

General Information

REF: FIRST AID WEB - ER4H

BASIC HEARING OF: 805572803ER4HDK

It is possible to view the device label both in the SW GUI and in the printed user manual.

Intended Use

ER4H qualifies as a medical device in that it provides information to physicians and nurses that is used to make decisions with diagnostic or therapeutic purposes for patients in the emergency room.

While most functions facilitate storage, archiving, communication, simple research, or administrative tasks, ER4H supports clinical decisions through

- Display of relevant patient data, such as vital sign values and out-of-range visual indicators
- calculation of the emergency/severity index (Triage)
- Configuration and calculation of clinical scores

Directions and user personnel

ER4H - FIRST AID WEB is a system that involves different figures within a hospital system:

- **Physicians:** are supported in emergency medical record management activities through an overview of patient data (summary), updated in real time.
- **Nurses:** operate on the system by performing all functions of completing medical activities such as: patient acceptance, assessment of severity in access, collection of vital p., recording of therapy administration.
- **Medical consultants:** manage all consultation referral activities if requested by the PS physician both for patients using general consultations (ER patients) and for patients referred to specialized pathways (see for example: FastTrack pathway)

Administrative staff: through ER4H FirstAid Web, according to the policies defined by the Customer, manages the activities of work list control, information to relatives as well as the generation of reporting files, statistical analysis, etc.

All personnel qualified to use ER4H must carry out the training activities required by the manufacturer.

WARNING!

The term "qualified personnel" includes all persons capable of operating and working on the *FIRST AID WEB* software safely and effectively, with knowledge of the language in which the manual is provided, signs, and commands in the manual and/or the software itself.

WARNING!

Personnel responsible for using the software must be trained by Dedalus and/or Dedalus-qualified hospital personnel during training. Personnel must have the characteristics outlined in this document. Compliance with these rules is a prerequisite for ensuring safety for operators and patients.

Patient population

Patients who can benefit from the use of ER4H FirstAid Web, are all patients who require emergency room activities.

Usage environment

- Emergency Department

Warnings and precautions

- The software is intended for professional use only. First aid personnel must be qualified and adhere to the principles of good first aid practice. All user documents provided must be read before using the software.
- To avoid computer viruses or abnormal operation of FIRSAID WEB, never download any software other than that provided by Dedalus. The user is authorized to change the behavior of the software only by changing the software configuration parameters described in the user documentation.
- The software may be used only for the intended purpose for which it was designed and as contractually agreed with Dedalus. Do not use it for purposes other than those specified in this manual. Do not use in environments other than those specified in this manual. Improper use may cause serious personal injury and/or property damage!
- Any serious accident that has occurred in connection with the device should be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established.
- Any serious incident that has occurred in connection with the device should be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established
- For any problem occurring during use and in any case not mentioned in this document and/or attachments, contact Dedalus Customer Service to resolve the problem encountered as soon as possible.
- Dedalus Customer Services is available for clarification and/or intervention by specialized personnel. All maintenance activities must be performed strictly by personnel authorized by Dedalus. Service performed by unauthorized persons may impair the function of the software. Dedalus assumes no responsibility for damage or injury caused by service performed by unauthorized personnel.

Contraindications

ER4H FirstAid Web does not make any clinical decisions regarding the patient. Treatment of the patient is completely the responsibility of the licensed health care professional. Performance of activities and administration of medications are completely the responsibility of the licensed health care professional.

ER4H FirstAid Web is not suitable for the lay user. Only the professional user can be allowed to use the system.

Data provided by ER4H FirstAid Web to other applications must be processed by an educated person before making a medical decision or providing treatment to a patient. The user must assess the plausibility of any computational results generated by before using them for clinical decisions.

ER4H can be used for documentation of additional treatment.

ER4H does not support the definition of chemotherapy treatment or parenteral nutrition and does not provide calculations or information needed for this purpose.

The use of ER4H FirstAid Web to support direct management of dispensing robots without a human check before dispensing to the patient is not authorized.

The use of ER4H FirstAid Web to support direct prescription management of respiratory and aesthetic machines is not authorized.

Useful life of the device

Dedalus reserves the right to discontinue software products or specific software versions for a variety of reasons, including products/versions that become obsolete or replaced by new software products/versions. In addition, DEDALUS reserves the right to discontinue support for obsolete operating systems and/or support for specific platforms (e.g. Windows/Mac/Linux) for its products.

Maintenance for a specific release of DEDALUS products is generally available for up to 12 months after that release has been replaced by a newer one. Releases that leave the 12-month support window are considered to have reached the end of their ordinary life cycle.

HW&SW REQUIREMENTS (CLIENT)

Hardware Requirements

- Processor 1 GHz or higher with support for SSE2
- RAM 1 GB for 32-bit or 2 GB for 64-bit
- Display resolution 1440x900 or higher.

N.B. If the resolution is lower than the requirements, the system will display a message on the screen to alert the operator that not all information may be displayed. :

Software Requirements client side

- Browser: All browsers listed in the table below are supported (pay attention to those that support digital signature if this is a required feature);
- PDF viewer: Adobe Acrobat Reader;
- Java runtime environment: Latest available version; if the browser used is 32-bit, JRE must also be 32-bit;
- Form PKCS11: latest version for the smart card in use (required for digital signature).