GE HealthCare

EK12
ECG Algorithm
v2

Regulatory and Safety Guide

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Revision 1
US English

Publication Information

The information in this manual applies only to the EK12 ECG Algorithm version 2. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

Each version of the EK12 algorithm will have a unique device identification (UDI) number. The UDI number is located in the output files.

This product complies with the requirements concerning medical devices from the following regulatory bodies.

Date of first CE mark - 2023.

The document part number and revision are on each page of the document. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	Date	Comment
1	13 September 2023	Initial release.

This document describes the EK12 ECG Algorithm, version 2 also referred to as the "program".

This document is intended to be used under the direct supervision of a licensed healthcare practitioner by trained operators in a hospital or facility providing patient care.

This document provides information required for the proper use of the product. Familiarize yourself with this information and read and understand all instructions before attempting to use this program.

Illustrations in this document are provided as examples only. Depending on system configuration, screens in the document may differ from the screens on your system. Patient names and data are fictitious. Any similarity to actual persons is coincidental.

To access other GE HealthCare Diagnostic Cardiology documents, go to https://www.gehealthcare.com/support/documentation, and visit the **Customer Documentation Portal**.

To access Original Equipment Manufacturer (OEM) documents, go to the device manufacturer's website.

Support

GE Healthcare maintains a trained staff of application and technical experts to answer questions and to respond to issues and problems that may arise during the installation, maintenance, and use of this product.

If you require additional assistance, contact your GE Healthcare representative, or GE Healthcare support at one of the following numbers:

- North America: 1-800-558-7044
- Europe: +49 761 45 43 -0

- Asia: +86 21 3877 7888

To contact GE Healthcare service support for the EK12 ECG Analysis Program, send an email to one of the email addresses as follows:

- EK12.Algorithm.Support@GE.com
- EK12_Algorithm_Support@GE.com

Contents

1 Regulatory Information 5
1.1 Introduction 5
1.2 Intended Use 5
1.3 Indication for Use 5
1.4 Contraindication 5
1.5 Prescription Device Statement 5
2 Safety Information 6
2.1 Safety Conventions 6
2.2 Algorithm Limitations 6
2.3 Minimum Recording Requirements 7
2.4 Results Limitations 7
2.5 Accuracy Dependencies 7
2.6 Retrospective Analysis 8
2.7 Noise and Confidence Levels 8
2.8 System or Device Integration 8
2.9 Other Regulatory Requirements 8
2.10 Reporting of Serious Incidents 8
3 Product and Packaging Information 10
3.1 Symbol descriptions 10
3.2 Intended clinical benefits 11
4 Equipment Identification 12
4.1 Serial Number Format 12
4.2 Serial number location 12
4.3 Unique Device Identifier (UDI) 13

1 Regulatory Information

1.1 Introduction

The EK12 algorithm (also referred to as "EK12" or the "algorithm") analyzes the electrocardiogram (ECG) for rhythm and measurements. This document is intended to be used by users of the EK12 algorithm, such as an ECG technician or physician, and those responsible for deploying EK12 as part of a system, such as the Independent Diagnostic Testing Facilities (IDTF). Familiarize yourself with this information and read and understand all instructions before attempting to use this algorithm product.

1.2 Intended Use

EK12 is software algorithm that analyzes ECGs for rhythm and measurements that is deployed as part of a system used to generate ECG reports / findings.

1.3 Indication for Use

EK12 analyzes 10 or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements.

EK12 is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician, operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards, for the review and assessment of an ECG.

EK12 is indicated for use on adults and pediatric patients older than 2 years.

The device is intended for use in an IDTF or a professional medical facility, such as a hospital, clinic, or physician's office.

1.4 Contraindication

EK12 cannot be used for active patient monitoring since it can only analyze pre-recorded ECG signals that are at least 10 seconds long. It does not provide any time-sensitive information, continuous display of information, alarms, or alerts intended to alert a caregiver to take an immediate clinical action.

1.5 Prescription Device Statement

CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

2 Safety Information

2.1 Safety Conventions

This section provides information about the safe use of this algorithm.

Disregarding the safety information provided in this manual is considered abnormal use of this algorithm and could result in injury, data loss, or a voided warranty.

A **hazard** is a source of potential injury to a person, property, or the system.

The manuals for this system use the terms DANGER, WARNING, CAUTION, and NOTICE to emphasize hazards and designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Table 2-1 Definitions of Safety Conventions

Safety Convention	Description
DANGER	Indicates an imminent hazard, which, if not avoided will result in death or serious injury.
WARNING	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data

The following safety messages alert you to potentially hazardous conditions that could arise during the normal use of this product, and recommend steps that can be taken to avoid those conditions. Safety messages pertaining to hazardous conditions that may arise during specific actions may also be provided during the discussion of those actions in this or other manuals for this product.

2.2 Algorithm Limitations

Since the EK12 arrhythmic event detection sensitivity and specificity is less than 100%, the algorithm may incorrectly identify the presence or absence of an arrhythmic event or provide an incorrect measurement. This is especially true when the signal is noisy.

CAUTION

INCORRECT IDENTIFICATION OF ABSENT EVENT

The algorithm may incorrectly identify the absence of an arrhythmic event.

EK12 results that identify the absence of arrhythmic events must be reviewed in accordance with established IDTF requirements and performance standards or by a qualified medical professional.

WARNING

INCORRECT IDENTIFICATION OR INCORRECT MEASUREMENT

The algorithm may incorrectly identify the presence of an arrhythmic event or provide an incorrect measurement (for example, QT interval measurements).

Do not treat the patient based solely on these EK12 results. A qualified medical professional should interpret the arrhythmic event information and measurements in conjunction with other patient data or clinical findings before determining a course of treatment.

2.3 Minimum Recording Requirements

The EK12 algorithm is:

- Capable of analyzing a single lead or multiple leads (up to 12) that have been simultaneously recorded so that they are time aligned.
- Able to accommodate a variety of sample rates, from 120 to 1000 samples per second. The following sample frequencies (Hz) are supported for EK12 v2.0: 120, 125, 128, 250, 256, 300, 360, 500, 1000.
- Restricted to signals that have a resolution of up to 20µV and a minimum bandwidth of 0.5 to 40Hz. That is, the lower value of the bandwidth must be 0.5Hz or less, and the higher value must be 40Hz or more.

EK12 has a data normalization process and is designed so that these various forms of input data should be transparent to the algorithm.

CAUTION

INCORRECT INPUT DATA RECORDING PARAMETERS

The algorithm may provide incorrect results.

ECG waveform input parameters provided to the EK12 algorithm should represent the specifications of the data recording device. If these parameters are incorrect or do not meet the minimum recording requirements, then the algorithm may provide incorrect measurements or rhythm events, or may provide no usable results.

2.4 Results Limitations

When used by IDTFs, EK12 assists in the identification of ECG rhythms that may be documented in a preliminary report presented to qualified medical professionals. EK12 results must be reviewed in accordance with established IDTF requirements and performance standards.

When used by a qualified medical professional, EK12 does not replace the need to read the ECG. All results generated by EK12 should be considered as preliminary until a qualified medical professional has reviewed and confirmed the ECG.

2.5 Accuracy Dependencies

The accuracy of the EK12 is dependent on signal quality and recording length. EK12 is indicated for ECG records of varying length, from 10 seconds to 24 hours. The better the signal quality and the longer the recording, the better the results are likely to be.

EK12 will attempt analysis of any recording that is 10 seconds or longer. If the data is too noisy and insufficiently long to minimize the impact of the noise, it will identify the ECG as noisy without any further information.

2.6 Retrospective Analysis

EK12 can analyze a recording, from 10 seconds to 24 hours long, from one to twelve leads. It analyzes the entire recording it is provided before returning an answer. EK12 cannot be used to analyze ECG signals on a sample-by-sample basis. EK12 is neither effective nor appropriate for real-time monitoring.

2.7 Noise and Confidence Levels

EK12 will calculate noise and confidence levels for each detected event. The user is advised to take these levels, or their own assessment of noise and confidence, into account in their own analysis of the ECG.

2.8 System or Device Integration

EK12 does not directly interface with the patient, nor does it directly generate a clinical report for a patient or physician. EK12 analyzes provided digital ECG samples and outputs digital information containing beat annotations, ECG measurements, and so on. These outputs can ultimately be presented on a display or a printed report by the receiving system/device.

For EK12 to properly operate, the host device or system must communicate with the algorithm using a pre-specified protocol. It is the responsibility of the host system or service to perform testing and a validation process to verify proper integration with the algorithm.

2.9 Other Regulatory Requirements

EK12 is considered a medical device.

When EK12 is integrated with another medical device, the combined entity must also fulfill all regulatory requirements as a medical device.

When EK12 is used by an IDTF, it must perform its own validation of EK12 as part of their operation and conform to all regulatory requirements.

2.10 Reporting of Serious Incidents

Report any serious incidents related to the use of this GE Healthcare device to the manufacturer and the health authority, or other competent authority, where the device is installed.

To report an incident to GE Healthcare:

- Contact your local service representative, or
- send an email to: in-box.complaints@ge.com

Provide the following information regarding the incident:

- Software version and serial number of the device. See 4.2 Serial number location on page 12.
- Date that the incident occurred.

- Description of the incident, including any patient or user impact or injury.
- Your contact information, including the facility name, address, contact name, title, and telephone number.

3 Product and Packaging Information

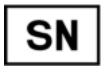
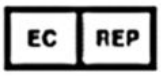
3.1 Symbol descriptions

The following table describes symbols or icons that are on the device or its packaging.

Any symbol on your device or packaging with markings in color indicates there may be a danger, warning, or mandatory action. Any symbol on your device or packaging that is in black and white provides additional information or may indicate a caution. Familiarity with these symbols assists in the use and disposal of the equipment.

For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Table 3-1 Symbols, icons, and descriptions

Symbol	Name	Description
	**Medical device**	The device is used for medical purposes.
	**Unique device identification**	Indicates a unique marking for identification of the medical device.
	**Serial number**	The manufacturer's serial number.
	**Date of manufacture**	The original manufacture date (year-month) for this device.
	**Manufacturer**	The name and address for the manufacturer of this device. It may also include the date it was manufactured.
	**Authorized representative in the European community**	The name and address of the authorized representative in the European community for this device.
Rx Only	**Rx only**	The US Federal law restricts this device to sale by or on the order of a physician.
	**Electronic instructions for use**	Instructions for use is available in electronic form. Consult the operating instructions before using the device or product.
	**Consult instructions for use**	Consult the operating instructions.

Continues on the next page

Table 3-1 Symbols, icons, and descriptions (Table continued)

Symbol	Name	Description
	**Consult accompanying documents**	 **CAUTION** CONSULT ACCOMPANYING DOCUMENTS There may be specific warnings or precautions associated with the device that are not otherwise found on the label. Consult the accompanying documentation for more information about safely using this device.
	**CE mark 0197**	This system bears CE mark 0197 indicating it conforms with the provisions of Council Regulation EU 2017/745 concerning medical devices.

3.2 Intended clinical benefits

EK12 is intended to support health care professionals in generating reports. The computerized ECG interpretations and measurements obtained from EK12 improves ECG interpretation accuracy, efficiency, and confidence among healthcare professionals.[*1]

[*1] Kashou, A.H., et al., *Impact of Computer-Interpreted ECGs on the Accuracy of Healthcare Professionals*. Current Problems in Cardiology, 2023. 48(11): p. 101989.

4 Equipment Identification

4.1 Serial Number Format

Each device has a serial number that uniquely identifies it and provides important information. You need the product code and the entire serial number before servicing or requesting support for your product. The serial number format is shown in the following illustration:

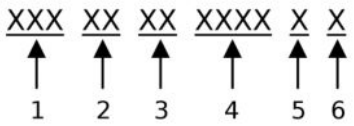


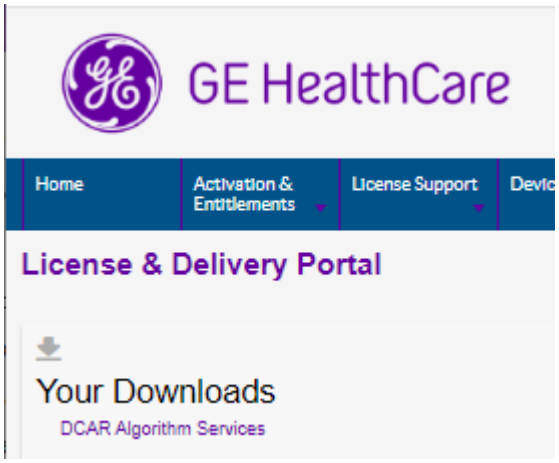
Table 4-1 Serial Number Format

Item	Name	Description
1	Product code	Three-letter code that uniquely identifies the product line.
2	Year manufactured	Two-digit code identifying the year the device was manufactured. Values range from 00 to 99 For example: 00 = 2000, 04 = 2004, 05 = 2005 (and so on).
3	Fiscal week manufactured	Two-digit code identifying the week the device was manufactured.Values range from 01 to 52. GE Healthcare's fiscal weeks correspond to the calendar week. For example, 01 = first week in January.
4	Product sequence	Four-digit number identifying the order in which this device was manufactured. Values range from 0001 to 9999.
5	Manufacturing site	One-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore, W = Wuxi, H = Helsinki.
6	Miscellaneous characteristic	One-letter code identifying manufacturing status. For example, P = device is a prototype, R = device was refurbished, U = device was upgraded to meet the specifications of another product code, A = device is in production.

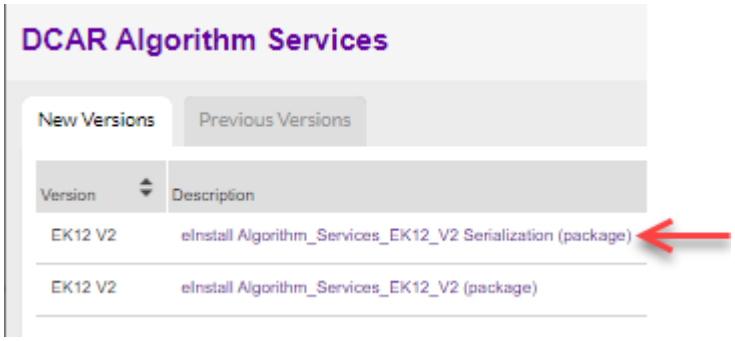
4.2 Serial number location

You can find the serial number for the EK12 v2 software in the eDelivery portal.

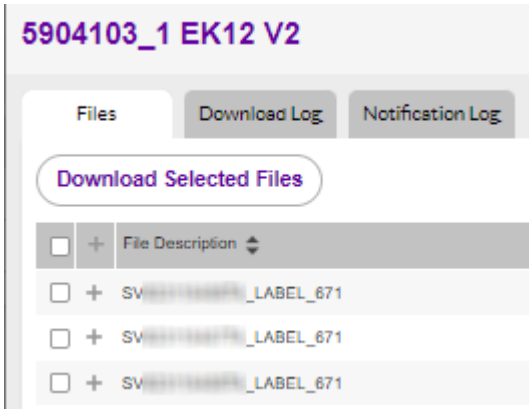
1. Log in at the eDelivery portal.
2. Click **DCAR Algorithm Services**.



3. Select the serialization package.



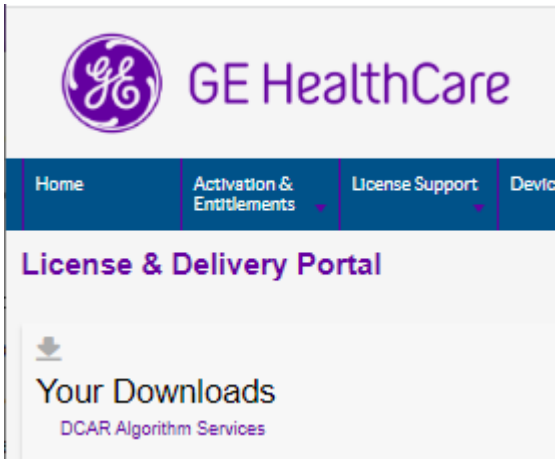
The entitlement list shows. The **File Description** and **File Name** contain the serial number for each download. You can also download a file to see an image of the label with the serial number.



4.3 Unique Device Identifier (UDI)

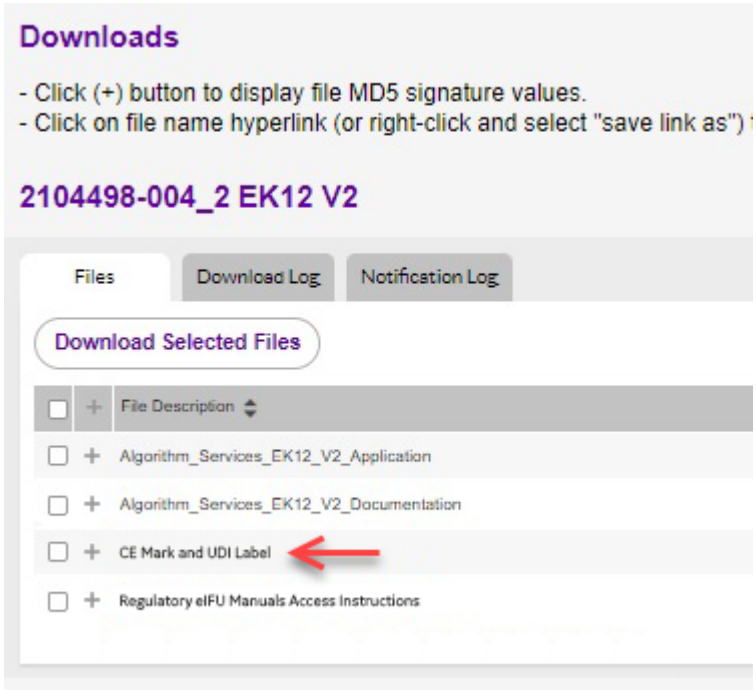
Medical devices require a Unique Device Identifier (UDI) for identification. You can find the UDI for the EK12 v2 software in the eDelivery portal.

1. Log in at the eDelivery portal.
2. Click **DCAR Algorithm Services**.



3. Select the package.

4. Download the **CE Mark and UDI Label**.



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