

**O4C**

**SAFETY AND PERFORMANCE INFORMATION**

## 1 Information general

REF: O4C

BASIC UDI DI: 805572803O4CK2

It's possible view the device label is in the interface graphics of the SW that in the manual user in format paper.

## 2 Intended use

O4C is a software that supports management \_ of the data of the patients surgical and neonatal, including planning from the activity diagnostic, surgical and anaesthesiological, the organisation from the resources and equipment, display of the risks surgical procedures of the patient and the definition of assistance intraoperative and postoperative to the patient.

## 3 Indications and user personnel

O4C is a tool That involves different figures within a system hospital:

- **Doctors:** they are supported in their planning and evaluation activities \_ clinical, reporting and in their operating room activities.
- **Nurses:** they are supported in their patient management activities in various stages of the journey surgical / births and in their operating room activities.
- **Technicians radiologist:** they are supported in their patient management activities and in their operating room activities.
- **Perfusionists:** they are supported in their patient management activities and in their operating room activities.
- **Midwives:** they are supported in their patient management activities, evaluation clinic and in their operating room activities.
- **Administrative:** they are supported in their planning / organizing activities from the activities and resources.

All personnel qualified to use O4C must carry out training activities foreseen by the manufacturer.



### ATTENTION!

The term "qualified personnel" includes all people capable of operating and intervening on the O4C 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 itself.



### 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.

## 4 Patient population

The patients that can benefit of use of the O4C they are all the patients surgical that they begin a process of waiting for an intervention , and that go through the various ones phases preparatory at the same: the visit specialist, inclusion in a list waiting, execution of pre-hospitalization and visit pre-operative anaesthetic, planning of the intervention and his execution, and the next possible stay in a recovery room.

In addition to the patients surgical, all patients. That they embark on a journey birth following a pregnancy they benefit of use of the O4C, and consequently the newborns at the time of birth.

## 5 Usage environment

- Clinic
- Department of the operating room
- Delivery room

## 6 Warnings and precautions

- The software is intended exclusively to use professional. All the documents user provided they must to be read before using the software.
- To avoid computer viruses or operation O4C abnormal, do not never download any software other than that provided by Dedalus. The user is authorized to change the behavior of the software only by modification the software configuration parameters described \_ in the documentation user.
- The software can be used only for the purpose expected for which it was designed and as contractually agreed with Dedalus. Do not use it for any purpose different from those specified. In the present manual. Do not use in environments different from those indicated in this manual. Use improper can cause serious damage to people and/or things!
- Any serious accident that occurred in connection with the device \_ needs to to be reported to the manufacturer and the authority qualified of the State member in which it is established the user and/or the patient.
- For any problem That Yes check during use and in every case not mentioned here \_ document and/or attachments, contact the Service Dedalus customers to solve the problem found In the shortest time possible.
- Dedalus Customer Services is available for clarifications and/or interventions by specialized personnel. All maintenance activities \_ they must to be performed strictly by personnel authorized by Dedalus. The service carried out by unauthorized persons can compromise the function of the software. Dedalus assumes no responsibility for damage or injury caused by the service carried out by unauthorized personnel.

## 7 Contraindications

O4C does not make any decisions clinic regarding the patient. The patient 's treatment is under complete responsibility of the operator healthcare authorized. The execution from the activities and administration of the drugs I'm under complete responsibility of the operator healthcare authorized.

O4C is not suitable for a non- expert user. Only them users professional can to be authorized to use the system.

The data provided by O4C ad other applications they must to be handled by an educated person before taking a medical decision or to provide treatment to the patient. The user needs to evaluate plausibility \_ of the results of the calculations generated before using them for decisions clinics.

O4C can to be used for documentation of treatments additional.

O4C does not support defining a treatment chemotherapy, nor nutrition parenteral and does not provide calculations or information necessary for this purpose.

It is not authorized the use of O4C to support management direct of dispensing robots without control human before \_ distribution to the patient.

It is not allowed use O4C to support management direct from the device prescription \_ respiratory and anaesthesiological.

It is not allowed use O4C to support collection direct of the parameters vital.

## 8 Useful life of the device

Dedalus yes reserves the right to discontinue the software products or software versions specific to one series of motifs, included products / versions That they become obsolete or replaced by new ones products / software versions. Furthermore, DEDALUS yes reserves the right to discontinue support for systems \_ operational obsolete and/ or platform support specifications (e.g., Windows /Mac/Linux) for i own products.

Maintenance for one \_ specific version of the DEDALUS products is generally available until 12 months after such release was \_ \_ replaced by one more recent. The versions That they go out from the 12 month support window \_ are considered to have reached the end of their normal life cycle.

## 9 Hw&Sw requirements

### 9.1 Client-side hardware requirements

**Client-side Hardware Requirements Desktop** – we recommend a device with at least:

- 4GB RAM
- Processor Quad Core
- Monitor at least 10"

- Resolution at least 1280x720
- Network speed at least 20Mbps

**Mobile client-side hardware requirements** – Only the following can be used on mobile devices:

- VPO
- Interventions

We recommend a device with at least:

- 2GB RAM
- Processor Quad Core
- 10"-13" monitors
- Resolution at least 1280x720
- Network speed at least 20Mbps

## 9.2 Client-side software requirements

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**Desktop client-side software requirements** – The requirements are listed below required on browsers:

- Firefox 102.0.X and later
- Chrome 109.0.X and later
- Edge 109.0.X and later

The browsers can be installed on Windows and Linux machines.

**Mobile client-side software requirements** – Only the following can be used on mobile devices:

- VPO
- Interventions

The minimum browser requirements are listed below:

- Firefox 102.0.X and later
- Chrome 109.0.X and later
- Edge 109.0.X and later

The browsers can be installed on IOS, Android and Windows Mobile tablets.

## 10 Clinical benefit

The advantages of the O4C system are many, not only in terms of reliability in managing the surgical and birth process and reduction of clinical risk, but also in terms of:

- Real-time availability of any patient's clinical documentation, with a complete and always updated view of their path.

- Elimination of repetitive and transcription work, with reduction of the risk of errors, considerable time saving for compiling reports and planning operating rooms.
- Automatic updating of the various agendas, with the possibility of monitoring all the main activities in real time.
- Constant monitoring of workloads and materials used in the operating room.

## 11 Clinical performance

Greater safety in terms of reduced errors in route planning, execution and recording surgery and the patient's birth path.