General information

REF: FARMASAFE@
BASIC UDI-DI: 805572803 FARMASAFE DG

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

Intended Use

FARMASAFE@ is intended for use in a hospital to manage the medication workflow from prescription by physicians to administration to the patient by nurses, after validation and dispensing by the pharmacist. It provides health care providers with an overview of a patient's past, present, and projected future medications.

Clinical decision support is provided by:

- visualization of relevant patient data;

- Dose calculation based on the patient's anthropometric data;

- The integration of a scientific reference database;

- Checks on drug safety.

Directions and user personnel

- FARMASAFE@ is used by the **physician** for:

Prescribe and tailor chemotherapy according to the patient's needs.

Prescribing other types of drugs.

Review the patient's active therapies.

Receive clinical decision support during prescriptions based on pharmacist configurations.

Collect clinically relevant information such as: patient allergies and anthropometric data.

- FARMASAFE@ is used by the **pharmacist** to:

Verify therapeutic and prescriptive appropriateness.

Decide how to prepare the drug and produce the labels and worksheet.

Tracking and controlling the drug preparation process.

Managing clinical trials.

Define and manage the hospital formulary, segmentation of the formulary for different areas of the organization, configuration of additional information on how to use/prepare/administer the drug.

Define and manage chemotherapy protocols in accordance with physicians and literature.

Define risk thresholds for dose control (e.g., high-risk or controlled drugs, LASA, ...)

- FARMASAFE@ is used by the **nurse, nursing student** for:

Document the execution of clinical activities, including deviations (non-administration, non-execution, dose change, range change, time change, bag change, pause, stop, and rescheduling).

Trace the drug preparation process and produce the labels and worksheet.

Track the drug delivery process.

- FARMASAFE@ is used by **administrative staff** to:

Creating documents and reports

- FARMASAFE@ is used by all **users** for:

Document the use of traceable products to meet legal requirements.

- FARMASAFE@ is used by all **recipients** for:

Print the prescription and a list of tasks to be performed off-line when the system is unavailable (when the system is down or when the patient is transferred to a department not covered by the system).

All personnel qualified to use FARMASAFE@ must carry out the training activities provided by the manufacturer.

WARNING!

The term "qualified personnel" includes all persons capable of operating and working on the FARMASAFE@ 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 assigned to use the Device must be properly trained by Dedalus s.p.a. and/or hospital facility personnel who have been qualified by Dedalus s.p.a. at the time of installation. The personnel must have the characteristics set forth in the specific section of this document. Compliance with these rules is a prerequisite for ensuring operator and patient safety.

Patient population

No restrictions on the type of patients who can receive benefit from the use of FARMASAFE@ either administratively or clinically.

Usage environment

- Department
- Outpatient clinic
- Pharmacy department
- Inpatient department
- Pedriatic department

Warnings and precautions

- The software is intended for professional use only. Personnel must be qualified and adhere to the principles of good work practice. All user documents provided must be read before using the software.
- To avoid computer virus or abnormal operation of FARMASAFE@, 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 s.p.a. 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 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 Ltd. Customer Service to solve the problem encountered as soon as possible.
- Customer Services Dedalus s.p.a is available for clarification and/or intervention by specialized personnel. All maintenance activities must be performed strictly by personnel authorized by Dedalus s.p.a. Service performed by unauthorized persons may impair the function of the software. Dedalus s.p.a assumes no responsibility for damage or injury caused by service performed by unauthorized personnel.
- Data provided by FARMASAFE@ to other applications must be processed by an educated person before making a medical decision or providing treatment to the patient.
- Selecting the right patient during documentation and accurately associating bed and patient in FARMASAFE@ are very important to ensure that data are assigned to the correct patient
- The user must assess the plausibility of any computational result generated by FARMASAFE@ before using it for clinical decisions.

Contraindications

- FARMASAFE@ does not independently diagnose any specific disease. FARMASAFE@ is not intended to be used as the sole source of information for making decisions with diagnostic or therapeutic purposes.
- FARMASAFE@ does not make any clinical decisions regarding the patient. Prescribing is completely the responsibility of the licensed health care provider. The performance of the activities and the administration of the medication are the complete responsibility of the licensed health care provider.
- FARMASAFE@ should not be used as the sole means of communicating prescriptions, orders, execution information. Data provided by FARMASAFE@ to other applications must be processed by an educated person before making a medical decision or providing treatment to a patient. The user must evaluate the plausibility of any computational results generated by before using them for clinical decisions.
- FARMASAFE@ can be used for documentation of additional treatment.
- FARMASAFE@ does not support the definition of parenteral nutrition and does not provide calculations or information necessary for this purpose. Documentation of parenteral nutrition is purely additional to the documentation required by regulations and good clinical practice for such products. Proper documentation of these aspects is the responsibility of the user and must be done by means external to FARMASAFE@.
- FARMASAFE@ is not authorized to be used to support direct management of dispensing robots without human control before dispensing to the patient.
- The use of FARMASAFE@ to support direct prescription management of respiratory and aesthetic machines is not authorized.

FARMASAFE@ is not suitable for the lay user. Only the professional user can be allowed to use the system.

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 the ordinary life cycle.

HW&SW REQUIREMENTS (CLIENT)

Hardware Requirements

Server side

The resources needed for the virtualization system can be provided with a server of the type:

- No. 2 CPUs E5520@2.2GHz (minimum)
- NO. 24 GB RAM
- No. 2 SAS 15K Rpm 320 GB disks in Raid 1 configuration
- The server will need to be on the list of HW certified by VmWare
- Software Needed List:
  - No. 01 VmWare Esxi 5.1 HYP license or later
  - No. 04 Oracle Enterprise Linux 6.X or later licenses
  - No. 01 Oracle Database Server 11G License or 19C License or PostgreSQL 12

Client side

Device capable of using one of the indicated browsers and equipped with a configurable screen with one of the following resolutions:

- 1024*768 resolution, optimal for the classic interface.
- Recommended minimum resolution 1280*800, optimal for material design interface.

Software Requirements client side

Server side

- Java 1.8.0_202
- Tomcat 9.0.19 with 4GB di RAM (handling 200 concurrent users)[1]
- Apache 2 WEB Server 2.4 with "mod_proxy_wstunnel" module or HAProxy
- Connecting Apache/Tomcat
- Port availability: HTTP (80) HTTPS (443)

Client side

As of, version 4.0.0, FarmaSafe@ can guarantee operation on the following browsers:

oChrome 48 (or higher)

oFirefox 43 (or higher)

oEdge

oExplorer IE9 (or higher) WITHOUT COMPATIBILITY

oSafari

OpenShift

If deploying in Red Hat OpenShift 4, it is necessary that the environment conforms to the SOUP description document.

Minimum requirements for memory and CPU are::

- CPU_REQUEST: 200m
- MEMORY_REQUEST: 600Mi
- CPU_LIMIT: 3000m
- MEMORY_LIMIT: 2400Mi

These values are intended as minimum parameters, to be changed on an ad hoc basis in case of specific needs.

This technology upgrade is required to finally boast multi browsing.

A pdf viewer is required on the client for print management; Adobe Acrobat Reader and IE9 (or higher) or Firefox 43 (or higher) browsers must be installed to support silent label printing.

Adobe Acrobat Reader, preferably to have no additional confirmation messages when printing, must be configured appropriately and, to facilitate the execution of printouts must be activated among the programs that start when the computer is started. However, the application supports all versions from 6 or later.

The label printer must be thermal; the label size is 10X6; the A4 printer must be set as the default in the operating system; the name of the label printers is valued in an application configuration file, so the name of the label printers must be the same at each location (e.g., LabelsFacop).

Optical barcode readers must be configurable to read the following encodings simultaneously:

- Code 39: format of barcodes produced by the application (e.g., barcode present on labels);
- Code 32 (or Pharmacode): the format of the AIC code found on Italian drug packages;
- Interleaved 2/5: code format found on some foreign drug packages.