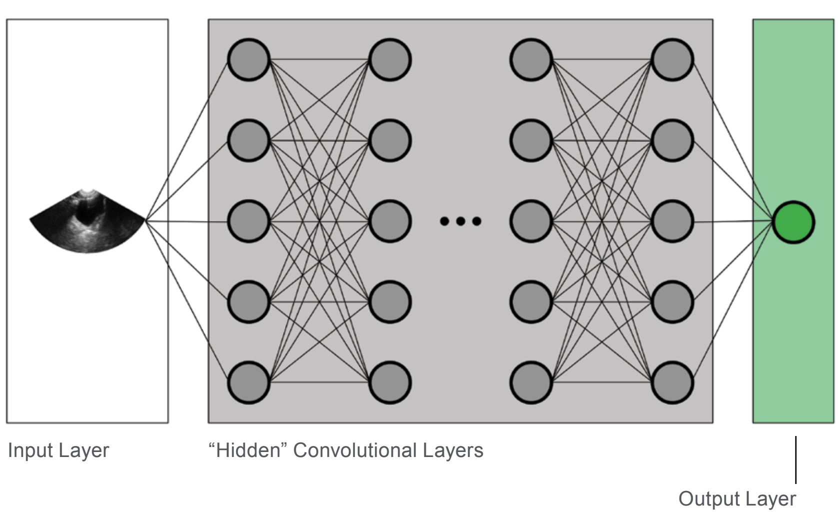


Figure 3. Conceptual illustration of an artificial neural network.

A CNN is a special type of artificial neural network that is designed to mimic the multi-stage processing of the human visual system. A CNN includes multiple "hidden" convolutional layers. The more convolutional layers, the deeper the network. These layers are trained to extract and describe image features at different scales, such as the appearance of local bladder wall edges and overall shape of bladders.

The latest generation BladderScan® device, BladderScan i10™, and a former generation, BladderScan® Prime Plus™, include ImageSense® deep CNN. (As a comparison, the

ImageSense neural network has orders of magnitude, more interconnections between neurons than that of Verathon's first AI algorithm NeuralHarmonics®.) Each layer of the ImageSense® neural network includes thousands of artificial neurons that are fed into many sets of so-called kernels. The convolutional layers are designed to learn key features of bladders at different scales in ultra-sound images. Specifically, we identify relevant features at smaller scales (e.g., via 5x5 small kernel size) up to larger scales (e.g., via 17x17 large kernel size). The CNN parameters, including number of layers, number of kernels per layer, and kernel sizes, were empirically determined to optimize the accuracy of bladder volume measurement.

The CNN learns to recognize bladders through training on clinical images and expert bladder tracings from the Verathon® Bladder Image Database. An illustrative example of a clinical B-Mode image with and without tracing of the bladder is shown in Figure 4. The expert clinician is able to detect the bladder in even complex anatomies. The expert is able to distinguish the bladder from other organs and tissues in the abdominal and pelvic regions, including the uterus, prostate, ovaries, adipose tissue, ascites, and cysts. Furthermore, the expert clinician is also able to recognize image artifacts, such as pubic bone shadowing, bowel gas clutter, and reverberation due to insufficient gel coupling. The well-trained CNN captures this expertise of clinicians to automatically detect and trace a bladder.

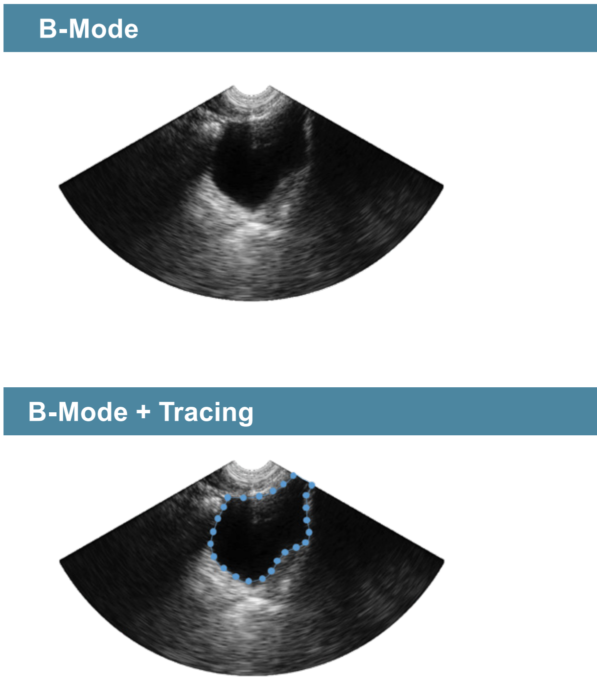


Figure 4. Conceptual example of a clinical B-Mode image of a bladder with and without tracing.

As the CNN better learns to detect bladders the kernel values are modified. This is analogous to changes of the synapses in our brain as we learn. We repeat the training of the CNN in order to improve agreement between the input data (i.e., B-Mode images and bladder tracings) and the CNN output. Training is complete once we have maximized the accuracy. For the ImageSense CNN we performed millions of training iterations to maximize accuracy.

The combination of the deep learning algorithm and a large number of clinical images from different patient types (e.g., gender, body mass index, age) enables an accurate and resilient bladder volume measurement algorithm.

Clinical Image Data Collection for the Verathon Bladder Image Database

The power of a deep learning algorithm for bladder volume measurement is best realized through availability of large numbers of bladder images. Verathon has conducted a number of clinical studies since 2014 to collect bladder images used for the engineering development of the ImageSense deep learning algorithm. To date the Verathon Bladder Image Database includes >38,000 images from more than 425 clinical subjects (approximately 45% adult male, 45% adult female, 10% pediatric subjects). Verathon continues to collect clinical bladder images for continuous improvement to our bladder volume measurement products.

Clinical study subjects that meet all inclusion and none of the exclusion criteria are consented to participate. Each subject receives pre-void ultrasound scans to measure bladder volume. The subject then voids into a calibrated urine collection device to measure the voided volume. The subject then receives post-void ultrasound scans of the bladder to measure bladder volume. All scans are performed by licensed clinicians.

For the most recent training for the ImageSense neural network, a clinical data set of >30,000 images from more than 330 subjects were selected from the Verathon Bladder Image Database. Expert clinicians traced the bladder in each B-Mode image of the training data set. The training B-Mode images with the corresponding expert bladder tracings were then used to train the neural network. Selection of the final neural network was done by evaluating neural network performance on images from the Verathon® Bladder Image Database that were not included in the training data set and which the neural network had not previously seen.

Verification and validation testing of the final neural network was performed on tissue-mimicking phantoms, in accordance with industry-standard practice. The testing confirmed accuracy of ± 7.5% (100-999 mL) and ± 7.5 mL (0-100 mL). This compares positively to manufacture published accuracy levels for in-class devices.[2]

Accuracy and Simplified Workflows Matter

BladderScan i10 leverages ImageSense to give trusted accuracy for every user and an accelerated workflow. Clinicians can rapidly and reliably measure bladder volume with consistent accuracy across all adult and pediatric patient types and anatomies. This is done with a point-and-click 3D scanning probe and automated aiming assist without the more complex “fanning” scan techniques required by some other bladder volume measurement devices. This is intended to help ensure accuracy in “real world” conditions over a wide range of clinical users and settings.

The exceptional accuracy and efficiency of ImageSense, paired with the intuitive touchscreen interface of BladderScan i10, assists clinicians in optimizing patient care and helping clinicians achieve the clinical objectives of reducing and avoiding catheter-associated urinary tract infections (CAUTI) and early detection of post-operative urinary retention (POUR).

1. Manufacturer published accuracies of comparable bladder measurement devices include ±15%, ± 15 mL for BioCon-750 (User Manual Rev 11.3. August 29, 2017); 0-999mL ± 10% or ± 10 mL for Signostics Uscan (User Manual P003948. Nov. 2019); 20-99mL: ≤ ±15mL, 100-999mL: ≤ ± 15% for PortaScan-3D (User Manual PTS3D-UM01-V05.00. Dec. 1, 2017); and ± (12.5% + 12.5ml) for BBS Revolution (User Manual PD-010-0002-50-16. 2017).
2. In-class devices include BioCon (15%, ± 15 mL accuracy) and Signostics Uscan (± 10% or ± 10mL accuracy).

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