General Information
REF: O4C
BASIC HEARING OF: 805572803O4CK2

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

Intended Use
O4C is a software that supports data management of surgical and neonatal patients, including planning diagnostic, surgical, and anesthesiological activities, organizing resources and equipment, visualizing patient surgical risks, and defining intraoperative and postoperative patient care.

Directions and user personnel
O4C is a tool that involves different figures within a hospital system:

- **Physicians:** are supported in their planning, clinical assessment, reporting, and operating room activities.

- **Nurses:** are supported in their patient management activities in the various stages of the surgical/birth pathway and in their operating room activities.

- **Radiology technicians:** are supported in their patient management and operating room activities.

- **Perfusionists:** are supported in their patient management and operating room activities.

- **Obstetricians:** they are supported in their patient management, clinical assessment and in their operating room activities.

- **Administrative:** are supported in their planning/organizing activities and resources.

All personnel qualified to use O4C must undertake the training activities provided by the manufacturer.

WARNING!

The term "qualified personnel" includes all persons capable of operating and working on the O4C 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 O4C are all surgical patients who begin a course of waiting for surgery, and who go through the various preparatory stages for the same: the specialist visit, inclusion on a waiting list, performance of the pre-hospitalization and preoperative anesthetic examination, planning of the surgery and its execution, and the subsequent possible stay in a recovery room.

In addition to surgical patients, all patients embarking on a birth pathway following pregnancy benefit from the use of O4C, and consequently the newborns at the time of delivery.

Usage environment
- Outpatient clinic
- Operating room department
- Delivery room

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 O4C, 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.
- For any problems that occur 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

O4C does not make any clinical decisions about the patient. Treatment of the patient is the complete responsibility of the licensed health care provider. The performance of activities and administration of medications are the full responsibility of the licensed health care provider.

O4C is not suitable for an inexperienced user. Only professional users may be allowed to use the system.

Data provided by O4C to other applications must be handled by an educated person before making a medical decision or providing treatment to a patient. The user must assess the plausibility of the results of the generated calculations before using them for clinical decisions.

O4C can be used for documentation of additional treatments.

O4C does not support the definition of chemotherapy treatment or parenteral nutrition and does not provide calculations or information necessary for this purpose.

O4C is not authorized to be used to support direct management of dispensing robots without human control before dispensing to the patient.

O4C may not be used to support direct prescription management of respiratory and anesthesia devices.

O4C may not be used to support direct collection of vital parameters.

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

- QuadCore Processor
- 4GB RAM
- Monitor at least 10"
- Resolution at least 1280x720
- Network speed at least 20Mbps

Software Requirements client side

- Browser: Firefox 54.0.X - Firefox 88.0.X and Chrome 69.0.X - Chrome 90.0.X;

The browsers will be able to be installed on Windows and Linux machines.

Mobile Client Requirements

The software requirements for using the O4C software through the use of browsers on Mobile devices are listed below.

Only the following will be usable on Mobile devices:

- VPO
- Interventions