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# Direct comparison of the novel automated screening tool (AST) versus the manual screening tool (MST) in patients with already implanted subcutaneous ICD

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ABSTRACT

*Background:* The subcutaneous implantable cardioverter–defibrillator (S-ICD) has evolved as a valuable alternative to the transvenous ICD, especially in young patients. Unfortunately, some of these patients are ineligible for S-ICD implantation due to specific electrocardiographic features. So far, these patients were identified by mandatory pre-implantation screening using the manual screening tool (MST), which lacks objective value. Therefore, a novel automated screening tool (AST) has been introduced recently for objective screening, which has not been evaluated yet.

*Methods/results:* We here first investigate the novel AST, in direct comparison to MST, in 33 consecutive patients with already implanted S-ICD system to compare predicted eligibility by screening tools with true sensing of the S-ICD system. Both screening tools reliably predicted true ineligible single vectors, but also suggested overall ineligibility in a similar fraction of patients (MST: 3.0%; AST: 6.1%), albeit the implanted S-ICD worked flawlessly in these patients. AST did not predict the finally selected sensing vector better than MST. There was a surprising mismatch between AST and MST for the predicted eligibility of single vectors; only in 49% of patients did both screening tools predict eligibility for the same vectors.

*Conclusions:* The novel AST predicted overall eligibility approximately similar to MST. Both tools predicted ineligibility in a few patients, who were actually eligible. There was a striking mismatch between both screening tools when eligibility of single vectors was predicted. Thus, the AST seems to be a valuable advance, due to its standardized and objective process, but it still lacks specificity.



## 1. Introduction

Entire subcutaneous implantable cardioverter–defibrillators (S-ICD) rose to a valuable therapy option to protect from sudden cardiac death within the past years [1,2]. In current ESC guidelines, this has led to a class-IIa-recommendation for patients without indication for pacing or cardiac resynchronization therapy (CRT) [3]. Inappropriate shocks of S-ICD systems, mostly driven by T-wave-oversensing, are a matter of an ongoing controversial debate, although optimization of detection algorithms led to a significant reduction of these events [4,5]. To assess the risk for T-wave-oversensing, preimplantation screening is mandatory. Initially, the manufacturer provided a manual screening tool (MST) to assess patient's eligibility [6]. MST exhibited high sensitivity to identify ineligible patients, but a rather low specificity to select eligible patients [7]. This problem seems to be most prominent in patients with several structural or electrical heart diseases [6,8–10]. Unfortunately, many patients selected for S-ICD implantation are young and suffer from electrical or congenital heart disease. Therefore, this creates a challenge for the sensing and detection algorithm of S-ICD systems due to salient ECG features. Thus, there is a need for a screening device that gives a better reflection of the true S-ICD sensing algorithm to predict eligibility more accurately [7].

Recently, the manufacturer provided an Automated Screening Tool (AST, Boston Scientific, 4100 Hamline Avenue North, St. Paul, MN 55112-5798 USA), embedded within the 4744 programmer, which approaches the S-ICD sensing algorithm. Thus far, the AST has not been evaluated in previous studies.

We therefore first investigated the AST in direct comparison to the MST in a cohort of patients, who already had an implanted S-ICD. This approach enables a direct comparison between the prediction of eligibility of both screening tools compared to true sensing of the implanted S-ICD system. To the best of our knowledge, this is the first direct

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comparison between screening tools and the true sensing of already implanted S-ICD systems.

## 2. Methods

### 2.1. Patients

A cohort of 33 consecutive patients ≥18 years of age with already implanted S-ICD presenting in the Division for Electrophysiology of the University Hospital Muenster between January and April 2017 was investigated. Patients with ongoing arrhythmia, such as atrial fibrillation or repetitive premature (supra-)ventricular complexes, were included in the analyses. Informed consent was obtained from all patients. The study was approved by the local research ethics committee (approval number: 2017-445-f-S) and conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

### 2.2. Screening protocol

Corresponding to the location of the implanted S-ICD, surface skin electrodes were placed above the S-ICD can (midaxillary line; 5/6th intercostal space); the proximal S-ICD sensing electrode (1 cm left lateral to the xiphoid process) and the distal S-ICD sensing electrode (14 cm cranial to the lower electrode). A ground electrode was placed in the right lower abdomen.

Screening was performed in supine and erect posture in rest and after exercise. The exercise test was performed with a bicycle ergometer, which started on 50 W resistance and subsequently increased every 2 min by 25 W. Patients, who were unable to perform the bicycle stress test, conducted consecutive squats. When patients felt that their maximum exercise capacity was reached, the test was ended. The screening ECG tracing was recorded 10 s after the exercise ended to enable equilibration of the signal quality.

The MST (model 4744, Manual Screening Tool) has previously been described [6,8,11]. The novel AST is a software tool on the manufacturer's programmer (Boston Scientific, 4100 Hamline Avenue North, St. Paul, MN 55112-5798 USA) (Fig. 1). Surface electrode placement is similar to screening with MST. Electrodes are connected with the programmer as indicated by color (i.e. red connector: cranial/parasternal; yellow connector: caudal/parasternal; green: midaxillary line/5/6th intercostal line; black connector as neutral electrode on the upper abdomen). The eligibility of all vectors is assessed fully automated. The automated gain setting adjustment ranges between 5 and 20 mm/mV on a printing speed of 25 mm/s. Results are presented tabulated for each vector in the various obtained postures (OK = eligible; FAIL = ineligible).

Parallel to the assessment with the screening tools, each vector of the already implanted S-ICD was interrogated via the programmer in the supine and erect posture at rest and during exercise.

### 2.3. Data analysis

The inter-observer reliability for data analysis with MST was measured between two electrophysiologists (N.B. and F.G.), who analyzed the data independently. In case of diverse results, an expert electrophysiologist (F.R.) determined the eligibility. A patient was considered overall eligible, if ≥1 vector was found eligible in supine and erect posture. In a separate analysis including the exercise test, overall eligibility was confirmed, if ≥1 vector was suitable in supine and erect posture and after the exercise test. A mismatch was found, if MST and AST differ in the prediction of eligibility of ≥1 vector/s (i.e. one screening tool predicts eligibility for a referring vector, whereas the other one predicts ineligibility for this vector) when screening without exercise. Borderline eligibility was defined for screening ECG vectors that intersect the fringe of the MST template tangentially. Eligibility of the sensing vector of the already implanted S-ICD system was confirmed, if consecutive QRS-complexes were gapless annotated by "S" (*sense*) and if double counting was absent.

### 2.4. Statistics

Statistical calculations were performed with SPSS® (build 1.0.0.903, IBM® SPSS® Statistics Subscription) and SigmaPlot 11.0 (build 11.2.0.5, Systat Software Inc.). If normal

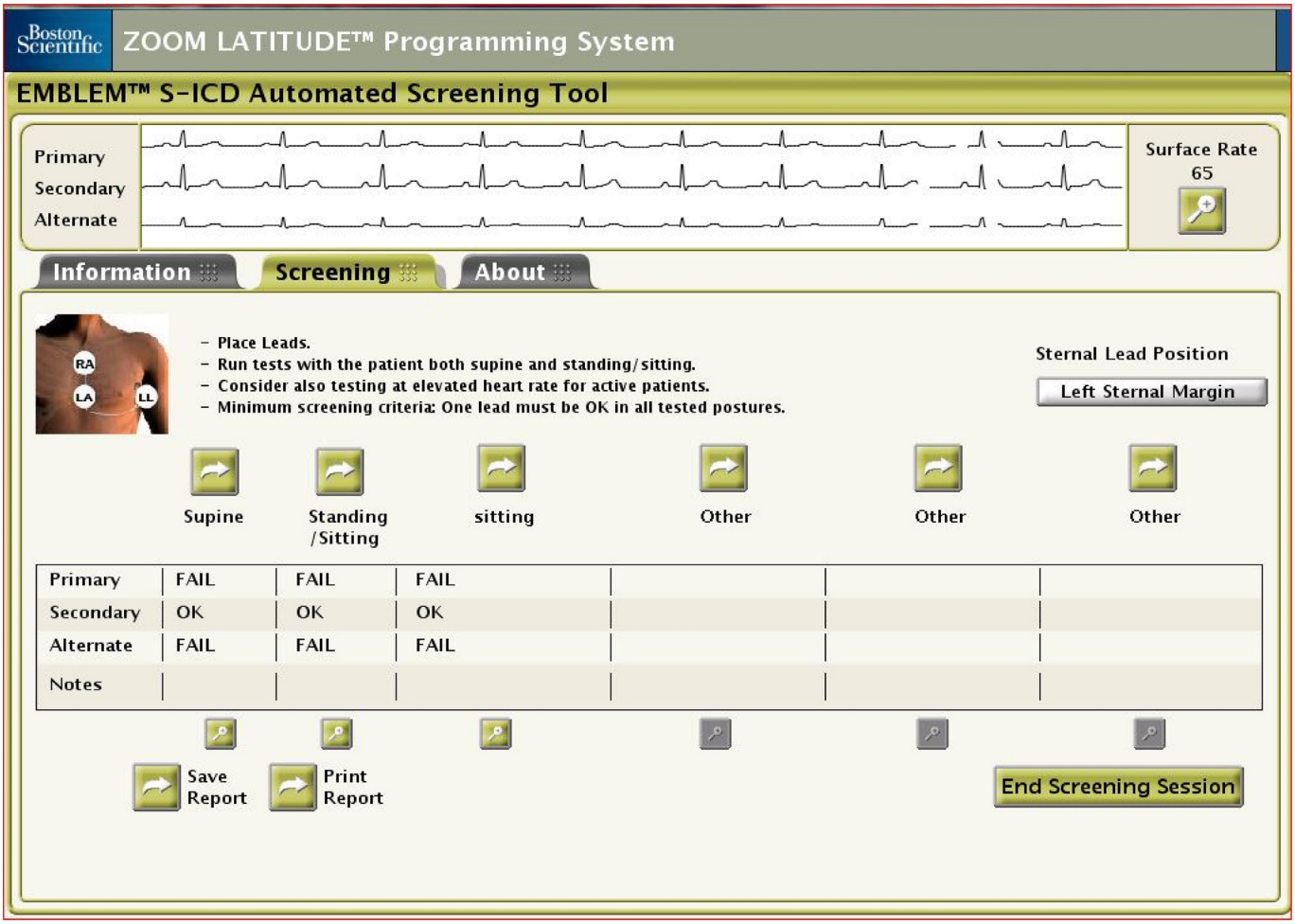


**Fig. 1.** Representative surface of the AST on the manufacturer's programmer. Electrode position is indicated in the illustration. Real-time tracings of the primary, secondary and alternative vector are recorded at the head. Sternal lead placement and posture or screening condition (e.g. with exercise) is selectable. At any posture or screening condition, eligibility is given as "OK", ineligibility as "FAIL". Reports can be stored and externalized. *This figure is shown with permission of Boston Scientific.*