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Horizon Scanning Technology Prioritising Summary

Hand-held portable mini ultrasounds for applications including emergency rooms and ambulances

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PRIORITISING SUMMARY

REGISTER ID: 000433

NAME OF TECHNOLOGY: HAND-HELD PORTABLE MINI ULTRASOUNDS

PURPOSE AND TARGET GROUP: MOBILE APPLICATIONS INCLUDING EMERGENCY ROOMS AND AMBULANCES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | | | |
|-------------------------------------|--------------------|--------------------------|--|
| <input type="checkbox"/> | Yet to emerge | <input type="checkbox"/> | Established |
| <input type="checkbox"/> | Experimental | <input type="checkbox"/> | Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> | Investigational | <input type="checkbox"/> | Should be taken out of use |
| <input type="checkbox"/> | Nearly established | | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | | |
|-------------------------------------|----------------|-------------|------------------|
| <input checked="" type="checkbox"/> | Yes | ARTG number | 118863
149841 |
| <input type="checkbox"/> | No | | |
| <input type="checkbox"/> | Not applicable | | |

The Signos device has TGA approval (ARTG 149841) and also received 510k premarket approval from the FDA on May 7th 2009 ([K090505](#)). The SonoSite NanoMaxx mini ultrasound received FDA approval on October 2nd 2009 ([K092058](#)), and although SonoSite has some ultrasound models registered on the ARTG, it is unclear whether or not the NanoMaxx is registered on the TGA.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		
United States	✓		
France	✓		

IMPACT SUMMARY:

Signostics Pty Ltd (Adelaide, Australia) provides the Signos and SonoSite, Inc (Washington, USA) provides the NanoMaxx™, hand-held personal ultrasound devices. These devices aim to provide a rapid response and immediate diagnostic information and it is envisaged that this technology would be used in ambulance services, emergency rooms and for point-of-care examinations.

BACKGROUND

The Signos is a palm-sized, hand-held personal ultrasound device that is comprised of two parts: a touch screen and a probe (Figure 1). The device weighs approximately 300 grams and can be worn around the neck like a stethoscope or carried in the pocket. The body of the device has a mini-USB port, a headphone jack, an AC adapter connection, a micro-SD slot for the downloading of images and comes equipped with a 2GB SD card¹. The device has a high resolution touch screen (240 x 320 pixels) and can operate with two interchangeable transducers: 3.5 MHz or 7.5MHz, both single crystal (Li 2009; Signostics Pty Ltd 2009). The Signos also has a built in microphone for the addition of notes during examination of the patient. The software, which is compatible with Windows XP or Vista, allows linear calliper measurements, the editing of patient information and a review of images (Li 2009). The Signos has a scanning depth of 0.3 to 18 cm depending on the type of transducer used. The battery can be charged via the power supply, USB connection or car charger. It takes approximately three hours to fully charge the battery which then has a life span of 60 minutes of continuous scanning, or 12-hours with four typical one-minute scans per hour (Signostics Pty Ltd 2009).



Figure 1 The Signos hand-held ultrasound (printed with permission Signostics)

CLINICAL NEED AND BURDEN OF DISEASE

It is difficult to estimate the clinical need for a hand-held ultrasound as it can be used in many clinical situations. Using the Queensland Ambulance Service's experience as

¹ A 2GB SD will store in excess of 10,000 B-Mode Images or 2,000 M-Mode images

a benchmark, in emergency ambulatory situations this type of device may be used several times per day. Use is likely to increase with greater diffusion of the device into hospitals and emergency departments, and with increased training of personnel.

DIFFUSION

In October 2009 it was reported that the Queensland Ambulance Service were trialling the use of the NanoMaxx ultrasound into their rapid response vehicles for assessment of patients at the scene of accidents. It is hoped that the assessment of high level trauma cases at the scene will give advanced warning to hospitals so that operating rooms would be made available if needed. At the current time, the project is in a proof-of-concept stage and one to two pre-hospital ultrasounds have been performed per day in the past five months. A more formal assessment of patient outcomes using the device will commence in March 2010. Two Intensive Care paramedics will undergo training with the device in February 2010. Although data have not been formally assessed it appears that the ultrasound has already contributed to a number of positive patient outcomes (personal communication Department of Community Safety, Queensland).

Signostics have been concentrating on distributing their product to primary healthcare users including general practitioners and physiotherapists. The University of Adelaide's medical clinic is currently trialling the device (personal communication Signostics).

COMPARATORS

The comparator for this technology would be conventional portable ultrasound performed at the bedside.

SAFETY AND EFFECTIVENESS ISSUES

There is a paucity of studies that describe the use of hand-held ultrasound (US) devices in clinical practice. The only studies identified describe the use of a previous generation of compact, portable, lightweight ultrasounds which are the size of a small laptop.

A 2005 review by Beaulieu and Marik described the use of these portable devices in several cardiology studies conducted from 2002 to 2004 (Gorcsan et al 2004; Vignon et al 2004; Vignon et al 2003; Bruce et al 2000; Rugolotto et al 2002; Rugolotto et al 2001). Beaulieu and Marik assert that hand-held US devices are especially useful in acutely ill intensive care patients where a physical examination, especially when diagnosing cardiopulmonary pathology, may not be feasible. These examinations tend to be directed towards a specific clinical question such as determining left ventricular function, and as such the examination is not as thorough as those performed with conventional US and may miss some findings. All of the papers included in the review reported favourable results with the use of hand-held US for echocardiography

compared to conventional US, however due to the age of these studies they will not be assessed in this summary as the technology will have changed significantly during the past 8-10 years. The authors suggest that hand-held USs are capable of reducing complications associated with central venous cannulation and should become standard use when aspirating chest fluid from patients on mechanical ventilation (Beaulieu & Marik 2005).

Trinquart et al (2009) reported on the use of a hand-held US to examine adult patients who had recently undergone a liver transplant for end-stage liver disease. In these patients, US is considered the imaging method of choice to detect complications including stenosis, thrombosis or pseudo-aneurysms of the hepatic artery. These complications occur in 8-10 per cent of liver transplant patients, are the leading cause of graft failure and are associated with significant mortality. Routine US may be difficult in an intensive care environment due to limitations of space. This study compared the assessment ability of a hand-held US (GE LogiqBook XP²) to conventional portable US (Sonoline Sienna, Siemens Medical Systems), both with a transducer frequency of 3.5 MHz. Radiologists were randomly assigned to either the hand-held or conventional US and blinded to the results obtained. Patients underwent paired examinations with both US devices (level II diagnostic evidence).

Twenty-four consecutive liver transplant patients (median age 54 years, 25th -75th percentiles 50-59) were examined a median of three days post-transplantation (25th - 75th percentiles 2-7.5 days). A total of 86, and therefore 43 paired, US examinations were performed. Nine patients had one, 11 patients had two and four patients had three paired examinations. The total examination time was significantly longer ($p < 0.01$) with the hand-held US compared to conventional US, and this effect was independent of the experience and seniority of the radiologist. With the hand-held US, 20 examinations (47%) lasted between 20-30 minutes and nine (21%) lasted longer than 30 minutes. Using conventional US, 14 (33%) examinations lasted between 20-30 minutes and none were greater than 30 minutes. This result was independent of operator. The quality of the grey-scale images was significantly lower ($p < 0.0001$) with the hand-held US (42% of images graded excellent) compared to conventional US (74% of images graded excellent). However, the diagnostic accuracy of the hand-held US was high in comparison to conventional US for the detection of ascites or pleural effusions and abdominal fluid collections (Table 1).

² The GE LogiqBook XP is not the same size as the NanoMaxx or Signos and is the size of a compact laptop

Table 1 Diagnostic accuracy of hand-held vs conventional US

	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]
Ascites or pleural effusions	93 [80, 100]	93 [83, 100]	88 [71, 100]	96 [89, 100]
Abdominal fluid collections	93 [78, 100]	100 [99, 100]	100 [99, 100]	97 [90, 100]

PPV= positive predictive value, NPV= negative predictive value

Abdominal fluid collections in two patients were missed by hand-held US, however these examinations were performed by a more junior radiologist and may be a reflection of lack of training. Ten pleural effusions were detected by conventional US and all were detected by the hand-held US. Both US devices failed to detect patency in the right hepatic vein after three examinations, which was later detected by CT. Apart from this case both devices detected patency in the portal branches, hepatic veins and inferior vena cava. Similarly, both devices failed to detect a signal in the right or left branch of the hepatic artery or in the hilum in four patients, later detected by CT. In two cases the hand-held US failed to detect a signal in the hepatic artery and in one case the hilum, which were all detected by the conventional US. There was poor agreement between the hand-held and conventional US for the systolic ascension time and the resistive index. Although the hand-held US did not appear to be as effective in assessing liver transplant patients, the authors consider that the technology will continue to improve at a rapid rate, making it a viable option (Trinquant et al 2009).

Lapostolle et al (2006) investigated the diagnostic ability of hand-held US devices by emergency physicians in out-of-hospital settings. Eight emergency physicians received training in the use of a hand-held US (SonoSite³ 3.5 MHz), focusing on the diagnosis of pleural, peritoneal or pericardial effusion and vascular disease, including deep vein thrombosis. In an emergency situation the physician would complete a clinical assessment of the patient and give a “clinical score” using a visual analog scale. The absence of a lesion would be assigned a score of zero, whereas a lesion present would be assigned 10. Clinical scores between three and seven were considered clinically doubtful. The hand-held US was the used to assess the patient and give an “ultrasound score” along the same lines and the difference between two scores is calculated. A final diagnosis was obtained in hospital at follow-up (level III-2 diagnostic evidence). If the US diagnosis increases the diagnostic accuracy (ie reflects the hospital diagnosis) then a positive value is attached to the absolute difference in scores. If the US diagnosis decreases the diagnostic accuracy (ie does *not* reflect the hospital diagnosis) then a negative value is attached to the absolute difference in scores.

³ The SonoSite used in this study is not as small as the NanoMaxx or Signos. The US used here is 2.4kg in weight and its dimensions are 30 x 19 x 6 cm.

A total of 169 emergency patients were included in the study and 302 US examinations were performed. The emergency physicians performed an US examination looking for suspected lesions including peritoneal effusion (n=143), pleural effusion (n=86), pericardial effusion (n=16) and vascular lesions (n=35). The median duration of examination was six minutes (range 5-10 minutes) for each patient. A final, in-hospital diagnosis was available for 158 (93%) patients with eight patients lost to follow-up and two patients dying before a final diagnosis was established. A total of 270 US examinations were performed on these 158 patients. The clinical scores and whether or not the US examination improved diagnostic accuracy (a positive US score) or decreased diagnostic accuracy (a negative US score) are summarised in Table 2. A zero score was attributed when the US examination did not change diagnosis. The in-hospital examination resulted in a lesion being diagnosed in 45 cases (17%). The US usefulness score was positive in 181 (67%) of the ultrasounds performed and therefore improved diagnostic accuracy. The score was negative for 22 (8%) of the ultrasounds performed indicating a decreased diagnostic accuracy and was zero for 67 (25%) of the ultrasound examinations indicating that US did not contribute to the clinical diagnosis. The authors considered that hand-held US contributed positively in an emergency situation, despite physicians often having to grapple with difficult situations such as poor patient access and poor lighting conditions to visualise the US screen. They stated that diagnostic capabilities would improve with increased physician training and advancements in the technology (Lapostolle et al 2006).

Table 2 Diagnostic performance of hand-held US according to clinical score

Clinical score	Positive n (%)	Zero n (%)	Negative n (%)	Median 25 th -75 th percentiles
0 n=36	3 (8)	30 (83)	3 (8)	0 (0-0)
1 n=54	30 (56)	22 (41)	2 (4)	1 (0-1)
2 n=43	33 (77)	5 (12)	5 (12)	2 (1-2)
3 n=25	22 (88)	0 (0)	3 (12)	2 (2-3)
4 n=23	21 (91)	1 (4)	1 (4)	3 (3-4)
5 n=45	42 (93)	2 (4)	1 (2)	4 (4-5)
6 n=11	8 (73)	0 (0)	3 (27)	2 (0-5)
7 n=11	10 (91)	0(0)	1 (9)	2 (2-5)
8 n=13	8 (62)	3 (23)	2 (15)	0 (1-7)
9 n=4	3 (75)	0(0)	1 (25)	8 (5-8)
10 n=5	1 (20)	4 (80)	0 (0)	0 (0-2)

Luca et al (2009) described the ability of the MicroMaxx⁴ (Sonosite, USA), a hand-held US device, to perform echocardiography (HCUE) compared to standard echocardiography. Consecutive patients (n=322) from a short stay unit with clinical diversity and patients randomised from the coronary care unit underwent a standard echocardiography, followed within a few hours by a HCUE (median time difference

⁴ The MicroMaxx, like the GE LogiqBook, is the size of a compact laptop. It weighs 3.5kg and its dimensions are 30.2 L x 27.7 W x 8.0 H cm, with a 26.4cm display.

between the two examinations was 2.8 hours, 25th -75th percentiles 1.4 - 5.1 hours). The eight clinicians performing the HCUE were trained in the use of the hand-held device to perform echocardiography for a total of 20 hours training time, in two hour blocks, scheduled over a two week period. Clinicians performing the HCUE were blinded to the results of the standard echocardiogram (level II diagnostic evidence).

A total of 314/322 (98%) of eligible patients underwent both standard and hand-held echocardiography. Standard echocardiography could not be assessed in one patient due to poor image quality and in 30 patients due to inferior vena cava dilation. Six assessments were made for each patient looking for the presence of left ventricle systolic dysfunction, mitral valve regurgitation, left atrium enlargement, left ventricle hypertrophy, pericardial effusion and inferior vena cava dilation. Clinicians reported that only 2-6 per cent of the six HCUE assessments made for each patient were indeterminate despite the high prevalence of obesity and chronic obstructive pulmonary disease. An indeterminate HCUE assessment occurred in 38/322 (12%) patients, of these 24 patients had one, four patients had two and 10 patients had three or more of the six assessments considered indeterminate. HCUE assessments were completed in a median time of 28 minutes (25th -75th percentiles 20-35 minutes). The diagnostic accuracy of the HCUE was calculated compared to standard echocardiography, however indeterminate HCUE results were considered positive in these calculations (Table 3). The sensitivity and specificity values for the diagnosis of each abnormality are moderate to excellent, however some values have large confidence intervals indicating a great deal of variation in measurement.

Table 3 Diagnostic test characteristics of HCUE for the detection of cardiac abnormalities

Abnormality	n (%)	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	LR +ve [95% CI]	LR -ve [95% CI]
Left ventricle systolic dysfunction	80/314 (25.5%)	85 [75, 92]	88 [83, 92]	6.9 [4.9, 9.8]	0.2 [0.1, 0.3]
Mitral valve regurgitation	11/314 (3.5%)	100 [72, 100]	83 [79, 87]	5.9 [3.9, 7.4]	0 [0, 0, 0.3]
Left atrium enlargement	19/314 (6.05%)	90 [67, 99]	74 [68, 79]	3.4 [2.5, 4.3]	0.1 [0.04, 0.4]
Left ventricle hypertrophy	33/314 (10.5%)	70 [51, 84]	73 [67, 78]	2.5 [1.8, 3.3]	0.4 [0.2, 0.7]
Pericardial effusion	3/314 (0.95%)	100 [29, 100]	95 [92, 97]	21 [6.7, 3.1]	0 [0, 0.6]
Inferior vena cava dilation	45/284 (15.8%)	56 [40, 70]	86 [81, 90]	4.0 [2.6, 6.0]	0.5 [0.4, 0.7]

LR = likelihood ratio

The authors concluded that the diagnostic accuracy of a hand-held ultrasound in performing echocardiography was moderate to excellent for the detection of six important cardiac abnormalities. As this study was conducted after a relatively brief training period, the accuracy may improve further with increased use and familiarity with the device (Lucas et al 2009).

COST IMPACT

The Signos manufactured by Signostics Pty Ltd (Australia) comes with a choice of two transducers: 3.5MHz (penetration to 18cm) or 7.5MHz (6-8cm). The current price is approximately \$5,000 +GST with one transducer supplied (personal communication Signostics).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

Portable, hand-held ultrasound devices may be useful in rural and remote communities as they allow for images to be downloaded and sent to larger, regional hospitals for examination.

Signostics are currently in the process of gathering clinical data on the use of the Signos. Several small, clinical research projects are being conducted in Adelaide using the device including a physiotherapy application observing diaphragm movement in patients in the ICU at Flinders Medical Centre (personal communication Signostics).

In February 2010, GE released the [Vscan imaging device](#) which is a smart-phone sized ultrasound

SUMMARY OF FINDINGS

Hand-held ultrasounds may be used for a number of disparate purposes, including ambulatory emergency situations, intensive care units and cardiac assessments. There were no published studies describing the use of the smaller, personal ultrasound devices. It is clear that this is a rapidly developing field and that all studies using the larger, portable ultrasounds reported favourable outcomes with additional diagnostic information added from the use of these devices. It would be prudent to await outcome data from the trial of the NanoMaxx in the Queensland Ambulance Service.

HEALTHPACT ACTION:

There is a clear clinical need for hand-held ultrasound devices especially in emergency situations. It would appear that the technology is advancing rapidly and that many clinicians may choose to use a hand-held device as an adjunct to clinical decision making. It is likely that this technology will diffuse naturally into the Australasian health scene and hospitals and/or clinicians will make individual decisions on whether or not to purchase this device. HealthPACT will assess any feedback from the introduction of these devices into the Queensland Ambulance Service, however in the short-term no further review by HealthPACT on this technology is required.

NUMBER OF INCLUDED STUDIES

Total number of studies	3
Level II diagnostic evidence	2
Level III-2 diagnostic evidence	1

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SEARCH CRITERIA TO BE USED:

Intensive Care/*methods
Ultrasonography/*instrumentation
Emergency Service, Hospital
Point-of-Care Systems