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### **Review Article**

## Update on the Organizational Aspects of Echocardiography in Italy (From Operator Training to the Report: 2007–2019): A Consensus Document by the "Società Italiana di Ecocardiografia e CardioVascular Imaging" Accreditation Area and Board 2017–2019

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## Abstract

In 2007, Società Italiana di Ecocardiografia e CardioVascular Imaging (SIECVI) already SIEC, published the document on the organization of echocardiography in Italy. In the years following the technological evolution, cultural and health factors have changed "the way, we do echo" as a tool for the different clinical pathways. The SIECVI Accreditation Area and Board 2017–2019 considered necessary to review and update the document in the light of innovation in the application of ultrasound for the heart disease assessment. In the document, we have considered the role of SIECVI in multimodal imaging, the need of training and certification of operators, the quality of echo machines, the accreditation of laboratories, the compilation of the report and its responsibility, and the presence of the sonographers in the EchoLab.

Keywords: Accreditation, certification, echocardiography

## INTRODUCTION

Ten years after the first publication of the document on the echocardiography organization in Italy,<sup>[1]</sup> it was deemed necessary to produce an update.

In the past 50 years, an extraordinary innovation in the application of ultrasound in cardiology has made echocardiography a cornerstone for the diagnosis and for the prognostic and functional evaluation of the most important cardiac diseases. In recent years, the technological evolution, cultural and health factors have changed "the way to make echo" as a tool for different clinical pathways.

We record a significant increase in the number of patients who may benefit echocardiographic examination. The evaluation

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of cardiotoxicity in patients with cancer chemotherapy or patient assessment of the pulmonary or surgery or even the use of transesophageal echocardiography (TEE) in the operating room is just one example. At the same time, it is possible to choose the right method for each patient and for each clinical scenario, from the echo stress for ischemic heart disease to the TEE for the valvular and prostheses studies, to the

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three-dimensional (3D)-TEE for the evaluation mitral valve
 disease and percutaneous treatment, to the patient monitoring
 during interventional procedures, cardiac surgery, and in

4 electrophysiology room.

The echo machines available today offer the clinical
cardiologist high-quality image and a large amount of
anatomical and functional information. Rapid technological
development has provided a good quality medical devices and
analytical capacity, more suitable for the use in coronary care,
in emergency rooms for performing a successful triage, and
diagnosis and treatment of cardiac emergencies.

12 The ease of use of the machines, the best image quality, and 13 application in noncardiological medical and technical areas stimulated to approach echocardiography and to undertake 14 specific training courses. As a result, the masters and the 15 minicourses on echocardiography have flourished, organized 16 by the scientific societies or universities, or by experienced 17 cardiologists to conferences, but not always structured in a 18 correct and orderly. 19

Today, the problem is not what it used to acquire images of a
particular anatomical data or to solve a practical question, but
rather what are the techniques, methods, and the most suitable
machine for each clinical question, because different options
for different specialists are available.

We need to understand how we can improve the diagnosis and
how to transfer the best results in clinical management. This means
that the cardiology educational programs (including training
and certification of skills) should be tailored according to the
technological innovations, new applications, and requirements.

# Società Italiana di Ecocardiografia eCardioVascular Imaging" and Multimodal Imaging

33 The noninvasive multimodality imaging of the heart is now 34considered a promising innovation in clinical practice, in 35different scenarios, as well as in research. There is a push towards 36 an integrated multimodal approach to cardiovascular disease, 37 including the assessment of the morphology, pathophysiology, 38 biology, risk stratification, prognosis and therapeutic guidance. At the same time, we must consider the multimodal complexity 39 and the need for continuous interaction with areas related to 40 biomedicine, bioengineering, epidemiology, and statistics.<sup>[2]</sup> 41

This process represents a change for both cardiovascular
specialists and cardiovascular imaging societies, which will
be more evident in future years, but that is already recognized
in our scientific society with the new name of Società Italiana
di Ecocardiografia e CardioVascular Imaging (SIECVI) and
its mission of "Collecting all those who promote, study, and
apply cardiovascular imaging in Italy."<sup>[3]</sup>

## 50 TRAINING AND CERTIFICATIONS

For many years, SIECVI promoted the organization of training
 courses, according to the institutional objectives of a sectoral

scientific society and obtained over 4000 certifications in the past 15 years.

The increasing impact of echocardiography in the diagnosis and treatment care pathway of patients requiring a special care and operator training to ensure the best quality of medical assistance. "Knowing and knowing how to do" is the centerpiece of this strategy, which aims to disseminate and ensure quality across the country through training courses aimed at training itself, certification and maintenance of competence.

Currently, there are six types of courses aimed at certification of competence: Basic Echocardiography, General Echocardiography, Vascular Ultrasound, Pediatric Echocardiography, and Transesophageal and Stress Echocardiography. Those courses are organized at national level, with the collaboration of teachers certified by the society. All courses include theoretical lessons, but from the practical cut, which responds to a syllabus that includes all the most important topics of echocardiographic and/or vascular diagnostics and end with a final learning assessment quiz and executable online. Subsequently, those students who wish to obtain the certification of competence, in the type of training course attended with a positive outcome, can continue the course by accessing the subsequent training phase at laboratories with a SIECVI accredited tutor and the final certification examination.

The learner's relationship with the tutor is considered crucial, as it is the checking "in the field" through the collection of a logbook to guarantee the quality of the operator who will then receive the certification. A promising alternative to tutoring, in the experimental phase, is represented by a 2-day path called "Path B of the certification of competence" in General Echocardiography, aimed at colleagues who already perform echocardiographic examinations in their everyday reality, but who have difficulties to access the training. In addition to "reviewing" image acquisition protocols and echocardiographic measurements that are detected in the main pathologies, the learner is guided to verify their technical skills directly in the execution of an echocardiographic examination, in its acquisition and measurement up to the phase of the report, with practical exercises on workstations, first collective, and then, individual through web, with final evaluative examination.

The opening of the courses to nonmedical health professions (nurses, perfusionists, and radiology technicians) must be interpreted as a force in the current landscape of the professionals who interact with patients.

Access to even certifications by the trainees, not allowed until a few years ago, allowed to qualify those who dedicate themselves daily to the clinical application of ultrasound method that can happen the  $2^{nd}$  year in many schools.

On the other hand, operators already experts on the basis of precise requirements can directly obtain the "certification of

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competence" presenting the logbook and only passing the final 1 examination. In addition, some professional figures such as 2 cardiac surgeons, internists, anesthesiologists, diabetologists, 3 sports doctors, and general practitioners who clinically "use" 4 echocardiographic examination in dedicated areas require more 5 and more frequently training and certification. 6

Faced with such a wide and diversified spread, SIECVI takes  $\mathbf{7}$ care to maintain a sufficient level of quality thanks to the 8 contribution of teachers, tutors, and learners who practice a 9 critical self-evaluation. 10

11 It is obvious that the certification of competence does not have an unlimited duration but needs a reassessment every 5 years 12for its maintenance. It is in the interest of the physician to 13 continue in practice, if warranted, of what it has been certified; 14therefore, this reevaluation is a guarantee of satisfactory 15 and lasting skills, which passes through the maintenance of 16 echocardiographic and the professional skill of the method. 17

18 In addition to the six types of training courses so far presented, SIECVI organizes specific training courses based on 19 professions, pathologies, and methods that do not include the 20 respective certifications, but which are of particular interest. In 21this regard, we recall the course in cardiovascular ultrasound in 22emergency unit and in 3D echocardiography and also the recent 23introduction of structural echocardiography for interventional 24cardiology; alongside, the various congresses proposed in the  $\mathbf{25}$ regional, macro-areas and National context, the frequency 26 of which represents one, but not the only indicator for the  $\mathbf{27}$ continuing competence.  $\mathbf{28}$ 

A challenge that the company always welcomes with enthusiasm is the improvement of perceived and actual quality of the courses by the shareholder. Interfering in a wide range of stakeholders (individuals, other companies, or academics), SIECVI has the opportunity to share the knowledge gained in the field of training and certification.

## ULTRASOUND DEVICES

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The quality of the equipment in recent years has taken a further step forward in quality, thanks to the growing competition between the producers with a relative improvement of the offer based on the type of equipment and software [Table 1].

Often the "specialists" who present the machine are dedicated to cardiology and no longer multispecialists; are, therefore, more and more updated and able to help the doctor understand how to integrate new technologies into the daily workflow.

Even in an emergency room or in a multispecialist outpatient's clinic, we can find good-quality equipment, so that a failure to diagnose because of a technical problem cannot be justified.

## THE LABORATORY ACCREDITATION

The reclassification of echocardiography<sup>[4,5]</sup> requires an update of the chapter concerning laboratories and their accreditation.

A previous document<sup>[6]</sup> on the process which leads to a "voluntary" accreditation has defined the laboratory requirements, product, structure, and implementation needed to obtain a high-quality result. This process was started by the SIECVI and conducted by the International Societies to define standards to ensure, not only the certification of operators but also the effectiveness, efficiency, and competency of the laboratory.

Through the accreditation according to predefined standards, SIECVI aims to improve the quality echocardiogram and equipment evenly across the country and wants to use it as an educational tool to improve the overall quality of the laboratories.

Most laboratories in the area carry out cardiovascular ultrasound activities that can be defined as screening, whereas there are facilities with higher workloads and a more complex diagnostic level. This complexity is mainly the result of the type of patients and their pathologies, but it is also due to the modalities of echocardiography performed (e.g., transesophageal, echo stress).[7-9] This kind of laboratories also performs teaching and research. However, it is known that all health facilities have critical numbers below which it is not possible to maintain a sufficient quality of services. This type of laboratory also carries out teaching and research activities.

	Specifications	Description
Stationary	Standard (M-mode, 2D, Doppler e color Doppler, TDI, strain)	Large, they are usually kept fixed in a room
high-end systems	Advanced (3D, contrast)	Powerful hardware
	Transesophageal probe	Often integrated with "onboard software"
		Extremely high-performance transthoracic probes
Intermediate	Standard (M-mode, 2D, Doppler e color Doppler, TDI, often strain)	They are echocardiograph machines for routine examinations
band	Often transesophageal probe	Less powerful hardware
Portable	Standard (M-mode, 2D, Doppler e color Doppler, TDI, strain)	Extremely manageable
	Often transesophageal probe	Different performances based on cost
		Sometimes higher performance than the intermediate band
Handheld/pocket size/palmtop	Often limited to 2D and color Doppler	Useful for "FAST" echo or integrated in the clinical evaluation (visit-extended)
Multidisciplinary	Standard (M-mode, 2D, Doppler e color Doppler, often TDI)	Cardiological setup present, extremely variable as performance

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In the reissue of the criteria for the accreditation of SIECVI 1 laboratories, the 2017-2019 board of directors have chosen 2 to maintain the quality of laboratories requiring a workload 3 sufficient to maintain it, and at the same time, identify the 4 laboratories that may represent points of reference SIECVI in 5 line with the educational purposes of the society. 6

It has been decided [Table 2] that level I accreditation in  $\mathbf{7}$ transthoracic echocardiography is addressed local laboratories 8 with a lower flow (small structures, local, private, etc.), in 9 which generally a single cardiologist operates. A minimum 10 of 500 TransToracic Echocardiography (TTE)/year is required 11 for this level and there must be at least one SIECVI-certified 12 cardiologist in general cardiovascular ultrasound, who is 13 the laboratory manager. Even if specialty examinations are 14performed in the laboratory, the level does not change. 15

Level II is addressed to laboratories included in facilities 16 with a more complex organization (public or accredited 17 hospitals, universities). To reach this level, the structure must 18 meet all the criteria of level I. At least 1500 examinations/ 19 year are required, and furthermore, the execution of at least 20one typology of specialty examinations Trans Esophageal 21Echocardiography (TEE, stress, vascular, and pediatric) in 22a number exceeding 200/year. In addition to the responsible 23cardiologist, as for the first level, there must be at least 24another cardiologist with SIECVI certification in general  $\mathbf{25}$ cardiovascular ultrasound. The manager or a different cardiologist of the group needs to be SIECVI certified for 26 the required specialty. In addition to the overall volume of  $\mathbf{27}$ examination required, tutoring activities (toward SIECVI  $\mathbf{28}$ students or specialists) and research have been included 29 in this level. In particular, the laboratory should form at 30 least two students SIECVI and/or postgraduate year, and 31 during the 5-year certification period shall be demonstrated 32at least one publication. 33

For the increasingly widespread application of echocardiography 34to structural and interventional cardiology, the board has 35decided to include structural and interventional level II that 36 identifies laboratories with level II accreditation, in which echo 37 is also performed in the support of interventional cardiology 38 and cardiac surgery. 39

These laboratories are in contact with the hemodynamics and cardiac surgery, perform at least 100 ETE dedicated, include at least a cardiologist with certification ETE SIECVI, and they represent a reference to a specific training in structural echocardiography and interventional.

The accreditation of the laboratory is carried out through the online compilation of the forms (Mod 3 and Mod 4) on SIECVI website (www.siec.it/certificazione-e-accreditamento/ accreditamento-laboratori/).

The accreditation request is evaluated by a committee to deliver its opinion. If approved, the accreditation is valid for 5 years, after which the request should be sent back.

## THE ECHO REPORT

The echo examination report is a summary of the information gathered during the review and answer the clinical question posed in the indication. To be known as a complete, it must meet the appropriate exposure data requirements, synthesis, being easy to understand and must provide clear diagnostic conclusions, understandable, and consistent with the morphological and numerical descriptions expressed.

The report includes a general and a final concluding part with common characteristics of each type of examination and a specific part for the type of examination performed.

- a. General section
  - General data with demographic and identification information: Name and Surname and patient identification number, gender, date of birth, age, weight, height, body surface area, arterial pressure, indication, date of execution, and quality of examination
- b. Specific section
  - ETT, ETE, Echo Stress, Vascular Echo, Pediatric Echo
- c. Conclusive section
  - Diagnostic conclusion.

The echocardiographic report, preferably using reporting software and echocardiographic database, must affix the morphological description; the morphological and functional

	Examinations/year minimum	SIECVI certification	Modality	Training	Research
Level 1	≥500 TEE	One certified TTE head cardiologist	TTE	-	-
Level 2	≥1500 TTE+ETE or stress	Two certified cardiologist	TTE + one	SIECVI	Inherent
Level 1 requirements + level 2 requirements + at least 1 specialty	≥200 examinations/year or vascular ≥200 examinations/ year/area or pediatric ≥200 examinations/year	One certified TTE head cardiologist	specialty ETE or stress or vascular or pediatric	students or fellow (at least 2/year)	publications and/or SIECVI
		One cardiologist with specialty certification			multicenter study (at least 1/5 years
Level 2 interventional	≥1500 TTE	Two certified cardiologists	TEE +	see above	
Level 2 requirement +	+	One certified TTE head	interventional		
interventional TEE	≥100 and interventional	cardiologist			
	cardiology or in cardiac surgery	One certified TEE cardiologist			

TTE=Transthoracic echocardiography, SIECVI=Società Italiana di Ecocardiografia e CardioVascular Imaging, TEE=Trans Esophageal Echocardiography

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parameters of the various structures preferring the quantitative
evaluation, with particular emphasis on structures and
parameters showing abnormalities. It is necessary to clearly
indicate those structures that, potentially relevant for the
answer to the clinical question posed in the indication, cannot
be explored for technical reasons.

For image acquisition windows, scanning maneuvers,
measurement techniques, nomenclature, normal range, and
data sets for specific diseases, reference is made to current
ASE-EACVI guidelines.<sup>[10,11]</sup>

## <sup>11</sup> Need to attach images to the text report

The report must always be accompanied by the iconographic
documentation (fixed images in variable number or moving
of variable duration) at the discretion of the operator/reporting
physician, but in any case, it should demonstrate the most
significant aspects reported in the report itself. The laboratory
of echo must, therefore, be equipped with an archive of moving
images, local or central server, for all examinations.

At the moment, there is no specific provision of law on the
storage of echocardiographic examinations, but it refers to
the provisions relating to radiological examinations as an
expression of imaging techniques.

The Decree of the Italian Ministry of Health of February 14, 1997, states that the reports drawn up by the doctor must be readily available indefinitely. As for the iconographic documentation, if it is not delivered to the patient, it must be kept and made available for a period not <10 years.</li>

Much more relevant, and in line with the spirit of the law, is
making available to patients who need to see the examination
images to refer physicians (clinical cardiologists, interventional
cardiologist, and cardiac surgeon), the complete examination
recording on digital media together with appropriate
visualization software.

Still images can be associated with the report when they have
information content sufficient and necessary although rarely
the echo information is exhausted from the static, differently
from the electrocardiogram or chest X-ray.

SIECVI recommends attaching the iconography in electronic
format on CD/DVD to the report. If the images resulted
of a poor quality, it must be recorded in the report the lack
of iconographic documentation and why. For hospitalized
patients, the report may not contain the iconographic
documentation, and the reference may be made to the archived
recording.

#### 46 Who is authorized to draw up the report of an 47 echocardiographic examination?

The report of any instrumental method is the written document,
official, and definitive with which the examination results are
communicated.

51 It includes, in addition to the execution of the examination,
52 different times ranging from the clinical history of the patient

to the interpretation, reporting, and communication of the diagnosis. Its purpose is to assist and guide the clinician in the study and definition of the pathology and treatment of the disease, during the diagnosis and follow-up, through rational and evidence-based medicine. *It is, therefore, the product of the technical work of synthesis and instrumental news, undergoing specialist revision of the method that applies handsigned and to be fully responsible.* 

In particular, the echocardiographic report expressed descriptively, accompanied by its iconographic documentation, has an indisputable forensic value and is considered as a real medical certification.

Moreover, as well known in the medical-legal headquarters and legislative, even in the absence of a legal framework of reference since it is exquisitely specialized performance; the performer responds to a greater extent than the simple provision of medical care, bearing in mind, the assumption of direct proportionality between the amount of medical liability and the degree of technical perfection of the performer doctor (*degree of expertise*).<sup>[12,13]</sup>

## **THE SONOGRAPHERS**

The technical profession of cardiovascular ultrasound (sonographer) is present abroad since 1990 (USA and UK) and has gradually spread throughout the world. In most nations, all echocardiographic examinations are acquired by nonmedical technicians and then reported out by cardiologists.

Even in Italy, there are now a lot of structures, mainly outside hospitals, which organize the work with the help of echocardiography technicians.<sup>[14,15]</sup> However, despite the formation of the sonographer is based on undergraduate and master postgraduate university courses, official recognition of their profession in public facilities is late.

In our view, their presence in the echo laboratory processed by the laboratory workflow in terms of efficacy for the completeness and quality of the captured images, which accuracy and reproducibility of its measurements, and for the best use of technology resources and the people of the laboratory itself, with a direct impact on the reduction of waiting lists for inpatient and outpatient.

The SIECVI, like other European scientific organizations such as the European Society of Cardiovascular Imaging (EACVI), supports the improvement of these figures, through theoretical training practical courses that lead to the certification of competence in various cardiovascular ultrasound fields and recognition of the activity of its associated sonographer.

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Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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## Author Query???

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