ER4H FIRSTAID WEB

SAFETY AND PERFORMANCE INFORMATION

General informations

REF: FIRSTAID WEB – ER4H
BASIC UDI DI: 805572803ER4HDK

It is possible to view the device label both in the graphic interface of the SW and in the user manual in paper format.

Intended use

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

While most features facilitate memorization, archiving, communication, simple search or administrative tasks, ER4H supports clinical decisions through

- View 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

Indications and user personnel

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

- **Doctors:** are supported in the management of the emergency medical record, through an overview of the patient's data (summary), updated in real time.
- **Nurses:** operate on the system carrying out all the functions of completing medical activities such as: patient acceptance, assessment of the degree of severity in access, collection of p. vital signs, recording of therapy administration.
- **Medical consultants:** manage all consultancy reporting activities if requested by the ED doctor both for patients who benefit from general consultancy (ER patients) and for patients referred to specialist paths (see for example: FastTrack path)

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

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

ATTENTION !

The term "qualified personnel" includes all people capable of operating and intervening on the *FIRSTAID WEB software* in a safe and effective manner, with knowledge of the language in which the manual is supplied, signs and commands present in the manual and/or on the software same.

ATTENTION !

The personnel responsible for using the software must be trained by Dedalus and/or by hospital personnel qualified by Dedalus during training. The staff must have the characteristics indicated in this document. Compliance with these rules is an essential requirement to ensure 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 comply with the principles of good first aid practice. All user documents provided should be read before using the software.
- To avoid computer viruses or anomalous functioning of FIRSTAID WEB, never download any software other than that provided by Dedalus. The user is authorized to change the behavior of the software only by modifying the software configuration parameters described in the user documentation.
- The software may only be used 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 indicated in this manual. Improper use can cause serious damage to people and/or property!
- Any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the competent authority of the Member State where the user and/or patient is established.
- Any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the competent authority of the Member State where the user and/or patient is established
- For any problem that occurs 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 clarifications and/or interventions by specialized personnel. All maintenance activities must be strictly carried out by personnel authorized by Dedalus. Service performed

by unauthorized persons may compromise the function of the software. Dedalus assumes no responsibility for damage or injury caused by service carried out by unauthorized personnel.

Contraindications

ER4H FirstAid Web does not make any clinical decisions regarding the patient. Patient treatment is entirely the responsibility of the licensed healthcare professional. The performance of tasks and administration of medications are completely the responsibility of the licensed healthcare professional.

ER4H FirstAid Web is not suitable for the lay user. Only 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 the patient. The user must evaluate the plausibility of any calculation results generated by it before using it for clinical decisions.

ER4H can be used for documentation of additional treatment.

ER4H does not support the definition of chemotherapy treatment, nor parenteral nutrition and does not provide calculations or information necessary for this purpose.

ER4H FirstAid Web is not authorized to be used to support direct management of dispensing robots without human supervision prior to dispensing to the patient.

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

Useful life of the device

Dedalus reserves the right to discontinue specific software products or software versions for a variety of reasons, including products/versions becoming obsolete or replaced by new software products/versions. Furthermore, 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 version of DEDALUS products is generally available up to 12 months after that release has been replaced by a newer one. Versions that leave the 12-month support window are considered to have reached the end of their normal life cycle.

HW&SW REQUIREMENTS (CLIENT)

Hardware Requirements

- Processor 2 GHz quad-core or better
- RAM 4 GiB or more
- 1440x900 resolution or higher and 19" screen or higher for desktop version
- 1024x768 resolution or higher and 8" screen size or higher for mobile version

NB: If the resolution is lower than the requirements, the system displays a message on the screen to warn the operator that not all information may be displayed.

Client-side software requirements

- Browsers: All browsers listed in the table below are supported

Browser	Version from
Chrome	118 or later
Firefox	118 or later
Microsoft Edge	118 or later

- PDF viewer: for correct viewing of PDF files it is advisable to install Adobe Acrobat Reader, set it as the default Windows application and configure the browser to open files with the default Windows application.