

Point-of-Care Echocardiography with Assistance Technology

Protocol *Cheat Sheet* for Statistical Reporting Purposes

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Table

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| Product | EchoGPS |
| What is does | AI-based software platform used during cardiac echocardiogram. |
| What is the benefit | Allows lesser-trained healthcare professionals, such as nurses, to generate cardiac images that would ordinarily require an expert sonographer to conduct. In some localities, expert sonographers are few and far between. Cardiologists make clinical treatment decisions on the basis of these images. |
| What they want to find out from this clinical trial | Are the images generated by nurses using EchoGPS just as “good” as images generated by experts w/o the use of EchoGPS? “As Good As” is defined multiple ways. See below. |

**How a cardiac echocardiogram is conducted using EchoGPS:**

The patient lies down on the exam table. The image acquirer uses an ultrasound wand and moves over different positions on the chest. The AI-software helps guide the image acquirer with an ultrasound display screen. For purposes of this study, each patient scan consists of ten(10) 2-dimensional views: PLAX, PSAX-AV, PSAX-PM, PSAX MV, AP4, AP5, AP2, AP3, SubC4, and SC-IVC. For each view position, if the acquirer gets close enough to where they are supposed to be, the software “autocaptures” the view. If the acquirer is not close enough but doesn’t want to spend any more time on that view, they choose “Save Best Clip”. Autocaptured images are the preferred state.

**How is the quality of an image judged?**

Multiple ways.

First, is the quality of the individual view.

A second way, at the patient level, is on the basis of whether cardiac clinical parameters can be assessed. Clinically assessing the health of a particular cardiac anatomical structure(clinical parameter) sometimes only takes 1 view and sometimes it takes multiple views. Since cardiologists make treatment decisions on the basis of the health of these clinical parameters, not individual views, another way of breaking down the quality of the total patient scan is the ability to assess these clinical parameters. The clinical parameters are divided into primary and secondary. The success of imaging on primary parameters are the primary endpoints. Nurse performance success will be compared to acceptance criteria.

Table Primary Clinical Parameters

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Panel Assessment Options** | **Success Criteria** |
| **Qualitative Visual Assessment of Left Ventricular Size** | * Normal or Borderline * Abnormal (Enlarged) * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of left ventricular size and determine if normal/borderline or abnormal (enlarged). |
| **Qualitative Visual Assessment of Global Left Ventricular Function** | * Normal or Borderline * Reduced (EF ≤ 50%) * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of global left ventricular function and determine if normal (or borderline) or reduced (EF < 50%). |
| **Qualitative Visual Assessment of Right Ventricular Size** | * Normal or Borderline * Abnormal (Enlarged) * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of right ventricular size and determine if normal/borderline or abnormal (enlarged). |
| **Qualitative Visual Assessment of Non-Trivial Pericardial Effusion** | * Normal or Borderline * Reduced   Image quality inadequate for visual assessment | Can qualitatively assess the presence or absence of non-trivial pericardial effusion. |

Table Secondary Clinical Parameters

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Panel Assessment Options** | **Success Criteria** |
| **Qualitative Visual Assessment of Inferior Vena Cava Size** | * Absent * Present * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of IVC size and determine if normal or dilated |
| **Qualitative Visual Assessment of Right Ventricular Function** | * Normal * Dilated * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of right ventricular function and determine if normal/borderline or reduced |
| **Qualitative Visual Assessment of Left Atrial Size** | * Normal * Enlarged * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of left atrial size and determine if normal or enlarged |
| **Qualitative Visual Assessment of Aortic Valve** | * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve) precludes assessment of normal/abnormal * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of aortic valve and determine if:   * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve) precludes assessment of normal/abnormal |
| **Qualitative Assessment of Mitral Valve** | * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve) precludes assessment of normal/abnormal * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of mitral valve and determine if:   * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve) precludes assessment of normal/abnormal |
| **Qualitative Assessment of Tricuspid Valve** | * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve, intracardiac lead) precludes assessment of normal/abnormal * Image quality inadequate for visual assessment | Can perform qualitative visual assessment of tricuspid valve and determine if:   * Appears structurally normal * Appears structurally abnormal * Suspected device (e.g., prosthetic valve, intracardiac lead) precludes assessment of normal/abnormal |

**Who judges image quality?**

How is the quality of an image judged?

Five independent cardiologists will rate each patient view on a scale of 1-5. A score of 3 or more is considered diagnostically sufficient. Each patient will have 10 quality scores corresponding to the 10 different views.

At the patient-clinical parameter level, the same cardiologists rate whether the 10 images, taken as a whole, enable them (Yes or No) to perform the qualitative diagnostic assessment called for by that clinical parameter. As indicated in the tables above, there are 4 primary clinical parameters and 6 secondary clinical parameters.

The median of the 5 cardiologists’ 1-5 view-level scores is assigned as the quality score for that view. Similarly, the majority of the 5 cardiologists’ Yes/No clinical parameter scores will be assigned as the image quality score at the patient-clinical parameter level.

**How do you know a poor quality image is due to the nurse’s performance and not just an inherently difficult patient to scan(e.g. an obese patient)?**

In addition to minimally-trained nurses, expert sonographers will also perform echocardiograms on the same patients, but without the assistance of the EchoGPS software. The cardiologists will rate each view and each patient-level parameter generated by the sonographer in the same manner as the images generated by the nurses. The cardiologists will not know whether the image generated was acquired by a nurse using EchoGPS or a sonographer without EchoGPS.

**Holy Grail question(but thankfully not one that has to be answered to approve the device)**

Do cardiologists arrive at the same clinical diagnosis using echocardiograms acquired by nurses with EchoGPS as they would using echocardiograms acquired by sonographers? Setting aside image quality, do cardiologists arrive at the same clinical assessment of cardiac health and functioning using either means of acquiring the echocardiogram?