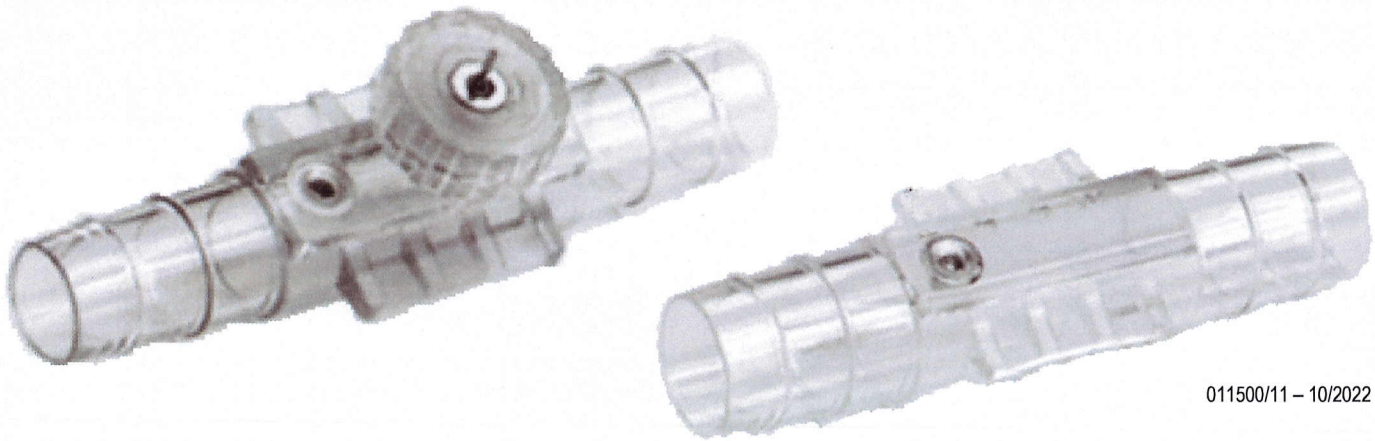
LivaNova

Health innovation that matters

SORIN | DATAMASTER

Arterial pO_2 - Venous SAT/HCT Disposable Connectors • Connettori monouso per pO_2 Arteriosa - SAT/HTC Venosa • pO_2 Artériel - SAT/HTC veineux Connecteurs jetables • Arterieller pO_2 - Venöse SAT/HCT Anschlüsse füe Einmalgebrauch • pO_2 arterial - SAT/HCT venoso Conectores desechables • Conectores descartáveis para pO_2 arterial - SAT venosa/HCT • Αναλώσιμοι συνδετήρες για αρτηριακή pO_2 - φλεβικό SAT/HCT • Arteriële pO_2 Veneuze SAT/HCT Disposable Connectors • Arteriel pO_2 - Venös SAT/HCT Prober för engångsbruk • Engans Connectors Arteriel pO_2 - SAT/HCT Venom • Kertakäyttöiset pO_2-valtimoliittimet ja SAT/HCT-laskimoliittimet • Arteriell pO_2 - venøse SAT/HCT-kontakter til engangsbruk • Konektory k jednomu použití: arteriální pO_2 a venózní SAT/HCT • Złacze tetnicze z czujnikiem pO_2, złacze Zylne z pomiarem SAT/HCT • Jednorazové konektory arteriálny pO_2 - venózny SAT/HCT • Priključki za merjenje pO_2 v arterijski krvi in nasičenja/hematokrita v venski krvi za enkratno uporabo • Artériás pO_2 - Vénás SAT/HCT eldobható csatlakozók • Arterinė pO_2 - veninė SAT/HCT vienkartinės jungtys • Arteriaalne pO_2 - Venoosne SAT/HCT, ühekordelt kasutatavad konnektorid • Arteriālais pO_2 un venozais saturācijas/hematokrita savienotāji, vienreizlietojami • Conectori de unică folosință pentru pO_2 arterial - SAT/HCT venos • Артериален pO_2 - Венозен SAT/HCT конектори за еднократна употреба • Atardamar pO_2 - Toplardamar SAT/HCT Tek Kullanimlik Konektörler • Одноразовые коннекторы для контроля pO_2 в артериальной крови и сатурации и гематокрита венозной крови • Arterijski pO_2 - venski SAT/HCT konektori za jednokratnu upotrebu • Arterijski pO_2 - Priključci za zasićenost i hematokrit venske krvi za jednokratnu uporabu • Артеріальний pO_2 - Венозні одноразові з'єднувачі SAT/HCT



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CONTENTS

A. DESCRIPTION

The Datamaster venous and arterial connectors are polycarbonate connectors equipped with pO_2 sensor (arterial only) and a metal well for temperature measurement.
The pO_2 sensor operates through an electro-chemical sensor. Temperature measurement is made through the temperature probe well integrated in both arterial and venous connectors. Arterial and venous probes carry a temperature probe, coupling with the probe well of the connectors.
The devices are single use, non-toxic, apyrogenic, supplied **STERILE**. The venous and arterial connectors are sterilised with ethylene oxide. The level of ethylene oxide residuals in the device is in conformity with the provisions of the legislation in force in the country of use. The arterial connector complete of pO_2 electrode sensor is sterilised by β irradiation.
The following device models are available:

VSAT VENOUS CONNECTOR FOR MONITORING OF VENOUS OXYGEN SATURATION AND HEMATOCRIT (connector with integrated temperature probe well, Fig. 2)

ApO_2 ARTERIAL CONNECTOR FOR MONITORING pO_2 (connector with integrated temperature probe well and pO_2 Clark electrode sensor, Fig. 1)

B. CLINICAL BENEFIT

The main benefit associated to the usage of the Datamaster connectors is to allow the Datamaster or B-Care5 equipment to perform according to its specifications and intended purpose.

C. TECHNICAL FEATURES

Device	Type	Max. blood flow rate (l/min)	Connectors size: (inches)
V12SAT	Venous	8.0	1/2" (12.7 mm)
V38SAT	Venous	5.0	3/8" (9,53 mm)
A38pO_2	Arterial with pO_2 sensor	8.0	3/8" (9,53 mm)
A14pO_2	Arterial with pO_2 sensor	5.0	1/4" (6,35 mm)

The connectors are made of polycarbonate with an integrated metal well for temperature measurement (Fig. 1 and 2, ref. 1).

D. INTENDED USE

INTENDED PURPOSE

The Datamaster venous and arterial connectors are devices used as part of the extracorporeal circulation circuit when it is required the monitoring of oxygen venous saturation (SO_2), haematocrit (Hct), venous temperature (venT), arterial partial oxygen pressure (pO_2) and arterial temperature (artT).
The devices are intended to be used for 6 hours or less.

PATIENT TARGET GROUP(S)

The devices are indicated for adults and pediatric patients.

LIMITATIONS

The devices are used in operating rooms. The arterial connectors must only be used with the Datamaster equipment, the venous connectors can be used together with Datamaster and B-Care5 equipments. The Datamaster can be used with the devices listed in paragraph K (MEDICAL DEVICES FOR USE WITH THE PRODUCTS).

INTENDED USERS

The Datamaster connectors should be used by qualified and skilled personnel, able to follow the indications and instructions for use contained in the information provided by the manufacturer.

E. INDICATIONS FOR USE

The devices are indicated for use in adult and pediatric patients undergoing surgical procedures requiring cardiopulmonary bypass.

F. CONTRAINDICATIONS

No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions.
Do not use the device for any purpose other than indicated.

G. SAFETY INFORMATION

Information to attract the attention of the user to potentially dangerous situations and to ensure correct and safe use of the product is indicated in the text in the following way:

WARNING

WARNING Indicates serious adverse reactions and potential safety hazards for the practitioner and/or the patient that may occur in the proper use or misuse of the device as well as the limitations of use and the measures to be adopted in such cases.

PRECAUTION

PRECAUTION Indicates all possible precautions the user must adopt for safe and effective use of the device.

SYMBOLS ON DEVICE LABELS

Explanation of the symbols on device labels is provided in the dedicated addendum "EXPLANATION OF THE SYMBOLS USED ON THE LABELS".

The following is general safety information to advise the operator when preparing to use the device.
Specific safety information is also given in the instructions at locations in the text where that information is relevant for correct operation.

WARNING

- **The user should carefully check the device during set-up and priming for leaks. Do not use if any leaks is detected.**
- **The device must only be used if STERILE.**
- **The arterial connector must be used following these instructions for use and the Data Master user's manual. The Venous connector must be used following these instructions for use, the Data Master user's manual and the B-Care5 user manual.**
- **For use by professionally trained personnel only.**
- **FRAGILE, handle with care.**
- **For single use and for single-patient use only: during use the device is in contact with human blood, body fluids, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. Due to its specific design it cannot be fully cleaned and disinfected at the end of use. Therefore, reuse on other patients might cause cross-contamination, infection and sepsis. In addition, reuse increases the probability of product failure (integrity, functionality and clinical effectiveness).**
- **Sterile Contents/Non-Pyrogenic Fluid Pathway unless package is opened or damaged.**
- **The device and its accessories must be handled applying sterile techniques.**
- **The device must not undergo any further processing.**
- **Do not resterilize.**
- **Always administer and maintain correct anticoagulant dosage before, during and after the bypass and provide its correct monitoring.**
- **Keep dry. Store at room temperature.**
- **After use, dispose of the device in accordance with applicable regulations in force in the country of use.**
- **Dispose of unused device in accordance with applicable regulations in force in the country of use.**
- **When using the device in conjunction with other CPB devices, always consider that the most restrictive of all flow rate range and time duration indications reported on the IFUs will set the limits for all the devices constituting the CPB system.**

PRECAUTION

- **Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.**
- **User and/or Patient should report to the manufacturer all serious incidents occurred in relation to the device. If the user and/or patient is established in a Member State of the European Economic Area, incident has to be reported also to the competent authority of the Member State in which the user and/or patient is established.**
- **For further information and/or in case of complaint contact SORIN GROUP or the authorized local representative.**

The following table summarizes harms potentially arising during the use of the medical device, including those related to side effects.

Systemic Inflammatory Response Syndrome (SIRS)
Embolism
Hypovolemia
Sepsis / Infection
Fever / Shock
Allergic reactions
Irritation
Cyto-toxic reactions
Cross contamination
User contamination
Environment contamination
Thrombosis / Bleeding
User skin tears
Hypersensitivity reactions
Genetic mutation
Cancer
Reprotoxic effects*
Transient blood gas imbalance

*The device contains 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannate-tradecanoate (DOTE). Considering the nature of body contact, the limited contact duration and the number of treatments per each patient, the amount of DOTE which might be released from the device do not raise specific concerns about residual risks.

H. PREPARATION AND SET-UP

WARNING

- **Do not use if sterile packaging is damaged, unsealed, or has been exposed to moisture or other conditions that would compromise the sterility of the device.**
- **Check the expiry date on the attached label. Do not use the device after the date shown.**
- **The device must be used immediately after opening the sterile packaging.**
- **The device must be handled aseptically.**

Remove the device from its sterile packaging.

WARNING

- **Carry out a visual inspection and carefully check the device before use. Transportation and/or storage conditions other than those prescribed may have caused damage to the device.**
- **Do not use solvents such as alcohol, ether, acetone, etc., as contact may cause damage to the device.**
- **Do not allow halogenated liquids such as Halothane and Fluothane to come into contact with the polycarbonate housing of the device. This could cause damage which may compromise the integrity and proper functioning of the device.**

1. VENOUS CONNECTOR

1. Remove the caps one at the time and connect the device to the venous line of the extracorporeal circuit, following the direction of blood flow as indicated by the arrow.
2. All connections must be secured by means of ties.
3. Place the venous probe in the specific parking and calibration site located on Data Master.
4. After completing calibration, remove the protection film from the connector window and attach the venous probe.

2. ARTERIAL CONNECTOR

1. Remove the protection cap from the pO_2 sensor.
2. All connections must be secured by means of ties.

PRECAUTION

Check that the sensor is screwed on safely to the arterial connector pos-lock (Fig.3).

3. Connect the pO_2 sensor to the arterial probe.
4. Begin calibration procedure.
5. When calibration is completed, removed the caps one at the time and connect the device to the arterial line of the extracorporeal circuit, following the direction of blood flow as indicated by the arrow.

If an arterial connector without pO_2 sensor is already included in the extracorporeal circuit arterial line:

a) Complete the procedure up to point 4.

b) When calibration is completed, disconnect the arterial probe from the pO_2 sensor , unscrew it (Fig. 1, ref. 2) using sterile method and remove it from the connector.

c) Remove the cap from the connector on the arterial line, screw the pO_2 sensor onto the pos-lock connection (Fig. 3) and return the arterial probe to the connector belonging to the extracorporeal circuit.

I. PRIMING AND RECIRCULATION PROCEDURE

WARNING

- **During priming procedure check for leaks. Do not use if any leaks is detected.**

Prime and debubble the Data Master connectors as follows:

1. While priming the oxygenator, prime the arterial and venous lines at flow rate ranging from 100 to 800 ml/min according to oxygenator size.
2. Tap the Data Master connectors until complete debubbling is reached. Make sure that no air bubbles are present inside the device prior use.
3. When oxygenator is primed increase main pump flow to the maximum value allowed by the oxygenator.

PRECAUTION

- **Prolonged contact time with priming solutions may alter device performance.**

J. DEVICE CHANGE-OUT

A spare device must always be available during perfusion. After 6 hours of use with blood or if situations occur, which lead the person responsible for perfusion to determine that the safety of the patient may be compromised, consider device replacement.
After replacing the device, calibration must be repeated.

PRECAUTION

Use sterile technique during the entire replacement procedure.

K. MEDICAL DEVICES FOR USE WITH THE PRODUCTS

PRECAUTION

- **The user should observe the warnings and precautions and follow instructions for use accompanying the devices.**

No counter-indications exist for the use of the products with any oxygenation system and cardiopulmonary bypass circuit, provided that lines have a size compatible with the connectors themselves (ref. paragraph C. TECHNICAL FEATURES).
The arterial connectors must only be used with the Datamaster equipment, the venous connectors can be used together with Datamaster and B-Care5 equipments.

L. RETURN OF USED PRODUCTS

Should the user be dissatisfied with anything related to the quality of the product, he may notify the distributor or the local representative authorised by SORIN GROUP ITALIA.
All notifications considered critical by the user must be reported with particular care and urgency. Below is the minimum information which must be provided:

- Detailed description of the event and, if pertinent, the conditions of the patient;
- Identification of the product involved;
- Lot number of the product involved;
- Availability of the product involved;
- All the indications the user considers useful in order to understand the origin of the elements of dissatisfaction.

SORIN GROUP reserves the right to authorise, if necessary, recall of the product involved in the notification for assessments. If the product to be returned is contaminated, it must be treated, packed and handled in conformity with the provisions of the legislation in force in the country where the product has been used.

PRECAUTION

It is the responsibility of the health institution to prepare and identify the products for recall shipments. Do not return products that have been exposed to blood borne infectious diseases.

ONLY for US customers

If for any reason the product must be returned to the manufacturer, a returned good authorisation (RGA) number is required from LivaNova USA, Inc. prior to shipping.

If the product has been in contact with blood or blood fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton to prevent damage during shipment, and it should be properly labelled with an RGA number and an indication of the biohazardous nature of the content in the shipment.

The shipping address for returned goods in the US is:

LivaNova USA, Inc.
14401 West 65th Way
Arvada, CO USA 80004

M. LIMITED WARRANTY

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.

SORIN GROUP ITALIA warrants that all reasonable care has been taken in the manufacture of this medical device, as required by the nature of the device and use for which the device is intended.
SORIN GROUP ITALIA warrants that the medical device is capable of functioning as indicated in these instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging.
However, SORIN GROUP ITALIA cannot guarantee that the user will use the device correctly, nor that the incorrect diagnosis or therapy and/or that the particular physical and biological characteristics of an individual patient, do not affect the performance and effectiveness of the device with damaging consequences for the patient.
Therefore, SORIN GROUP ITALIA, whilst emphasising the need to adhere strictly to the instructions for use and to adopt all the precautions necessary for the correct use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from the improper use of this device.
SORIN GROUP ITALIA undertakes to replace the medical device in the event that it is defective at the time of placing on the market or whilst being shipped by SORIN GROUP ITALIA up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser.
The above replaces all other warranties, explicit or implicit, written or verbal, including warranties of marketability and/or functionality. No person, including any representative, agent, dealer, distributor or intermediary of SORIN GROUP ITALIA or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressly stated herein. SORIN GROUP ITALIA disclaims any variations to the Warranty terms and to the information instructions for use as explicitly contained herein. The purchaser undertakes to comply with the terms of these Warranty terms and in particular agrees, in the event of a dispute or litigation with SORIN GROUP ITALIA, not to make claims based on alleged or proven changes or alterations made to these Warranty terms by anyone in contrast and/or in addition to what is herein agreed.
The relationship between the parties regarding the contract (even if not stipulated in writing) to whom this warranty is issued, as well as any dispute related to it or in any way connected with it, as well as any relationship or dispute concerning this warranty, its interpretation and execution, nothing excluded and/or reserved, are governed exclusively by Italian law and jurisdiction. The court appointed in the event of the above-said disputes shall exclusively be the Court of Modena (Italy).