P4C

SAFETY AND PERFORMANCE INFORMATION

1 General information

REF: P4C

BASIC UDI DI: 805572803P4CK7

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

2 Intended use

P4C Drug Therapy module is intended to be used in a hospital for managing the workflow of drugs from the prescription by doctors to the administration by nurses to the patient, after the validation and dispensation by the pharmacy. It provides care givers an overview of past, present and intended future medications of a patient.

Support for clinical decision is provided by:

- **displaying relevant patient data,**
- **integrating scientific databases for reference, and**
- **medication safety checks.**

C4C Score calculation & display and **Balance calculation & display** functions are intended to document derived medical data to support clinical workflows and to review trends in order to support diagnostic and therapeutic decisions.

3 Indication and intended users

P4C is used by the **physician and medical resident** to:

- Create, edit, and update any type of prescription on service, procedure, drug, and device.
- Prescribing with the help of protocols (The configuration of these prescription templates is done by physicians and/or pharmacists in the master data).
- Define and prescribe a patient care plan, in conjunction with other clinical professionals, supported by protocols,
- View clinical decision support information during prescriptions via alerts generated from third-party databases (DSS) or user-defined in master data.
- Gather clinically relevant information.
- Review patient health conditions, data trends, and plan of care.

P4C is used by the **pharmacist** to:

- Obtain support across the entire pharmaceutical validation workflow of the set of hospital drug prescriptions for all patients.
- Monitor and propose pharmaceutical substitution and inquire about other interventions.

- Manage the indirect supply of medications actually needed to accomplish the reordering of medications to a department and patient at the point of care.
- Definition and maintenance of the hospital formulary, segmentation of the formulary for different areas of the organization, default prescription and administration configuration, and additional information on how to use/prepare/administer the medication.
- Definition of alert threshold for dose control and level of severity of drug interaction (e.g., high-risk drugs or narcotics, LASA,..)

P4C is used **by the nurse, nurse resident, and other healthcare professionals** to:

- Document the performance of clinical activities (administering, not administering, not performing, dosage change, rate change, time change, bag change, pause, stop, and reschedule).
- Transfer consumption to inventory management systems.
- Gather information about the patient's condition, problems, needs, and clinical observations such as vitals, scales, and scores.
- Create, edit, and update orders for care planning and prescribing on behalf of a physician when authorized (e.g., emergency situation).
- Review patient health conditions, data trends, and plan of care.

P4C is used by the **nursing assistant** to:

- Document execution of clinical activities (execution, non-execution, bag change, pause, stop and reschedule activities under their responsibility).
- Gather information about the patient's condition and clinical observations such as vitals.
- Review patient health conditions, data trends, and plan of care.

P4C is used by **administrative staff** to:

- Search for patient information in the external/internal database and its confirmation
- Create documents and reports
- Bed management
- Administrative management of patient's EMR included (including closure and signature)

P4C is used by all intended users to document the use of traceable products to meet legal requirements.

P4C is used by all intended users to print the prescription and a list of tasks to be performed off-line when no system is available (when the system is down or when the patient is transferred to a department not covered by the system).

All personnel qualified to use P4C must undertake the training activities provided by the manufacturer.

WARNING!

The term "qualified personnel" includes all persons capable of operating and working on the P4C 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 to ensure the safety of operators and patients.

4   Patient population

No limitation on the type of Patients who may receive a benefit from the use of P4C both administratively and clinically.

5   Ambiente di utilizzo

- Department
- Ambulatory
- Pharmacy department
- Emergency Room
- Intensive Care Unit
- Rehabilitation Department
- Pediatric department
- Operating Room
- Lab
- Radiology Department
- Diagnostic service department

6   Warning cautions

- 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 viruses or abnormal operation of P4C, 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 it in environments other than those specified in this manual. Improper use may cause serious damage to people and/or property!
- The software may only be used in accordance with the hardware and software requirements enclosed with this file.
- In this regard, please note that the supported web browser Google Chrome and Mozilla Firefox
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which 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 solve the problem as soon as possible.
- 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.

7   Controindicazioni

- P4C does not take any clinical decision regarding the patient. The prescription is fully under the responsibility of the physician. The activity execution is fully under the responsibility of the physician and the nurse.
- P4C must not be used as sole means for communication of orders execution information. Data provided by P4C to other applications must be handled by an educated person before taking medical decision or providing treatment to the patient. The user must assess the plausibility of any calculation results generated by P4C prior to using them for clinical decisions.
- P4C can be used for documentation of additional treatment.
- P4C does not support the definition of a chemotherapy protocol treatment, neither parenteral nutrition and does not provide calculations or information necessary for this purpose. The documentation of chemotherapy, labile blood products and parenteral nutrition is purely additional to the documentation required by regulations and good clinical practice for such products. Appropriate documentation of theses aspects is the responsibility of the user and must be done by means external to the scope of P4C.
- P4C must not be used for calculating chemotherapy dosage and compound dosage, radioactive products dosage but as described earlier, additional documentation is authorized to save information related to those prescriptions to have a global view on the patient treatment.
- P4C must not be used to support direct management of dispensation robots or prescription of respiratory and aesthetic machines.
- Selecting the right patient during documentation and accurate association of bed and patient in P4C are very important in order to ensure that data is allocated to the correct patient.
- P4C should not be used to support direct management of dispensing robots or prescribing of respiratory and aesthetic machines.
- Selection of the right patient during documentation and accurate bed and patient association in P4C are very important to ensure that data are assigned to the correct patient.

8   Device lifetime

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 of 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.

9   Hw&Sw Requirement (CLIENT)

9.1   Hardware Requirements client side

- Minimum Configuration
- 1 gigahertz (GHz) or higher, 32-bit (x86) or 64-bit (x64) processor
- 4GB RAM
- Monitor Resolution 1366x768
- 10/100/1000 Mbps network connection
- Optimal configuration
- 2 gigahertz (GHz) or higher, 32-bit (x86) or 64-bit (x64) processor
- 8GB RAM
- Monitor Resolution 1920x1080
- 100/1000 Mbps network connection

For the use of secure administration, i.e. administration by reading the AIC code of the drug, both from CareManager and Patient Chart it is necessary to use Bar Code Readers, the specifications are given below:

9.1.1   Lettori Barcode

The reader must have several characteristics:

- It must be wireless because the medication cart is unlikely to reach the bedside.
- Must not disconnect from its base (which also acts as a charger)
- It must allow for automatic reading, like supermarket checkouts. So the nurse passes the drugs being set up and administered, keeping his hands free, only then does he hold the gun and read the patient bracelet.
- The reader shall also be programmable in reading to include and exclude codes.

Example of devices already used elsewhere or during our quality assurance tests

- Zebra ds2208
- Inateck wireless 2D BCST-50
- Gryphon™ 2D GM4500

To use the secure administration component, smartphones can be used exclusively from CareManager

9.1.2   Smartphone

It is an HTML5 frontend and therefore it is a web page, not an APP.
Devices certified for this use are:

- **Zebra TC51 (Healthcare version)**
- **Datalogic Memor 10 (Healthcare version)**

They can be used with gloves on.

9.1.3   Requisiti software lato client

- Sistema operativo: WINDOWS 7 o superiori;
- Browser: Chrome ver. 77 o superiori, Firefox ver.83 o superiori;
- Java: JRE 7.

10 Clinical benefit

P4C is intended to increase safety of care delivered to a patient by

- prescription error check
- eliminating illegibility issues and the need for transcription, and errors in selected calculations.
- reducing risk of cognitive errors
- adding transparency in the drug prescribing process

P4C allows reduction of the prescription errors.

11 Clinical performance

Increased safety in terms of reduction of the prescription errors.