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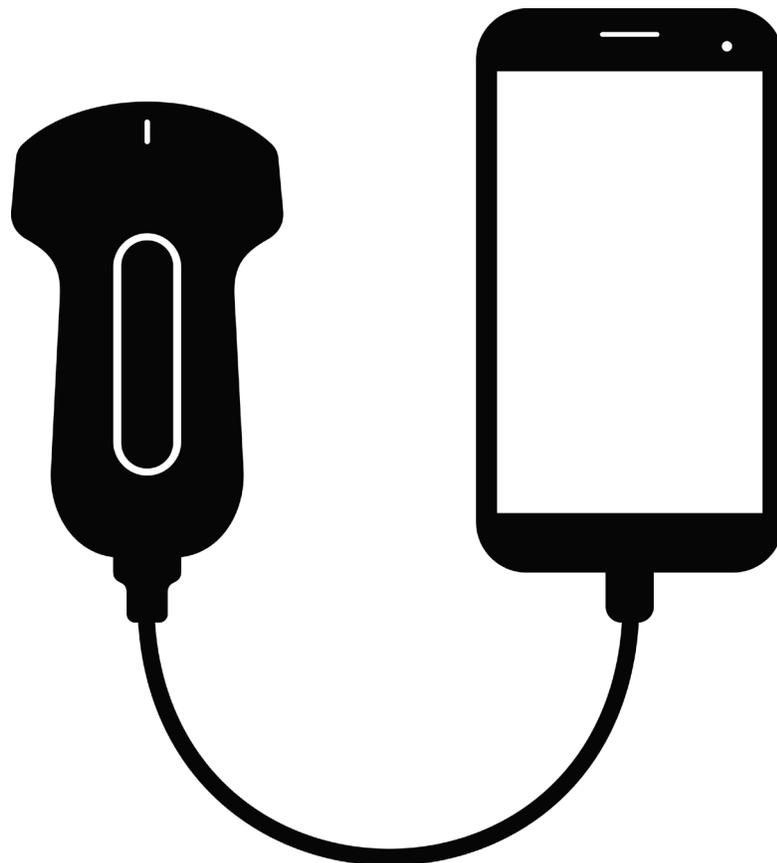
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Smartphone-Connected Ultrasound Devices



iStock Image: Portable Ultrasound

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Methods

CADTH Horizon Scanning bulletins present an overview of the technology and available evidence. They are not systematic reviews and do not involve critical appraisal of all studies or include a detailed summary of study findings. The evidence provided in the summary of the evidence is based on a CADTH Rapid Response Summary With Critical Appraisal report prepared to support this bulletin.¹ The detailed summaries are not presented in this document, but rather in the published reports on the [CADTH website](#). They are not intended to provide recommendations for or against a particular technology.

Literature Search

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was app and smartphone-based portable ultrasound devices. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2014 and August 29, 2019. Regular monthly alerts updated the search until January 3, 2020.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was smartphone- or tablet-based ultrasound. Grey literature was included when it provided additional information to that available in the published studies.

Peer Review

A draft version of this bulletin was reviewed by one clinical expert. The manufacturers were also given the opportunity to comment on an earlier draft; manufacturer input was received.

Summary

- Smartphone- or tablet-connected ultrasound devices are an evolution of point-of-care ultrasound devices resulting in smaller, more compact, less expensive devices compared with conventional ultrasound devices.
- Currently, three smartphone- or tablet-connected ultrasound devices are available in Canada.
- Smartphone- or tablet-connected ultrasound devices likely have a place in care similar to existing point-of-care ultrasound devices.
- No cost-effectiveness studies regarding the use of smartphone- or tablet-based ultrasound systems were identified.

Background

Diagnostic ultrasound involves the use of sound waves to visualize soft tissue and moving structures like the heart. Over the past two decades, ultrasound systems have become smaller and more portable, shifting their use from dedicated ultrasound suites operated by specialized staff to the patient bedside and physician office, where they are used by clinicians at the point-of-care.^{2,3} Devices used for point-of-care ultrasound (POCUS) differ in both capability and application from ultrasound systems used in diagnostic suites.⁴ For example, traditional ultrasound systems (i.e., an ultrasound suite) are used to perform complex, comprehensive examinations, whereas POCUS devices are typically used to answer a specific clinical question and have fewer features than conventional ultrasound systems.^{3,4}

Continued miniaturization of ultrasound technology and the advent of smartphones and tablets have furthered the portability of POCUS.^{2,5,6} Today, several manufacturers produce ultrasound probes that connect to smartphones or tablets.^{4,7-11} More recently, a smartphone-connected ultrasound system became available at a price point of less than US\$2,000 leading to speculation that the use of such technology could quickly expand into previously underserved areas.¹²

The Technology

This bulletin focuses on four smartphone- or tablet-based ultrasound devices:

- Butterfly iQ (Butterfly Network Inc., Guilford, Connecticut)⁷
- Clarius (Clarius Mobile Health, Burnaby, British Columbia)⁸
- Lumify (Philips Healthcare)⁹
- Sonon (Healcerion, Seoul, Korea).¹⁰

Smartphone- or tablet-connected ultrasound devices (sometimes called hand-held, pocket, or portable ultrasound devices) are a type of POCUS intended for use by trained clinicians at the bedside or in a clinician office setting.^{2,4} As with other types of POCUS devices, the rationale for using smartphone- or tablet-connected ultrasound devices is that they allow a clinician to answer a specific clinical question (e.g., investigate for the presence of an abdominal aortic aneurysm) at the time of treatment without needing to refer the patient to an imaging specialist or for the patient to book a separate ultrasound examination.^{2,4} Smartphone- or tablet-based ultrasound devices are designed to be light and compact enough to be held in the hands.⁴ They generally provide fewer features, options, and controls than larger ultrasound systems.^{6,13}

A typical smartphone- or tablet-connected ultrasound device consists of one or more ultrasound probes (also known as transducers) that connect to a commercially available smartphone (e.g., an iPhone) or tablet wirelessly or via an external port (e.g., a micro USB). The probe may be powered by its internal own rechargeable battery or by the smartphone or tablet itself. Using an app installed on the smartphone or tablet, clinicians can view ultrasound images captured by the probe on the screen in real time. The app may also allow the clinician to control the probe's settings.⁴ The transducer type (e.g., convex, linear) and calculation packages available in the app determine the kinds of examinations a smartphone- or tablet-based ultrasound system can perform.⁴ They may be used to assist treatment and patient management in fields such as obstetrics and gynecology, cardiology, endocrinology, orthopedics, emergency medicine, and family medicine.⁴ Images and other data captured by the probe may be transferred to compatible picture archiving and communication systems (PACS), electronic medical records, or to the manufacturer's cloud servers.⁴ Brief descriptions of the key

features of the Butterfly iQ, Clarius, Lumify, and Sonon devices follow. A detailed comparison of portable ultrasound devices, including smartphone- and tablet-connected ultrasound devices, is maintained by ECRI.⁴

Butterfly iQ

The Butterfly iQ device consists of a single ultrasound probe capable of emulating linear, curved, or phased transducers.⁷ The company has replaced traditional piezoelectric crystal-based transducer technology with a single silicon chip that contains a “2D array of 9000 capacitive micromachined ultrasound transducers (CMUTs)”⁵ – what the manufacturer calls “Ultrasound-on-Chip.”⁷ Unlike a crystal-based transducer, CMUTs are not limited to one frequency of sound. Instead, they can be programmed to emit and detect multiple frequencies.⁵ This means that a single CMUT can replicate the function of multiple crystal-based probes in order to perform ultrasound scans of the whole body.⁵ According to the manufacturer, the probe’s built-in battery is capable of providing more than two hours of scanning time.⁷

The Butterfly iQ software is available as an app for iPhone, iPad, and some Android smartphones.^{14,15} The software includes a number of pre-set functions designed to make the system easier to use compared with manually controlling all settings.¹⁵ Images and other data are stored on the company’s cloud server.

Clarius

Clarius Mobile Health produces multipurpose (e.g., convex, phased array) and specialty (e.g., linear, endocavity, microconvex) piezoelectric crystal-based ultrasound probes that connect wirelessly to a user’s smartphone or tablet.^{16,17} The manufacturer states that the technology used to transmit sound beams and reconstruct them into images (called beam forming) allows the probe to capture images with quality similar to larger, cart-based POCUS systems.^{18,19} According to the manufacturer, the probe battery has a scan time of 60 minutes and a sleep time of seven days between charges.²⁰

The Clarius software is available as an app for Android and iOS devices. Images can be stored locally on the user’s smartphone or tablet, sent wireless to a PACS server, or sent to the company’s cloud servers.⁴ The software includes functions such as digital calipers, examination pre-sets, and onscreen annotation.⁴ According to the manufacturer, the software also employs artificial intelligence features to automatically adjust settings to improve the quality of the scan.²¹

The software also offers users the ability to share ultrasound sessions in real time with other clinicians remotely via email or text message through the Clarius Live feature.²²

Lumify

Philips Healthcare produces three wired ultrasound probes (flat linear, convex, and phased array) under the Lumify name.^{4,9} The probes connect to compatible smartphones and tablets, and are powered by the user’s device.^{4,9}

The Lumify software is available as an app for Android devices.⁹ Images can be sent to a PACS server using a wired or wireless connection.^{4,9} The software includes an obstetrics analytics package and functions such as digital calipers, examination pre-sets, and onscreen annotation.⁴

Lumify is also compatible with Reacts (Innovative Imaging Technologies, Montreal, Quebec)²³ – a real-time video telehealth solution that allows images, video, and audio to be streamed from the Lumify user’s device to other Reacts users.²⁴

Sonon

Healcerion produces two ultrasound probes under the Sonon name (one convex and one linear) that connect wirelessly to the user’s compatible smartphone or tablet.¹⁰ The probe’s battery has a reported scan time of three hours and a standby time of 12 hours.^{4,10}

The Sonon software is available as an app for Android and iOS devices.⁴ The software includes an unspecified analytics package and is capable of sending images and data to a PACS server.^{4,10}

Availability

We identified three smartphone- or tablet-based ultrasound systems approved for use in Canada:

- The Clarius probes were licensed as Class III medical devices by Health Canada in 2016.²⁵
- Lumify was licensed as a Class III medical device by Health Canada in 2017.²⁶
- Sonon’s two probes were licensed as Class III medical devices by Health Canada in 2016 and 2017.^{27,28}

Butterfly iQ is not available for use in Canada. The manufacturer anticipates it will be available in 2020.²⁹ The device received US FDA 510(k) clearance (under the name Poseidon) in 2017³⁰ and received a CE mark in 2019 for marketing in Europe.³¹ It is currently available to clinicians in the US, the UK, Europe, Australia, and New Zealand.²⁹

Cost

Butterfly iQ

According to the manufacturer's website, list prices for the Butterfly iQ system are, as follows:³²

- single-user licence plan with one probe is US\$1,999 and US\$420 per year's subscription
- team licences with 1 to 100 probes re US\$1,999 to US\$199,900, with up to 10 to 100 users available for US\$1,200 per year to US\$22,800 per year's subscription
- enterprise licensing is available on request.

Subscriptions for the Butterfly iQ system can be pre-paid up to three years in advance.³²

Clarius

According to the manufacturer's website, the list price for a current generation Clarius ultrasound scanner is C\$6,475 (C\$8,975 for the endocavity scanner).¹⁶ There is no additional subscription cost and the purchase price includes unlimited cloud storage and user licences.

Lumify

Pricing for the Lumify scanner was not available from the manufacturer. ECRI reported a list price of US\$10,910.⁴

Sonon

Pricing for Sonon was not available from the manufacturer. ECRI reported a list price of US\$6,000 for each probe.⁴

Other Cost Considerations

The costs of POCUS ownership must also be taken into account for the maintenance and operation of the system.⁴ These costs may include: replacement probes, staff training and salaries, maintenance and repair, and hardware and software updates.⁴

No information about the potential of smartphone- or tablet-connected ultrasound systems to increase or decrease health care costs was identified in the literature search.

Who Might Benefit?

POCUS has been adopted as a tool in a variety of clinical settings including obstetrics and gynecology, cardiology, endocrinology, orthopedics, emergency medicine, and family medicine.⁴ Smartphone- or tablet-connected ultrasound systems, as an evolution of POCUS, have a similar place in care.⁴ Their portability and typically lower price compared to other POCUS systems

may allow smartphone- or tablet-connected ultrasound to be used by more clinicians and in more settings, including remote, austere, or military environments.³³⁻³⁶ This could impact the approximately 20% of people in Canada who live in rural or remote communities.³⁷ Smartphone- or tablet-based ultrasound devices are also viewed by some as the next extension of traditional physical examination² and the manufacturer of the Butterfly iQ device views its devices as a means of bringing medical imaging to the many people around the world who do not currently have access to it.³³

Current Practice

No Canadian guidelines on the use of smartphone- or tablet-connected ultrasound were identified. Internationally, position papers or position statements about the use of hand-held or pocket ultrasound have been published by organizations such as the American College of Emergency Physicians (ACEP),¹³ the European Association of Cardiovascular Imaging (EACVI),⁶ and EFSUMB – the European Federation of Societies for Ultrasound in Medicine and Biology.³⁸ Key messages from these position statements and papers include:

- The same standards for the use of POCUS devices apply to smartphone- or tablet-connected ultrasound device.¹³
- Only qualified personnel should perform POCUS examinations using hand-held ultrasound devices.^{13,38}
- When documenting patient examinations that use hand-held ultrasound devices, it is important to note that the exam performed was a POCUS or focused cardiac ultrasound examination and not a comprehensive ultrasound examination.⁶
- For the evaluation of abdominal conditions, hand-held ultrasound should be limited to examinations with "few and clear examination objectives."³⁸
- There is value in echocardiography using a hand-held ultrasound device, but the devices are only suitable for some cardiac targets and considerations for its use differ depending on the setting (e.g., out-of-hospital versus in-hospital).^{6,38}
- Hand-held ultrasound is suitable for some lung examinations (i.e., pulmonary edema and pleural effusions) and to guide thoracentesis.⁶
- Hand-held ultrasound is still in its earlier stages of development and more research is necessary to fully understand its place in care.^{6,13,38}

In Canada, guidance for the use POCUS is provided by organizations such as CAR–Canadian Association of Radiologists,³ the Canadian Association of Emergency

Physicians,³⁹ the Canadian Point of Care Ultrasound Society,^{40,41} and Sonography Canada.⁴²

Summary of the Evidence

CADTH completed a review of the clinical effectiveness of smartphone-, tablet-, or app-based portable ultrasound in September 2019.¹ The review identified no relevant studies (i.e., health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies) evaluating the clinical effectiveness of these devices.

Other Research

A subsequent CADTH literature search for this horizon scanning bulletin identified six studies using the Lumify system,⁴³⁻⁴⁸ one examining the Sonon system,⁴⁹ and one systematic review examining several systems.⁵⁰

A prospective non-randomized study examined the use of Lumify for transthoracic echocardiography and the authors concluded that it performed well compared to standard echocardiography.⁴⁴ In a second prospective, non-randomized study using the Lumify system, the authors concluded that hand-held echocardiography had good correlation with a standard echo exam for pediatric patients.⁴⁵

The potential role of the Lumify system has also been examined for use in plastic surgery.^{46,47} In one study, the authors concluded that Lumify had the ability to qualify, visualize, and predict the tissue strength of the superficial facial system.⁴⁶ In a second study, the authors concluded that Lumify could be useful for preoperative planning and decision-making guidance for plastic surgeons performing perforator flap reconstruction.⁴⁷

A retrospective study evaluating a cardiopulmonary limited ultrasound examination examined the use of the Lumify system to perform brief POCUS examinations prior to hospital admission.⁴⁸ The authors found that an abnormal cardiopulmonary limited ultrasound examination was associated with longer length of stay and concluded that Lumify could be a useful tool for stratifying new admissions.

The Lumify system has also been used to guide the placement of regional anesthesia blocks; however, the identified study did not report imaging-related outcomes.⁴³

One study examining the Sonon system was identified.⁴⁹ This prospective non-randomized study compared wireless ultrasound to digital vaginal examination to monitor the progress of labour. The authors concluded that a wireless ultrasound device might be useful in this setting, but that more research is needed to understand its role.

A technology agnostic systematic review of hand-held echocardiography for the evaluation of valve disease was also found.⁵⁰ The review evaluated the accuracy of these devices compared with physical examination or standard echocardiography. The authors concluded that hand-held ultrasound devices were accurate, sensitive, and could be useful for bedside use in the context of cardiac valve disease.

Safety

No information on the safety of smartphone- or tablet-based ultrasound systems was identified.

ECRI notes that imaging using POCUS devices is generally considered to be risk-free, but accuracy depends on the skill of the operator, and that maintenance must be performed regularly according to the manufacturer's guidelines.⁴

Cost-Effectiveness

No information on the cost-effectiveness of smartphone- or tablet-based ultrasound systems was identified. The 2018 EACVI recommendations for the use of hand-held ultrasound devices note that no large-scale studies on the cost-effectiveness of hand-held ultrasound devices in cardiology have been conducted and cost benefits of the technology are therefore theoretical.⁶

Concurrent Developments

The Vscan ultrasound system (GE Healthcare)⁵¹ is a hand-held ultrasound system that uses a proprietary tablet to view images and control settings. It was approved for use in Canada as a Class III medical device in 2010.⁵² The literature search identified a number of studies evaluating the use of Vscan for clinical applications such as echocardiography,^{48,53,54} endocrinology,⁵⁵ ophthalmology,⁵⁶ emergency medicine,⁵⁷ orthopedics,⁵⁸ and obstetrics.⁵⁹ The device has generally been found to be useful for POCUS examinations.

The search also identified a study that explored using deep learning on POCUS images captured by a Clarius ultrasound scanner to estimate left-ventricular ejection fraction.⁶⁰

Operational Issues

As a type of POCUS, many of the implementation issues of using and deploying smartphone- or tablet-connected ultrasound are addressed in guidance from Canadian and international organizations.^{3,4,6,13,39} Of note, local and regional programs and leadership are cited as a key factor to the successful implementation of POCUS.³⁹ Proper device maintenance and quality assurance programs to ensure POCUS devices are functioning correctly have also been cited as important when implementing the technology.^{3,4} When considering smartphone- or tablet-connected ultrasound devices, the search identified four issues that may be unique to their implementation: infection control, documentation and billing, education and training, and data storage and security.^{6,13}

AECP's appropriate use criteria note that smartphone- or tablet-connected transducers should not be used in situations requiring a high level of disinfection unless they have been designed for this purpose.¹³ CAEP has produced a full set of infection control considerations, including the need for clear infection control policies that would also apply to smartphone- or tablet-connected ultrasound devices.³⁹

AECP notes that examinations performed using smartphone- or tablet-connected ultrasound devices, provided they can be appropriately documented and archived, should be eligible for clinician billing.¹³ EACVI suggests that standard language is needed when documenting ultrasound examinations using hand-held ultrasound devices. CAR also emphasizes the importance of proper documentation and ensuring the patient understands the difference between POCUS and a more comprehensive exam.³

Education and training needs may also differ with smartphone- or tablet-connected ultrasound devices.⁶ EACVI recommends that only trained operators use hand-held ultrasound devices

and outlines approaches that could be used to gain these skills. They also recommend users have both competence in acquiring and interpreting ultrasound images, and education and training specifically in the use of hand-held ultrasound devices.⁶

Regarding data storage and security when using smartphone- or tablet-connected ultrasound devices, AECP stresses the importance of allowing only qualified health professionals to use the device.¹³ It is also important that only equipment approved for use by the organization be used in the clinical setting – to do otherwise could be a violation of privacy legislation.¹³ Smartphone- or tablet-connected ultrasound devices should be designed to integrate into workflows and electronic medical records, including the ability to integrate images into existing PACS or other systems.¹³ Similarly, EACVI recommends that images from hand-held ultrasound examinations be stored in an appropriate system for “later review as a clinical baseline reference, as well as for medico-legal issues and quality control.”⁶ Examination results should also be documented in patient records.¹³ CAEP makes similar recommendations for POCUS and suggests this practice is now the standard.³⁹

Final Remarks

In the future, smartphone- or tablet-based ultrasound devices may play a role in expanding access to ultrasound in remote, austere, and military settings.³⁴⁻³⁶ This could be driven by lower device costs: There is speculation that the price of Butterfly iQ might be as low as US\$500 for a single probe in the coming years¹² and researchers at the University of British Columbia are working to develop technology that may lead to an ultrasound probe with a price of C\$100.⁶¹ In the meantime, groups like CAEP and EACVI note the need for research in the POCUS and hand-held ultrasound space that is patient outcome-focused, evaluates hard end points, and evaluates the true costs of adopting the technology.^{6,39}

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