Protocol title	PROSPECTIVE EVALUATION OF HEARTFOCUS: A SOFTWARE SUPPORTING THE ACQUISITION OF CARDIAC ULTRASOUND EXAMS
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Primary Hypothesis	The primary hypothesis is that novices without previous experience in ultrasound examination could obtain diagnostic-quality acquisitions with the software HeartFocus.

Objectives	The primary objective of the study is to evaluate if ultrasound exams, performed with the HeartFocus software by novices, nurses without prior ultrasound experience, are of sufficient quality to analyze visually: • The left ventricular size, • The left ventricular function, • The right ventricular size, • The presence of non-trivial pericardial effusion. The secondary objectives are: • To evaluate the agreement between the acquisitions obtained by experts and those obtained by novices in terms of quality and echocardiographic parameters (secondary endpoints 1 to 4) • To evaluate the impact of the investigating centers, prior cardiac diagnoses, and obese patients on the quality of ultrasound exam • To evaluate the time to acquire a limited ultrasound exam for a novice with the HeartFocus software. • To evaluate the performance of HeartEF, to automatically calculate the ejection fraction
Number of Subjects	240 patients will be included, 120 in Site 01 and 120 in Site 2 As part of their training, novices will practice cardiac ultrasound acquisition on 72 patients (36 in Site 01 and 36 in Site 2). Those patients will be not included in the analysis. They will sign a different consent form.
Study Duration	• Length of inclusion period: 5 months • Duration of follow-up per participant / inclusion for the training: approximately 30 additional minutes • Duration of follow-up per participant / inclusion for the analysis: approximately 40 additional minutes • Total research duration: 5 months for inclusion + 5 months for outcome analysis.
Study Design	This prospective multicentric international non inferiority pivotal investigation will evaluate the ability of the Heartfocus software in

	supporting novices for the acquisition of 10 reference views of cardiac ultrasound. The 10 reference views are the following: • Parasternal long axis, • Parasternal short axis at the aortic valve, • Parasternal short axis at the mitral valve, • Parasternal short axis at the papillary muscles, • Apical 5-chamber, • Apical 4-chamber, • Apical 3-chamber, • Apical 2-chamber, • Subcostal 4-chamber, • Subcostal inferior vena cava. Novices will be nurses without prior ultrasound experience who have received dedicated training on cardiac ultrasound and on Heartfocus software. Patients included in the study will be adult patients scheduled for an echocardiogram at one of the two investigating centers. Ultrasound exams will be limited to the acquisition of 10 reference views (Table 1). Patients will receive 2 additional limited exams, which consist of the acquisition of ultrasound clips for each of the 10 references views: • one by a novice, nurses having received a dedicated training of 2 days, with the Clarius phased array probe and the HeartFocus software with the guidance system, • one by an expert (experienced sonographer/cardiologist) with the Clarius phased array probe and the HeartFocus software without the guidance system. A total of 8 novices will perform the acquisition on 30 different patients each. In total 240 patients will be included in the analysis, half in each investigator center. The exams (240 acquired by novices, 240 by experts) will be assessed by a review committee, composed by 5 different cardiologists. Each exam will be reviewed by all 5 cardiologists from this committee.
Inclusion Criteria	• Patient (male or female) over 18 years old,

	• Patient having an echocardiography examination scheduled in one of the two investigation centers, • Patient who has given his consent to participate in the research and signed consent form, • Social security affiliation (for France only).
EXCLUSION CRITERIA	• Patient subject to a measure of legal protection (safeguard of justice, guardianship, or curatorship), • Patient deprived of liberty by judicial or administrative decision, • Patient being unable to give his consent, • Pregnant or breastfeeding women (declarative), • Patient with cardiac anatomy that does not allow reference electrocardiographic sections to be made (situs inversus, single ventricle, congenital anomalies, etc), • Patient having benefited from prior echocardiographic exams whose reports mention poor or weak echogenicity, • Patient having known chest deformity that has already been mentioned in previous reports or has been the subject of investigations (pectum excavatum), • Patient who has undergone total or partial pneumonectomy.
ENDPOINTS	All endpoints will be assessed by 5 different cardiologists, from the review committee. The criteria will be assessed on the exams obtained by novices and those obtained by experts, for each patient. Cardiologists will not know if the exam was performed by a novice or an expert. **Primary endpoints:** The cardiologists will evaluate whether the ultrasound exam performed has sufficient quality to visually analyze (binary yes/no) : • The left ventricular size (yes/no) • The left ventricular function (yes/no) • The right ventricle size (yes/no) • The presence of non-trivial pericardial effusion (yes/no) **Secondary endpoints:** 1- The cardiologists will evaluate whether the ultrasound exam performed has sufficient quality to visually analyze (binary yes/no): • The function of the right ventricle? • The size of the inferior vena cava? • The size of the left atrium?

- The aortic valve?
- The mitral valve?
- The tricuspid valve?
- The segmental kinetics?

2- The cardiologists will evaluate whether the quality of each clip is good enough for their interpretation (binary yes/no) (Yes : ACEP>= 3)..

3- The cardiologists will determine on the ultrasound measurements: (qualitative yes/no)

- Is there a left ventricular hypertrophy?
- Is there a right ventricular hypertrophy?
- Is there a dilation of the left ventricle?
- Is there a dilation of the right ventricle?
- Is there a dilation of the left atrium?
- Is there a dilation of the right atrium?
- Is there an abnormal left ventricular function?
- Is there an abnormal right ventricular function?
- Is there an abnormal mitral valve?
- Is there an abnormal tricuspid valve?
- Is there an abnormal aortic valve?
- Is there a pericardial effusion?
- Is there a dilatation of the inferior vena cava?
- Is there a kinetic disorder?
- Is there another abnormality? (comments)

4- The cardiologists will determine on the acquisitions the following ultrasound measurements (quantitative)

- Left ventricular
  - End-systolic and end-diastolic volumes
  - Left ventricular function.
  - Left ventricular parameters will be assessed by cardiologists using the Simpson Biplane method and through the HeartEF algorithm developed by DESKi.
- Parasternal analysis
  - Septal wall thickness
  - Posterior wall thickness
  - Internal diameter of the left ventricle (systole and diastole)

	○ Aortic diameter • Diameter of the inferior vena cava 5- The acquisition time for the limited ultrasound exam
Medical Devices / Clinical Investigation Strategies /Procedures	The HeartFocus software has not yet obtained the FDA or CE certification. This clinical trial aims to collect clinical evidence for FDA and CE certification. The device is classified as Class IIa - software under MDR in Europe and Class II in US following FDA classification. HeartFocus software is compatible with the ultrasound probe Clarius phased array. This probe has received FDA certification and CE certification.
Analysis	Patient description: The population will be described in terms of demographics, ultrasound parameters, and pathology. Endpoints: For all quality criteria, the percentage of success and its confidence interval will be evaluated for acquisitions performed by experts and acquisitions performed by novices. This analysis will be performed via a multi-reader, multi-case power analysis. For each qualitative ultrasound measurement, taking into account the experts' acquisition as the reference, the following parameters will be evaluated: • Percentage of agreement • Sensitivity • Specificity • Precision • Recall • F1-score • Area under the curve For each quantitative ultrasound measurement: • The mean, standard deviation and 95% confidence interval of the difference will be calculated between the measurements made on the acquisitions obtained by the experts and those obtained by the novices • Bland-Altman plots and correlation plots will be performed. Sensitivity studies will be performed on the investigating centers, prior cardiac diagnoses, and obese patients.

	The evaluation of HeartEF will be performed by comparing the results from the algorithm to the manual cardiologist's analysis.

EXPECTED IMPACTS	From a medical point of view, there will be no direct benefit for the patient included in the analysis. At a larger scale, HeartFocus software will outlook access to ultrasound exams by allowing non-experts (emergency physicians, residents, general practitioners, paramedics, and nurses) to acquire cardiac ultrasound exams of sufficient quality for their analysis, without any previous experience in echography. This would improve patient management by optimizing the care pathway, with echography being used as a screening or follow-up tool for patients.