

K964122

## CHAPTER 34: SUMMARY OF SAFETY AND EFFECTIVENESS

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### 1.0 USE

#### 1.1 What it is

STAR is a software device that is intended to be used as the ST and Arrhythmia analysis engine in host computing devices. It can be ported to host computing devices that meet STAR specifications.

#### 1.2 What it does

The STAR device provides ST Analysis, Cardiotach Analysis, and Arrhythmia Analysis capability to compatible computing host devices.

#### 1.3 Where Can it be Used

STAR can only be used in prescription host devices that meet the STAR interface and environment specifications.

#### 1.4 Who Uses it on Whom

STAR is intended to be used by clinicians to monitor cardiac function in neonatal, pediatric, or adult patients.

#### 1.5 Who Prescribes it

In the USA, Federal law restricts STAR to sale by or on the order of a physician.

#### 1.6 Where is it Used

It is intended to be used in a professional health care facility.

It is not intended for home use.

### 2.0 Indications for Use

The indications for use of the STAR ST and Arrhythmia algorithm software device are:

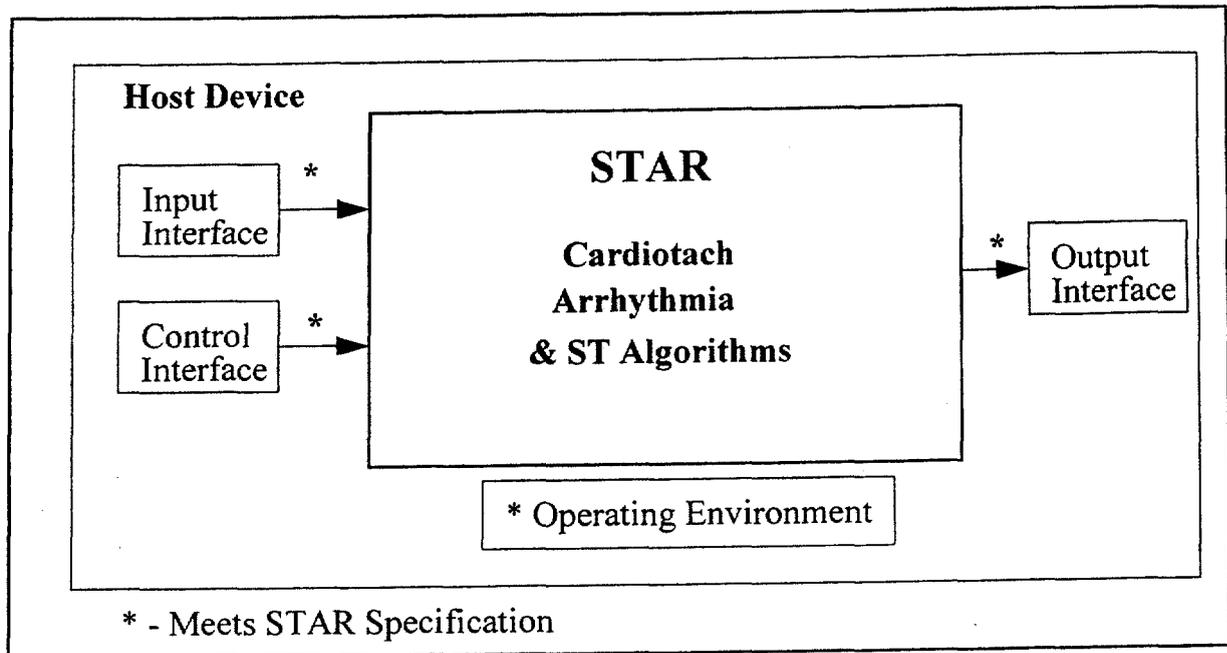
- Condition: the clinician decides to continuously monitor cardiac arrhythmia and / or ST segment.
- Part of body or type of tissue interacted with: ECG signal obtained from electrodes attached to the skin of adult, pediatric, and neonatal patients
- Frequency of use: As prescribed by clinician.

- Physiological purpose: To gain information for treatment or to rule out causes of symptoms.
- Prescription versus over-the-counter: STAR is a prescription device

### 3.0 How it Works

The STAR (ST and Arrhythmia) algorithm is a software engine that analyzes patient ECG's and produces parameters, events and alarms. It is designed so that it is machine (host) independent and can, therefore be used in more than one device. STAR currently operates in the Windows NT, UNIX and a proprietary HP real-time operating system. STAR has a fully specified ECG signal interface, control interface, and output signal interface as well as operating environment specifications as shown in the following STAR Block Diagram.

FIGURE I: STAR BLOCK DIAGRAM



In addition to the STAR algorithm, the complete ST and Arrhythmia monitoring application encompasses several aspects: user interaction and control, data management, and alarm presentation and annunciation. That functionality is provided by the host product in which the STAR algorithm is embedded.

#### 4.0 Summary of Major Features

- (1) Arrhythmia analysis and ST segment analysis are "combined" into one software device.
- (2) The common source code of the STAR algorithm can be configured to achieve the appropriate level of functionality and to conform to the operating environment of the device.
- (3) STAR software is written to be independent of the host device with complete specifications of the following:
  - ECG signal input interface,
  - control input interface,
  - output interface,
  - and operating resource requirement.
- (4) STAR algorithm performance is fully validated independent of the final host device.
- (5) QRS detection and arrhythmia analysis on multiple leads of ECG.

#### 5.0 How it Compares to other Devices

STAR is similar to the predicates when operating in the single lead configuration and has improved performance when operating in the multi-lead configuration when compared to single lead devices.

#### 6.0 How was it Verified and Validated

STAR Verification and Validation was a multi-phased activity. During early development, tests were created to test logical components, the integration of the logical components and the overall arrhythmia and ST algorithm performance in the STAR off-line development environment. As it became possible to port the STAR algorithm into host environments, additional unit and integration testing was performed within host environments.

The algorithm was first shown to satisfy performance expectations such as accuracy, portability, configurability and efficiency. Then a Final Qualification, Verification, and Validation of STAR was performed by the Algorithm R&D Development Team by repeating White Box, Gray Box, and Black Box tests on STAR. Publicly available data bases used to validate STAR performance included the MIT, AHA, Creighton University, and European Society of Cardiology (ESC) ST-T databases.

## **7.0 How we Know it is Safe and Effective When Used as Labeled**

The defined and controlled development processes followed and the documented test results obtained from extensive testing coupled with user documentation of STAR and host devices produces a very high confidence level that the device is safe and effective when used as intended.

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