

# **American Society of Echocardiography**

## **Hand-Carried Cardiac Ultrasound (HCU) Device: Recommendations Regarding New Technology**

**A Report from the Echocardiography Task Force on New Technology of the  
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### **Executive Summary**

The newest introduction to echocardiography is a *hand-carried ultrasound* (HCU) device. It is a small echocardiographic machine that typically weighs less than 6 pounds and can obtain echocardiographic images and data. However, either the device or the context of the examination does not fulfill the criteria for a comprehensive or complete echocardiographic examination. The American Society of Echocardiography believes that HCU will extend the concept of the “complete physical examination,” allowing more rapid assessment of cardiovascular anatomy, function, and physiology. However, appropriate user-specific training (Level 1 at a minimum) and assumption of responsibility are essential to ensure the most accurate acquisition, interpretation, and use of the data.

The logical evolution of “sophisticated” technology into a more general application has been repeated throughout industrial and medical history.<sup>1-3</sup> The early implementation of sophisticated technology was often rightly considered unique or too complex or disruptive to be used by a minimally trained person.<sup>4</sup> The natural concern of the sophisticated user is that inappropriate interpretation or application of data gained by a poorly skilled user may result in adverse medical, ethical, and social consequences. However, the natural evolution of technology is the development of simpler forms of application and ultimately wide dissemination to general users.<sup>5,6</sup> It has always been crucial that the knowledge and skill required for responsible use be disseminated as effectively as the technology itself. There appears to be a role for a user-specific, focused cardiovascular ultrasound examination.<sup>7-9</sup> The era of a technology-extended physical examination appears to have arrived, having been brought about by improvements on an old concept of a hand-carried ultrasound scanner.<sup>10-12</sup>

### **What Is a Hand-Carried Cardiac Ultrasound Device?**

Miniaturization of medical ultrasound equipment has evolved in a logical sequence from transesophageal, intravascular, and intracardiac echocardiographic transducers to small full-featured ultrasound machines and now to small hand-carried cardiac ultrasound (HCU) devices. An HCU device is a small ultrasound machine (typically it weighs less than 6 pounds) used to obtain echocardiographic images and data unique to it. However, either the device or the context of the examination does not fulfill the criteria for a state-of-the-art limited or comprehensive echocardiographic examination (Table 1). Dissemination of such technology will and should generate many questions regarding proper use, training, safety, and impact on medical care, and inevitably the HCU examination will be compared with a state-of-the-art echocardiographic examination.

The diagnostic capabilities of or expectations for a small HCU imager are perceived to be more limited in scope or application and examinations using such equipment are more narrowly focused than the conventional limited or comprehensive echocardiographic examination. The essential components of a conventional echocardiographic examination include the following:

1. Appropriate ultrasound technology: a cardiovascular ultrasound machine or system that can obtain multiple function displays, including image, spectral Doppler, color flow Doppler, electrocardiography, M-mode, or other special functions such as images obtained by transesophageal echocardiography; provide on-screen documentation of imaging variables, time, and date; and provide a comprehensive user interface
2. Trained personnel capable of obtaining high-quality images and accurately interpreting the echocardiographic information
3. The ability to archive the acquired images and information and generate a report suitable for auditing and payer reimbursement

The newly introduced HCU technology is a whole new concept in cardiovascular ultrasonography which may not fulfill all of the above criteria. It will empower the user to see within the human body harmlessly, thus extending the concept of a more comprehensive physical examination and resulting in improved patient care or understanding or both.<sup>13</sup> However, inappropriate use or misapplication can temper the acceptance and limit the value of the HCU device.

The American Society of Echocardiography (ASE) believes that the availability and possible functionality of small HCUs will only increase over time and that a large and diverse group of users will evolve. The following is an overview of the Society's current recommendations regarding implementation of HCU technology in a clinical cardiovascular practice.

### **Who will use the HCU Device?**

Level 2- or 3-trained echocardiographers should be competent to use the HCU device. In addition, nearly all cardiologists trained in the past 2 decades have achieved Level 1 training and familiarity with echocardiography. However, they usually have not personally performed or interpreted a diagnostic ultrasound examination. With additional training, such physicians could use HCU technology to extend the physical examination.

With the availability of inexpensive HCU technology, a further progression of cardiovascular ultrasonography beyond the cardiovascular specialist likely will occur. There may be a graduated progression of HCU use from the cardiologist to the internist-cardiologist, general internist, primary care physician, registered nurse, medical school student, and allied health personnel. For the best result, this evolution should be carefully articulated and orchestrated. User-specific training will be essential to the success of this evolution in technology application. This transition is analogous to use of the Swan-Ganz catheter, which initially was used only by invasive cardiologists who performed heart catheterization. However, with appropriate need and training, this technology has evolved to use by noncardiologists, such as anesthesiologists, critical care physicians, and pulmonologists.

Because the small HCU device may evolve into a full diagnostic device, its use and dissemination will not rest simply on the size of the instrument but on the individual user and his or her understanding of and response to the information imparted. The use of the HCU device most likely will evolve according to defined needs. Expertise, appropriate training, and use will be defined within the context of the user's expectations and, most importantly, willingness to assume responsibility for how the information is obtained, interpreted, and used.

## **How Will HCU Be Used?**

### ***User-Specific, Focused Examination***

The ASE believes that a principal use of HCU is to extend the accuracy of the bedside physical examination.

A focused examination is commonly equated with use of the HCU device. This suggests that a state-of-the-art examination may not always be necessary to answer specific, pertinent user questions. However, the words “targeted,” “focused,” and “limited” are often equated with “incomplete,” “inadequate,” or “inaccurate,” which may lead to inappropriate overutilization or underutilization of this and other diagnostic methods, maneuvers, or technology.

Each examiner will determine which image or information is important to his or her specific need and must take personal responsibility for the quality and use of the obtained information. User-specified applications will vary and must be based on clinical guidelines specified by each user group. Similar to the use of the stethoscope, the examiner’s need and expertise may be completely different from one encounter or individual to another. The intent is appropriate reduction of underutilization and overutilization of more expensive technology. At the same time, the onus of responsibility for appropriate application must rest solely on the user. We believe that, similar to current medical practice, appropriate user-specific application will depend directly on the training and expertise of the user. A limited examination increases the possibility of missing relevant information. The user must be held accountable for the content of the examination and for appropriate training, application, documentation, and interpretations of the HCU data.

### ***Safety***

Medical ultrasonography is one of the safest diagnostic imaging technologies,<sup>14,15</sup> is applied to diverse patient groups (such as fetus and infant) and

organ systems (such as brain, eyes, ovaries and testes, heart), and can be adapted to work with various specific scanning probes (such as external, intravascular, transvascular, intracardiac, transesophageal).

It is generally recognized that medical ultrasonography, when reasonably used, has no known serious side effects. Despite this knowledge, there is a need for general precautionary recommendations because it may not be totally innocuous in all circumstances<sup>16</sup> and it would be best to 1) avoid unnecessary or repeated application without a defined indication, 2) avoid unnecessary insonation of vulnerable structures such as the fetus, and 3) avoid tampering with or prevent inadvertent changes in the energy output or electronics. Without evidence of adverse effects, HCU technology should not be restricted from general, unlimited access. As with other commonly available technologies, the user should be held accountable for the responsible application of HCU technology.<sup>16</sup>

### ***Training***

There are specific training and credentialing recommendations for physicians and sonographers performing a state-of-the-art limited or complete echocardiographic examination (Table 2).<sup>17-20</sup> The performance of a targeted HCU examination carries a prerequisite for training and competency, which directly relates to appropriate interpretation or reliance on the obtained information. Training must be individualized and tailored to specific needs. The ASE specifically recommends that persons who use HCU for cardiovascular education or self-instruction have at least level 1 of training.<sup>18</sup> However, level 1 training is considered inadequate for the independent performance and interpretation of a comprehensive clinical echocardiographic examination.

For a person to attain sufficient experience to take responsibility for comprehensive clinical echocardiographic studies, the ASE and the American College of Cardiology (ACC) have published guidelines<sup>17</sup> and which have recently been revised<sup>18</sup>.

The ASE strongly recommends that the user should have level 2 training (a total of 150 personally performed examinations and 300 interpreted studies is recommended in the new guidelines). Persons with less than level 2 training who use HCU must fully acknowledge the increased potential of inadequate information and misinterpretation. They must take full personal responsibility to ensure appropriate care of the patient and obtain sufficient backup and adherence to practice standards. This approach will safeguard the patient's interests and ensure accurate diagnosis, optimal management, and appropriate use of more expensive comprehensive examinations. By definition, an HCU examination does not provide all the features necessary to perform and interpret a complete echocardiographic examination. This document addresses a "type of examination" and is not "machine-specific." The ASE fully recognizes that a small device may someday be capable of obtaining a complete echocardiographic examination and consequently require full adherence to the complete ASE and ACC training recommendations (Table 2).<sup>17-20</sup>

### ***Regulation***

Societal or governmental overregulation is not desirable or in the best interest of the patient. We recommend medical labeling that would restrict nonmedical uses, such as "ultrasound photography" or tampering with the device output.

### ***Cost***

Even now, HCU technology is substantially less expensive than standard larger state-of-the-art devices. Currently, the HCU technology does not meet the expanded role and multifunctional specifications of larger devices. However, this will not be the case in the future. Cost is directly related to the expense of technology development and production. Thus, the cost of HCU technology is expected to decline. Accordingly, affordability will increase and technology dissemination and patient care

will be facilitated.<sup>4</sup> The cost of technology does not itself define the applicability or completeness of the examination or potential reimbursement.

***HCU vs. State-of-the-Art Ultrasound Examination (Table 1)***

Obtaining high-quality anatomical and functional imaging is the primary use of diagnostic ultrasonography. This is the major similarity between an HCU device and a state-of-the-art comprehensive diagnostic ultrasound machine. Other features such as spectral Doppler and color flow Doppler imaging extend the application and information obtained. An HCU device may incorporate these additional functions.

**Conclusion**

An evolutionary change in medical technology is occurring with the introduction of the HCU imager. The ultimate configuration is a use-specific small ultrasound machine capable of being used during any medical encounter. This technology can extend the concept of the “complete physical examination,” allowing more rapid assessment of cardiovascular anatomy, function, and physiology. Because diagnostic ultrasonography is extremely safe, the information obtained is unique, and the cost is relatively low, wide dissemination of the HCU device is expected. Specific groups of health care workers or individual medical practices are expected to embrace this technologic advancement rapidly.

A family of user-specified HCU devices may evolve which will complement and extend the classic physical examination and advance noninvasive medical diagnosis. As with any test or examination, society should be most concerned about the inappropriate use or inaccurate data acquisition, interpretation, and response to the result. For this reason, the ASE recommends a minimum of level 1 training for independent performance or interpretation of HCU and level 2 for independent performance or interpretation of comprehensive echocardiography. User-specific training and assumption of responsibility will be essential to ensure the most appropriate use of the obtained

information. Reimbursement for specified testing will obligate appropriate training, and a method of permanent record keeping suitable for auditing.

### **Future**

As technology changes, revisions to this report may be required. It is assumed that protocols and scenarios for different types of HCU cardiac examinations will develop. The ASE Task Force on New Technology will provide additional specific training and competency guidelines as these changes become evident.

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Table 1.—Comparison of Hand-Carried Ultrasound With Current State-of-the-Art  
Echocardiographic Examinations

Variable	Hand-carried ultrasound	Current examination	
		Limited	Comprehensive
Scope	Brief, extension of physical examination	Goal-directed, follow-up	Goal-directed, complete
Report	Limited, if any	Permanent and complete	Permanent and complete
Minimal training (ASE recommended)	Level 1	Level 2	Level 2-3
ICAEL accreditation	To be determined	Recommended	Recommended
Duration of examination	Brief, < 15 min	15-30 min	Long, > 30 min
Archived image	Limited, if any	Yes	Yes

ASE, American Society of Echocardiography; ICAEL, Intersociety Commission for Accreditation of Echocardiography Laboratories.

Table 2.—Minimum Recommended Levels of Training in Echocardiography

Level	No. of personally performed examinations	No of personally interpreted examinations	Objectives	On completion
1	Total 75	Total 150	Introductory experience	Perform with supervision
2	Total 150	Total 300	Performance, interpretation	Perform independently
3	Total 300	Total 700	Laboratory director and teacher	

Modified from Ryan et al.<sup>18</sup>