American College of Emergency Physicians®

ADVANCING EMERGENCY CARE

POLICY STATEMENT

Approved September 2024

Appropriate Use Criteria for Handheld/Pocket Ultrasound Devices

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Technological advances have allowed miniaturization of ultrasound technology such that point-of-care ultrasound is available for use with modern tablets and smartphones. Since 2009, a multitude of products have become available in the U.S. market for use with both iOS and Android operating systems. These "pocket devices" target both the in-hospital and out-of-hospital markets. Some have the ability to store patient data, interface wirelessly with image archival systems, and insert information into electronic health records or electronic workflow solutions. They have demonstrated image quality comparable to conventional machines when used by trained physicians, and good concordance with CT imaging.[1-5] With increased accessibility to point-of-care ultrasound, promoting responsible use of these systems is required.

The same applications that have been set as standard for point-of-care ultrasound practice apply to pocket devices. The American College of Emergency Physicians (ACEP) policy, "Ultrasound Guidelines: Emergency, Point-of-care, and Clinical Ultrasound Guidelines in Medicine" contains detailed descriptions regarding settings of use, scope of practice, training, credentialing, quality assurance, and reimbursement.[6]

1. Information Security and Workflow
   a) As with cart-based ultrasound machine types, tablet and smartphone ultrasound should be supervised and used only by qualified health professionals.[6]
   b) Equipment used in a clinical setting should be approved by the hospital, clinical department, medical group, or other institution.
      i) This includes both the tablet or phone and the transducer(s).
      ii) If a physician wishes to purchase a device using personal funds and intends to apply this device to their clinical environment (whether for education, diagnosis or both), they should discuss this with relevant hospital services including but not Limited to information technology and security, bioengineering, legal and risk services and department administration.
      iii) A health professional should not use personally-purchased devices in a clinical setting without approval from the above services, as this may violate patient safety including Health

Insurance Portability and Accountability Act (HIPAA) compliance, and hospital information security practices or medicolegal processes.

iv) The software associated with pocket devices may be associated with assistive video technologies for telehealth, artificial intelligence integrations, and geolocation services for fleet tracking and management. These components should also be addressed with IT security and risk management.

c) Pocket devices should be designed to implement neatly into institutional workflow solutions and electronic health record systems. They should facilitate integration of images into the institution's picture archiving and communication systems, or other relevant systems. They should enable provision of and access to documentation of examination findings in the electronic health record.

2. Bioeffects and Safety
   a) All machines, including pocket devices, should display safety profiles including mechanical index and thermal index.
   b) All health professionals using ultrasound should understand these basic safety principles.
   c) Devices that generate heat should have mechanisms to advise the operator when overheating is an issue. Examinations should be stopped if a patient complains of discomfort from heat.
   d) The transducers, tablets and smartphones should all follow Guidelines for Cleaning as proposed by ACEP. Transducers that attach to pocket devices should not be used in situations that require high level disinfection (eg, intraoral, endovaginal) unless otherwise specified by the company, as they may not be designed for invasive purposes or built to withstand high level disinfection agents. Purchasers should discuss with vendors the applications appropriate for these devices and ensure they meet FDA clearance.

3. Use in Clinical Practice
   a) Emergency ultrasonography, and therefore many aspects of clinical ultrasonography, is a "separate entity distinct from the physical examination that adds anatomic, functional and physiologic information to the care of the acutely-ill patient."[6]
   Ultrasound is a stand-alone diagnostic test that is not comparable to other bedside instruments that simply enhance the provider's own senses (eg, stethoscope auscultation amplifies auditory information already available to the provider). It converts high frequency inaudible sound waves into electrical impulses that produce clinically significant data surpassing what is obtainable by physical examination. Interpretation of this complex information requires substantial additional training to use accurately and effectively.
   b) As such, examinations performed using a pocket device may be treated the same as examinations performed using a conventional machine,[7] provided images obtained are of diagnostic quality.
   c) Use of information from the pocket device that does not fulfill criteria for a diagnostic examination[6] (eg, simply writing a narrative of the findings in the patient record without retaining images), should be in compliance with written policies of the institution or practice.
   d) Examinations completed for diagnostic or procedural purposes using pocket devices should be performed or supervised by credentialed and privileged providers and should comply with the credentialing and privileging requirements of the department and institution.
   e) Similar to examinations performed using standard point-of-care ultrasound machines, examinations performed using pocket devices should undergo similar documentation processes that reflect the nature of the exam and its relevant findings. Documentation as dictated by regulatory and payer entities may be more extensive, and examples can be found in the ACEP Emergency Ultrasound Standard Reporting Guidelines.[8]
   f) Prudent judgement regarding applications performed using pocket ultrasound for diagnostic purposes should be made. Examinations completed should be relevant to a patient's chief complaint(s).

g) Pocket ultrasound devices may add value to the medical system by increasing availability and knowledge of clinical ultrasonography. Hospital-wide deployment of pocket ultrasound may:
   i) Improve departmental and extra-departmental resource utilization
   ii) Improve patient safety by reducing medical errors in decision-making, treatment and procedures
   iii) Improve communication and transfers of care
   iv) Avoid premature discharge and return visits
   v) Facilitate telemedicine and teleguidance
   vi) Improve education and point-of-care ultrasound performance using augmented reality and automated machine guidance

h) As such, examinations performed using pocket devices that are archived and documented appropriately should be eligible for billing and reimbursements similar to current practices using conventional compact or cart-based machines.[9]

i) Professional billing should not be affected by self-purchase of a device (if allowed by the institution) but technical fees may be affected.[10] Consultation with the department, institution, hospital system or legal counsel may be advised.

References

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