NISSHA
MEDICAL TECHNOLOGIES

INTEGRAL PROCESS
Cables & Leadwires

INSTRUCTIONS FOR USE
SpO_2 Cables

- TEMPERATURE LIMITS
- PROTECT FROM MOISTURE
- LOT CODE
- QUANTITY
- EXPIRY
- MEDICAL DEVICE
- SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT
- CAUTION
- NON-STERILE
- MANUFACTURER
- LATEX FREE
- READ INSTRUCTIONS FOR USE
- REFERENCE
- EC ACCORDING TO EU MDR 2017/745

The classification rules may vary from country to country. According to the EU MDR 2017/745 or the **Australian D Regulations, SpO_2 connection cables** are products of **Class I.** According to the rules of **FDA (USA) or Canada, SpO_2 connection cables are Class II.**

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

ISO 13485:2016
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EN ENGLISH

SpO_2 CABLES

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. IDENTIFICATION / FIELD OF APPLICATION

IDENTIFICATION
The **SpO_2 interface cable**, designed by **Nissha Medical Technologies**, is the component which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

The **interface cable** can only be used with the electromedical device (pulse oximeter) for which it has been designed. This is shown either on the device or on its packaging. The compatible devices (sensors, fastening equipment, etc.) are listed in the **Nissha Medical Technologies** commercial catalogue **(COMM/DOCU001/018)** which can be viewed and downloaded on the company's website at HS.Nisshamedical.com/ifu.

FIELD OF APPLICATION
The **Nissha Medical Technologies** SpO_2 interface cable can be used with any patient (adult, infant, neonates) wherever the arterial oxygen saturation needs to be measured using the non-invasive method.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES
The envelopes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Nissha Medical Technologies offers a full range of **SpO_2 interface cables**.

If you wish to place any subsequent orders, please use the code number shown either on the **Nissha Medical Technologies** SpO_2 interface cable or on its packaging;

For further information about this product, please either contact Nissha Medical Technologies or visit the company's website at www.NisshaMedical.com.

II. STORAGE / PACKAGING / SYMBOLS

STORAGE

The storage conditions for **SpO_2 interface cables** are as follows:

- Ambient temperature: 10 to 50 °C- 50 to 122 °F

PACKAGING

Nissha Medical Technologies SpO_2 interface cables are packaged individually.

When it is not in use, the **Nissha Medical Technologies SpO_2 interface cable** must be stored in its original packaging in order to prevent any damage which might reduce its service life, performances and/or safety level.

III. PERFORMANCES / RELIABILITY / SAFETY / COMPATIBILITY / MECHANICAL and ELECTRICAL INTEGRITY / SYMBOLS / ALLERGICITY

PERFORMANCES / RELIABILITY

Nissha Medical Technologies SpO_2 interface cables are inspected both during and at the end of the manufacturing process according to protocols drawn up in line with the specifications of current standards and regulations on this type of product.
The final results of the tests, which have been carried out on a group of representative types of cables according to a technical protocol drawn up by **Nissha Medical Technologies** , have been confirmed by an accredited Laboratory.

(Gmed technical report no. 5358010/1T)

They have also undergone clinical testing and assessments.

SAFETY

Nissha Medical Technologies SpO_2 interface cables are designed and manufactured in accordance with the general and special specifications of the relevant current European and/or international standards:

(Standards EN IEC 60601-1 / EN ISO 9919, etc.)

Nissha Medical Technologies SpO_2 interface cables are an integral part of the "applied part" to the patient as defined by the **EN IEC 60601-1** International safety standard.

The **SpO_2 interface cable's safety class, type of protection (BF, CF)** and **degree of protection** against electric shocks are closely linked to those of the electromedical device to which it is connected.

Low frequency leakage currents, measured in accordance with the recommendations of the current standards which are applicable to this product, are below the authorised values for the highest safety level.

WARNING

- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.

PLEASE NOTE

Nissha Medical Technologies may not be held liable for any incidents which might occur to the patient, to the user and to any other persons caused by the presence of dangerous electrical currents coming from the electromedical device if there is any fault at all.

COMPATIBILITY

On the company's website (www.NisshaMedical.com), Nissha Medical Technologies offers its customers a downloadable document including information on the device's compatibility along with technical details about it.

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MECHANICAL and ELECTRICAL INTEGRITY

In order to ensure that the SpO_2 interface cable offers good mechanical resistance to traction and to flexion and to reduce any leakage currents which might travel through the patient, **Nissha Medical Technologies** uses high quality materials for the manufacturing of the devices.

The moulded connectors are fitted with soft inserts designed to minimise the risk of the cable breaking at this point.
The contact surface of the connector pins is treated in such a way as to reduce the contact resistance between two pins as far as possible even after a large number of connections and disconnections.

(Test report no. CPB1097 – CPB1897/CPB2897)

Nissha Medical Technologies SpO_2 interface cables can withstand repeated defibrillation shocks. They have no accessible metal parts.

When it is not in use, a cable must be stored in its original packaging in order to prevent any untimely damage to its insulating sheath and its conductors which might reduce its lifetime, performances and/or safety level.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:


or


Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ALLERGICITY

The insulating materials used to manufacture **Nissha Medical Technologies SpO_2 interface cables** have been subjected to allergicity tests. These tests have not shown the presence of any products which might develop an intolerable allergic reaction.

IV. INSTALLATION / USE / MAINTENANCE / HYGIENE / STERILISATION

INSTALLATION

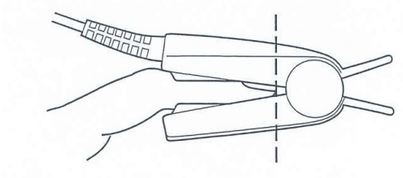
Please follow these instructions for optimum installation and operation of the **SpO_2 interface cable**:

(see also the instruction manual for the particular electromedical device)

On the patient's side:

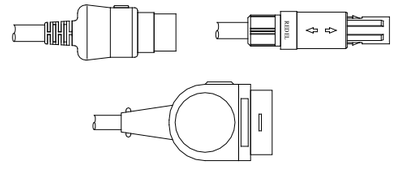
- First of all connect the interface cable to the appropriate **SpO_2 sensor**.
- Place the **SpO_2 sensor** on the chosen site on the patient, which must be suitable for the measurement, referring to the instructions in the leaflet which came with the particular electromedical device. Make sure the SpO_2 sensor suits the patient (adult, infant, neonate)

Example below showing how to position the sensor on the finger:



Do not push the finger in too deeply

Examples of plugs:



On the device's side:

- Connect the **SpO_2 interface cable** to the appropriate device (pulse oximeter).
- Start the device and make sure that it is working properly by reading the instruction leaflet for the electromedical device.

HOW TO USE:

GENERAL CONDITIONS
The conditions for using the **Nissha Medical Technologies SpO_2 interface cable** are as follows:
- Ambient temperature: 10 to 50 °C- 50 to 122 °F

SPECIAL CONDITIONS
- **Do not use an SpO_2 interface cable if there is any risk to the patient (e.g. damaged insulating material).**

PREVENTIVE MAINTENANCE
The service life of the **SpO_2 interface cable** depends on a large number of parameters e.g.
- How many times it is applied
- Adherence to preventive maintenance
- Being kept in a good state of hygiene

A regular visual and electrical inspection of the conductors will determine whether the **SpO_2 interface cable** needs to be replaced.

WARNING:
⚠ **If you need to take a cable out of the department to another department for maintenance or expertise, it is the responsibility of the department which has made use of the cable to clean and disinfect it before transferring or moving it.**

CORRECTIVE MAINTENANCE
- There is no corrective maintenance for this product. If it is damaged it must be discarded immediately.

HYGIENE

PLEASE NOTE:
Do not allow any liquid to get inside the various connectors on the interface cable.

When using the **Nissha Medical Technologies SpO_2 interface cable** in departments where a level of sterility must be adhered to, you must proceed to use the cleaning and/or disinfection methods described below.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
CAUTION	When cleaning or disinfecting the cables make sure that the plugs at the end of the cables do not become immersed in any liquid to avoid any electrical problems
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

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Automatic cleaning:	Is strictly not applicable
Manual cleaning:	• Clean the **Nissha Medical Technologies SpO_2 interface cable** and its connecting cable (including the connector) with a cloth soaked in soapy warm water
Disinfection:	**(Taken from the study by the ANIOS Laboratory, no. 6416.94/0387)** **Method A** • fill a dip tank with a 0.5% HEXANIOS G+R solution • partially immerse the cable keeping the ends dry in order to avoid any electrical problems on the connectors • allow a contact time of 15 minutes • rinse the cable • dry the cable with absorbent paper • during the immersion rub the ends of the cable using a LINGET ANIOS wipe. **(Replace the solution every 48 hours)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Please follow the standard protocol of packaging of your institution before sterilization
Sterilization: ⚠	• sterilization time: 22 hours which takes into account 20 hours of gas exposure • sterilizing agent: Carbon Dioxide + Ethylene Oxide (80/20%) • initial vacuum: -70 kPa • relative humidity: >60% • temperature: 50 °C • Ethylene oxide concentration: 530 g/m3 • pressure: 120 kPa • final vacuum: -70 kPa • aeration **(Test report 001: sterilization test / ECG cables – RE/IP/BPF – Revision 0 dated 26/02/98**
Please Note:	**Never sterilize** the cables and accessories in an "autoclave" **using boiling water or steam**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

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V. GUARANTEE/LIABILITY

Any unused **SpO_2 interface cable** kept in its original packaging and which has not suffered any visible damage is guaranteed by **Nissha Medical Technologies** for one year.

Nissha Medical Technologies guarantees the device's conformity to the specifications of the current safety and performance standards applicable to it.

PLEASE NOTE:

The class and type of protection against electric shocks are also linked to those of the electromedical device (pulse oximeter) to which the sensor and its cable are connected.

Always read the instruction manual for the particular device and any accessories used with it before placing the device into service.

Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

MODE D'EMPLOI
CÂBLE INTERFACE POUR CAPTEURS SPO_2

- **TEMPERATURE LIMITS** (10°C 50°F / 50°C 122°F)
- **PROTECT FROM MOISTURE**
- **LOT CODE** (LOT)
- **QUANTITY** (QTY)
- **EXPIRY** (Use By)
- **MEDICAL DEVICE** (MD)
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE** (NON STERILE)
- **MANUFACTURER**
- **LATEX FREE** (Not made with natural rubber latex)
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE** (REF)
- **EC ACCORDING TO EU MDR 2017/745** (CE)

Les règles de classification varient suivant les pays. Ainsi selon la EU MDR 2017/745 ou la "MD Regulations" australienne et de par sa destination, le câble interface pour capteurs de SpO_2 est de classe I. Selon les règles de la FDA (USA) ou du Canada il est de classe II

- L'utilisateur doit s'assurer que le capteur de SpO_2 relié à l'oxymètre par l'intermédiaire du câble interface SpO_2 est adapté à l'appareil et au type patient (adulte, enfant ou nouveau né).
- Consulter la notice d'instructions de l'appareil électromédical avant toute mise en application du câble interface Spo_2.
- Eloigner le câble interface SpO_2 des sources de rayonnement électromagnétique.
- Les câbles interface SpO_2 (ainsi que les capteurs de SpO_2 standards) ne sont pas conçus pour être utilisés en salle d'IRM.
- En salle de chirurgie s'assurer que le câble interface SpO_2 (en tout ou partie) se trouve en dehors du champ opératoire.
- Faire en sorte qu'aucun liquide ne puisse atteindre les contacts des connecteurs.
- En cas de transfert d'un câble hors du service vers un autre service ou pour maintenance ou expertise, il est de la responsabilité du service utilisateur de nettoyer et de désinfecter le produit avant de l'expédier ou de le transférer.
- Ne jamais stériliser les câbles et accessoires en autoclave à la vapeur ou à l'eau bouillante
- La classe et le type de protection contre les chocs électriques sont également à liés ceux de l'appareil électromédical (oxymètre de pouls) sur lequel le capteur et son câble sont connectés.
- Consulter le mode d'emploi de l'appareil concerné et des accessoires annexes avant toute mise en service du dispositif.
- Nissha Medical Technologies ne peut être tenu responsable d'incidents survenant en cas de non respect des règles d'installation et d'utilisation mentionnées dans ce mode d'emploi.

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FR FRANÇAIS

CÂBLE INTERFACE POUR CAPTEURS SPO_2

Prière de lire attentivement les informations suivantes
L'inobservation des précautions d'emploi pourrait avoir des conséquences néfastes pour le patient.

Remarque importante:
Ce document fournit une aide à l'utilisation des câbles interface pour capteurs de SpO_2. Il n'y est pas fait référence à une technique médicale particulière. Le fabricant décline toute responsabilité pour tout problème résultant d'une mauvaise utilisation du dispositif.

I. IDENTIFICATION / DOMAINE D'APPLICATION

IDENTIFICATION
Le **câble interface SpO_2**, conçu par Nissha Medical Technologies est **l'élément** reliant le **capteur SpO_2 de mesure non invasive** et en continu de la saturation artérielle en oxygène et l'appareil électromédical.

Le **câble interface** est utilisable uniquement avec l'appareil électromédical (oxymètre de pouls) pour lequel il a été conçu. Indication est donnée sur le dispositif ou sur son emballage. Les dispositifs (capteurs, moyens de fixation,…..) compatibles sont listés dans le catalogue commercial Nissha Medical Technologies *(COMM/DOCU SpO_2/001/12/A)* consultable et téléchargeable sur son site Internet: www.NisshaMedical.com.

DOMAINE D'APPLICATION
Le **câble interface SpO_2 Nissha Medical Technologies** est utilisable pour tout type de patient (adulte, enfant, nouveau-né ou prématuré) partout où la mesure de la saturation artérielle en oxygène par la méthode non invasive est demandée.

ATTENTION:
L'utilisateur doit s'assurer que le capteur de SpO_2 relié à l'oxymètre par l'intermédiaire du câble interface SpO_2 est adapté à l'appareil et au type patient (adulte, enfant ou nouveau né).

PROPRIETE ANTIBACTERIENNE
Les enveloppes des **câbles médicaux bioactifs** Nissha Medical Technologies comportent un additif chimique composé de matériaux non toxiques qui leur confère en surface un pH légèrement acide, semblable à celui de la peau humaine, voisin de 5. La plupart des agents pathogènes responsables des maladies nosocomiales sont détruits dans cet environnement.

Nissha Medical Technologies propose une gamme complète de **câbles interface SpO_2.**

Pour vos commandes ultérieures, utilisez le numéro de code figurant sur le câble interface SpO_2 Nissha Medical Technologies ou sur son emballage.

Pour complément d'informations sur ce produit, contacter Nissha Medical Technologies ou consulter son site Internet : www.NisshaMedical.com.

NISSHA MEDICAL TECHNOLOGIES

II. STOCKAGE / CONDITIONNEMENT

STOCKAGE

Les conditions de **stockage des câbles interface SpO_2** sont les suivantes :

- Température ambiante : 10 to 50 °C- 50 to 122 °F

CONDITIONNEMENT

Les **câbles interface SpO_2 Nissha Medical Technologies** sont conditionnés unitairement.

Le **câble interface SpO_2 Nissha Medical Technologies**, en attente d'utilisation, doit être stocké dans son emballage d'origine afin d'éviter toute détérioration susceptible de diminuer sa durée de vie, ses performances et/ou son niveau de sécurité.

III. PERFORMANCES / FIABILITE / SECURITE / COMPATIBILITE / INTEGRITE MECANIQUE et ELECTRIQUE / SYMBOLES / ALLERGICITE

PERFORMANCES / FIABILITE

Les **câbles interface SpO_2 Nissha Medical Technologies** sont contrôlés en cours et en fin de fabrication selon des protocoles établis conformément aux spécifications des normes et règlementations actuellement en vigueur les concernant.
Le résultat final des essais, pratiqués sur un groupe de types représentatifs selon un protocole technique établi par Nissha Medical Technologies, a été confirmé par un Laboratoire agréé.

(Rapport technique du Gmed n°5358010/1T)

Ils ont également fait l'objet d'essais et d'appréciation cliniques.

SECURITE

Les **câbles interface SpO_2 Nissha Medical Technologies** sont conçus et réalisés conformément aux spécifications générales et particulières des normes internationales, européennes et nationales actuellement en vigueur les concernant.

(Normes IEC 60601-1/NF EN ISO 9919…)

Les **câbles interface SpO_2 Nissha Medical Technologies** font partie intégrante de la « partie appliquée » au patient telle que définie par la norme internationale de sécurité **IEC 60601-1**.

La **classe de sécurité**, le **type de protection (BF, CF)**, le **degré de protection** contre les chocs électriques du **câble interface SpO2** sont intimement liés à ceux de l'appareil électromédical sur lequel il est connecté.

Les courants de fuite basse fréquence, mesurés conformément aux recommandations des normes actuellement en vigueur et applicables à ce produit ont des valeurs inférieures à celles autorisées pour le niveau le plus élevé de sécurité.

MISE EN GARDE

⚠
- Consulter la notice d'instructions de l'appareil électromédical avant toute mise en application du **câble interface Spo_2**.
- Eloigner le **câble interface SpO_2** des sources de rayonnement électromagnétique.
- En salle de chirurgie s'assurer que le câble interface SpO_2 (en tout ou partie) se trouve en dehors du champ opératoire.
- Faire en sorte qu'aucun liquide ne puisse atteindre les contacts des connecteurs.

ATTENTION

⚠ Nissha Medical Technologies ne saurait-être tenu responsable d'incidents survenant au patient, à l'utilisateur et aux autres personnes causés par la présence de courants électriques dangereux en provenance de l'appareil électromédical en cas de défaut.

COMPATIBILITE

Nissha Medical Technologies met à la disposition de sa clientèle, sur son site internet (www.NisshaMedical.com), un document téléchargeable comportant des informations sur la compatibilité du dispositif ainsi que des renseignements techniques le concernant.

FR FRANÇAIS

INTEGRITE MECANIQUE et ELECTRIQUE

Pour assurer une bonne résistance mécanique du câble interface SpO_2 à la traction, à la flexion et diminuer les courants de fuite qui pourrait circuler à travers le patient, **Nissha Medical Technologies** utilise des matériaux de haute qualité pour la fabrication du dispositif.

Les connecteurs surmoulés sont équipés de manchons souples minimisant le risque de rupture du câble à ce niveau.
La surface de contact des broches des connecteurs est traitée de façon à diminuer au maximum la résitance de contact entre deux broches même après un nombre important de connexions et de déconnexions.

(Rapport d'essais n°CPB1097 – CPB1897/CPB2897)

Les **câbles interface SpO_2 Nissha Medical Technologies** peuvent supporter des chocs de défibrillation répétés. Ils ne possèdent aucune partie métallique accessible.

Un câble, en attente d'utilisation, doit être stocké dans son emballage d'origine afin d'éviter toute détérioration intempestive de sa gaîne isolante et de ses conducteurs pouvant diminuer sa durée de vie, ses performances et/ou son niveau de sécurité.

SYMBOLES SECURITE DES PARTIES APPLIQUEES

Explication des symboles utilisés sur le dispositif électromédical:

 or 

Indique que les câbles et accessoires de Spo_2 respectivement de type CF ou BF sont équipés d'une protection spéciale contre les chocs électriques (Notamment en ce qui concerne les courants de fuite admissibles) et les chocs de défibrillation.

⚠ **La classe et le type de protection (BF, CF) contre les chocs électriques sont définis par ceux de l'appareil électro médical sur lequel le câble interface de SpO_2 Nissha Medical Technologies est connecté.**

ALLERGICITE

The insulating materials used to manufacture **Nissha Medical Technologies SpO_2 interface cables** have been subjected to allergicity tests. These tests have not shown the presence of any products which might develop an intolerable allergic reaction.

IV. INSTALLATION / UTILISATION / MAINTENANCE / HYGIENE / STERILISATION

INSTALLATION

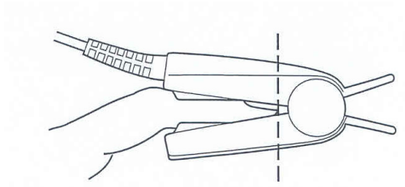
Pour une installation et une utilisation appropriées du **câble interface SpO_2**, suivre les instructions suivantes :

(voir également le mode d'emploi de l'appareil électromédical concerné)

Côté patient :

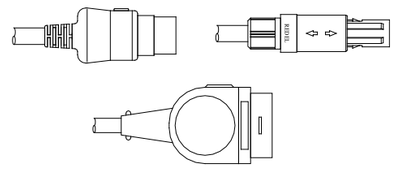
- Connecter d'abord le câble interface au **capteur SpO_2** approprié.
- Placer le **capteur SpO_2** sur le site patient choisi et propre à la mesure en se référant aux instructions de la notice de l'appareil électromédical concerné). Il est important de s'assurer que le capteur est adapté au type de patient (adulte, enfant, nouveau né)

Exemples de positionnement du capteur sur le doigt :



Ne pas insérer le doigt trop profondément

Exemples de fiche:



Côté appareil :

- Connecter **le câble interface SpO_2** à l'appareil (oxymètre de pouls) approprié.
- Mettre l'appareil en marche et s'assurer de son fonctionnement en consultant la notice d'intructions de l'appareil électromédical.

UTILISATION:

CONDITIONS GENERALES
Les conditions d'utilisation du **câble interface SpO_2 Nissha Medical Technologies** sont les:
- Température ambiante : 10 to 50 °C- 50 to 122 °F

CONDITIONS PARTICULIERES
- **Ne pas utiliser un câble interface SpO_2 présentant un risque pour le patient (isolant détérioré par exemple).**

MAINTENANCE PREVENTIVE
La durée de vie du **câble interface SpO_2** est fonction d'un nombre important de paramètres. Pour
- Le nombre d'applications
- Le respect de la maintenance préventive
- Le maintien en bon état d'hygiène

Un contrôle régulier, visuel et électrique, des conducteurs déterminera si le remplacement du **câble interface SpO_2** est à effectuer.

MISE EN GARDE :
⚠ **En cas de transfert d'un câble hors du service vers un autre service ou pour maintenance ou expertise, il est de la responsabilité du service utilisateur de nettoyer et de désinfecter le produit avant de l'expédier ou de le transférer.**

MAINTENANCE CORRECTIVE
- Il n'y a pas de maintenance corrective pour ce produit.

HYGIENE

PLEASE NOTE:
⚠ **Ne pas faire pénétrer de liquide à l'intérieur des connecteurs du câble interface.**

L'utilisation du câble interface SpO_2 Nissha Medical Technologies en salle stérile peut imposer l'application d'une procédure de stérilisation. Nissha Medical Technologies préconise de procéder aux méthodes de désinfection et ou de stérilisation décrites ci-après.

INSTRUCTIONS DE RETRAITEMENT DE CABLES MEDICAUX REUTILISABLES (D'après NF EN ISO 17664:2004)

Fabricant: Nissha Medical Technologies	
Dispositif(s): câble interface SpO_2	
AVERTISSEMENTS	Les extrémités du câble comportent des connecteurs de liaison électriques. Ceux-ci ne peuvent pas être immergés afin d'éviter tout problème électrique.
Limites du retraitement	Les câble interface SpO_2 Nissha Medical Technologies sont conçus pour supporter des chocs de défibrillation et des cycles de nettoyage, désinfection et stérilisation répétés. La fin de durée de vie est principalement déterminée par les conditions d'utilisation
INSTRUCTIONS	
Lieux d'utilisation:	Retirer les excès de salissure en nettoyant le câble avec un chiffon/papier jetable
Confinement et transport:	Il est recommandé de retraiter les instruments dès que possible après utilisation et éviter que des dispositifs potentiellement contaminés soient transportés en des lieux éloignés sans précaution.
Préparation pour le nettoyage:	Pas d'exigence particulière

Nettoyage : automatisé	Non applicable car les connecteurs d'extrémités ne doivent pas être humidifiés
Nettoyage : manuel	• Nettoyage du **câble interface SpO_2 Nissha Medical Technologies** et des prolongateurs (connecteur compris) avec un linge imbibé d'eau savonneuse
Désinfection:	**(Tirée de l'étude du Laboratoire ANIOS, n° 6416.94/0387)** **Méthode** • remplir un bac de trempage avec une solution à 0,5% d'HEXANIOS G+R • immerger partiellement le câble en protégeant les extrémités pour éviter tout problème électrique sur les connecteurs • respecter un temps de contact de 15 minutes • rincer le câble • sécher le câble avec du papier absorbant • pendant l'immersion frotter les extrémités du câble à l'aide d'une LINGET ANIOS. **(Renouveler la solution toutes les 48 heures)**
Séchage :	sécher le câble avec du papier absorbant
Maintenance, contrôles et essais :	Vérifier visuellement l'aspect et l'intégrité du câble interface SpO_2
Conditionnement:	Suivre les protocoles de conditionnement de l'établissement que ce soit pour un conditionnement individuel en sachet ou par lot.
Stérilisation: ⚠	• temps de stérilisation : 22 heures dont 20 heures d'exposition au gaz. • agent stérilisant : Dioxyde de Carbone + Oxyde d'Ethylène (80/20%). • vide initial : -70 kPa • humidité relative : >60% • température : 50 °C • concentration en Oxyde d'Ethylène : 530 g/m3 • pression : 120 kPa • vide final : -70 kPa • rinçage **(Rapport d'essai 001 : essai de stérilisation / câbles ECG – RE/IP/BPF – Révision 0 du 26/02/98)**
Attention:	**Ne jamais stériliser les câbles et accessoires en autoclave à la vapeur ou à l'eau bouillante**
Conservation:	Voir les conditions de stockage dans ce mode d'emploi

Informations supplémentaires:	Les informations indiquées ci-dessus proposent des méthodes validées par le fabricant mais indicatives. Libre au service compétent d'utiliser une ou des méthodes alternatives qu'il aura lui-même validé. Des informations complémentaires ainsi que les déclarations de compatibilités sont disponibles sur le site internet www.NisshaMedical.com
Contact fabricant:	Toutes les informations de contact sont indiquées en bas de cette page ou sur le site internet www.NisshaMedical.com

FR FRANÇAIS

V. GARANTIE / RESPONSABILITE

Tout câble interface SpO_2 non utilisé et conservé dans son emballage d'origine et n'ayant subi aucun dégât apparent est garanti un an par Nissha Medical Technologies.

Nissha Medical Technologies garantit la conformité du dispositif aux spécifications des normes de sécurité et de performances qui lui sont applicables et actuellement en vigueur.

ATTENTION:
La classe et le type de protection contre les chocs électriques sont également à liés ceux de l'appareil électromédical (oxymètre de pouls) sur lequel le capteur et son câble sont connectés.

Consulter le mode d'emploi de l'appareil concerné et des accessoires annexes avant toute mise en service du dispositif.

Nissha Medical Technologies ne peut être tenu responsable d'incidents survenant en cas de non respect des règles d'installation et d'utilisation mentionnées dans ce mode d'emploi.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

GEBRAUCHSANWEISUNG

SCHNITTSTELLENKABEL für SpO_2-Sensoren

- **TEMPERATURE LIMITS** (10°C 50°F / 50°C 122°F)
- **PROTECT FROM MOISTURE**
- **LOT CODE** (LOT)
- **QUANTITY** (QTY)
- **EXPIRY** (Use By)
- **MEDICAL DEVICE** (MD)
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE** (NON STERILE)
- **MANUFACTURER**
- **LATEX FREE** (Not made with natural rubber latex)
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE** (REF)
- **EC ACCORDING TO EU MDR 2017/745**

Gemäß den Klassifizierungsregeln der europäischen Richtlinie **EU MDR 2017/745** und ihrem Verwendungszweck gehören die **SpO_2-Schnittstellenkabel** zur Klasse I.

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

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SCHNITTSTELLENKABEL für SpO_2-Sensoren

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. BESCHREIBUNG / ANWENDUNGSGEBIET

BESCHREIBUNG

Das von Nissha Medical Technologies entwickelte **SpO_2-Schnittstellenkabel** ist das Element, das den SpO_2-Sensor für die nicht-invasive und kontinuierliche Messung der arteriellen Sauerstoffsättigung mit dem elektromedizinischen Gerät verbindet.

Die **Schnittstellenkabel** können nur mit dem elektromedizinischen Gerät (Pulsoxymeter) verwendet werden, für das sie entwickelt wurden. Eine entsprechende Angabe befindet sich auf der Vorrichtung oder ihrer Verpackung. Die kompatiblen Vorrichtungen (Sensoren, Befestigungsmittel, ...) sind im Verkaufskatalog von Nissha Medical Technologies ***(COMM/DOCU001/018)***, der auf der Internetseite von Nissha Medical Technologies eingesehen und heruntergeladen werden kann, aufgelistet: www.NisshaMedical.com.

ANWENDUNGSGEBIET

Das **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** kann überall da verwendet werden, wo die Messung der arteriellen Sauerstoffsättigung mittels der nicht-invasives Methode erforderlich ist.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES

The enveloppes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Nissha Medical Technologies bietet ein vollständiges Sortiment an **SPO_2-Schnittstellenkabeln** an.

Verwenden Sie bitte die Code-Nummer, die auf dem SpO_2-Schnittstellenkabel von Nissha Medical Technologies oder seiner Verpackung angegeben ist, für spätere Bestellungen.

Für weitere Informationen über dieses Produkt wenden Sie sich bitte an Nissha Medical Technologies oder besuchen Sie den Internetauftritt: www.NisshaMedical.com.

II. LAGERUNG / VERPACKUNG / SYMBOLE

LAGERUNG

Die **SpO_2-Schnittstellenkabel** sollten unter folgenden Bedingungen gelagert werden:

- Umgebungstemperatur: 10 to 50 °C- 50 to 122 °F

VERPACKUNG

Die **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** sind einzeln verpackt.
Die **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** müssen, solange sie nicht gebraucht werden, in ihrer Originalverpackung aufbewahrt werden, um jegliche Beschädigung zu vermeiden, die ihre Lebensdauer, ihre Funktionsfähigkeit und / oder ihren Sicherheitsstandard herabsetzen könnte.

III. FUNKTIONSFÄHIGKEIT / ZUVERLÄSSIGKEIT / SICHERHEIT / KOMPATIBILITÄT / MECHANISCHE und ELEKTRISCHE FEHLERFREIHEIT / SYMBOLE / ALLERGIEAUSLÖSUNG

FUNKTIONSFÄHIGKEIT / ZUVERLÄSSIGKEIT

Die **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** werden während der Produktion und nach Produktionsende gemäß Protokollen, die in Übereinstimmung mit den Bestimmungen der für sie derzeit geltenden Normen und Regelungen erstellt wurden, überprüft.

Das Endergebnis der Prüfungen, die an einer Gruppe repräsentativer Typen gemäß einem von Nissha Medical Technologies erstellten technischen Protokoll durchgeführt wurden, wurde von einem zugelassenen Labor bestätigt.

(Technischer Bericht der Gmed Nr. 5358010/1T)

Sie waren ebenfalls Gegenstand von Tests und klinischen Bewertungen.

SICHERHEIT

Die SpO_2-Schnittstellenkabel von **Nissha Medical Technologies** wurden in Übereinstimmung mit den allgemeinen und besonderen Bestimmungen der für sie derzeit geltenden nationalen, europäischen und / oder internationalen Normen entwickelt und hergestellt:

(Normen IEC 60601-1 / NF EN ISO 9919...)

Die SpO_2-Schnittstellenkabel von **Nissha Medical Technologies** sind Bestandteil des am Patienten „angebrachten Teils", der in der europäischen Sicherheitsnorm IEC 60601-1 definiert ist.

Die **Sicherheitsklasse**, der **Schutztyp (BF, CF)** und der Schutzgrad gegen elektrische Schläge der **SpO_2-Schnittstellenkabel** sind eng mit denen des elektromedizinischen Geräts verbunden, an das sie angeschlossen sind. Die Werte der Niederfrequenz-Ableitströme, die gemäß den Empfehlungen der derzeit für dieses Produkt geltenden Normen gemessen wurden, liegen unter den Werten, die für die höchste Sicherheitsstufe genehmigt wurden.

WARNUNG

⚠
- Vor jeder Anwendung des **SpO_2-Schnittstellenkabels** die Gebrauchsanweisung des elektromedizinischen Geräts lesen.
- Das **SpO_2-Schnittstellenkabel** von Quellen elektromagnetischer Strahlung fernhalten.
- Im Operationssaal muss sichergestellt werden, dass sich das **SpO_2-Schnittstellenkabel** (das gesamte Kabel oder Teile davon) außerhalb des Operationsfeldes befindet.
- Sicherstellen, dass keine Flüssigkeit an die Kontakte der Steckverbinder gelangen kann.

ACHTUNG

⚠ Nissha Medical Technologies haftet nicht für Schäden, die der Patient, der Anwender oder andere Personen durch das Vorhandensein gefährlicher elektrischer Ströme erleiden, die durch Schäden an dem elektromedizinischen Gerät entstanden sind.

KOMPATIBILITÄT

Nissha Medical Technologies stellt seinen Kunden auf seiner Internetseite (www.NisshaMedical.com), ein Dokument zum Herunterladen zur Verfügung, in dem Informationen zur Kompatibilität der Vorrichtung sowie weitere technische Informationen enthalten sind.

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MECHANISCHE und ELEKTRISCHE FEHLERFREIHEIT

Um eine gute mechanische Widerstandsfähigkeit der **SpO_2-Schnittstellenkabel** gegenüber Zugbeanspruchung und Biegebeanspruchung zu gewährleisten und die Ableitströme zu minimieren, die über den Patienten zirkulieren könnten, verwendet Nissha Medical Technologies für die Herstellung der Vorrichtung qualitativ hochwertige Materialien.
Die aufgegossenen Steckverbinder sind mit flexiblen Hülsen ausgestattet, um das Risiko eines Kabelbruchs an dieser Stelle zu minimieren.
Die Kontaktfläche der Stifte der Steckverbinder wird so behandelt, dass der Kontaktwiderstand zwischen zwei Stiften selbst nach einer Vielzahl von hergestellten und wieder gelösten Verbindungen so gering wie möglich ist.

(Prüfbericht Nr. CPB1097 – CPB1897/CPB2897)

Die **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** können wiederholten Stromstößen zur Defibrillation standhalten. Sie verfügen über keinerlei zugängliche Metallteile.
Die Kabel müssen, solange sie nicht gebraucht werden, in ihrer Originalverpackung aufbewahrt werden, um jegliche unerwünschte Beschädigung ihrer Schutzhüllen und ihrer Adern zu vermeiden, die ihre Lebensdauer, ihre Funktionsfähigkeit und / oder ihren Sicherheitsstandard herabsetzen könnte.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:

 or 

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ALLERGIEAUSLÖSUNG

Die Isolationsmaterialien, die bei der Herstellung der **SpO_2-Schnittstellenkabel** von Nissha Medical Technologies verwendet werden, wurden Allergieauslösungstests unterzogen. Bei diesen Tests konnten keine Produkte nachgewiesen werden, die eine unzulässige allergische Reaktion auslösen könnten.

IV. INSTALLATION / ANWENDUNG / WARTUNG / HYGIENE / STERILISATION

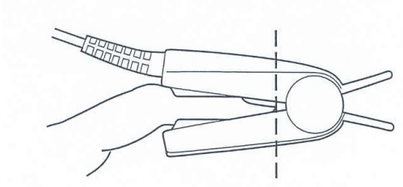
INSTALLATION

Für eine optimale Installation und Anwendung der **SpO_2-Schnittstellenkabel** ist die folgende Anleitung zu beachten:

(Siehe auch die Gebrauchsanweisung des betreffenden elektromedizinischen Geräts)

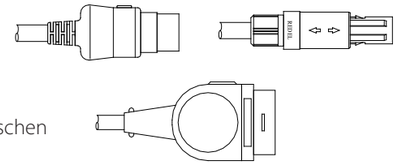
Patientenseitig:

- Zuerst das Schnittstellenkabel an den zugehörigen **SpO_2-Sensor** anschließen.
- Den **SpO_2-Sensor** auf der gewählten und für die Messung geeigneten Stelle auf dem Patienten platzieren, wobei die Anleitungen der Gebrauchsanweisung des betreffenden elektromedizinischen Geräts berücksichtigt werden.
  Beispiele für die Positionierung des Sensors auf dem Finger:



Den Finger nicht zu tief einführen

Beispiele für Stecker:



Geräteseitig:

- Das **SpO_2-Schnittstellenkabel** an das zugehörige Gerät (Pulsoxymeter) anschließen.
- Das Gerät einschalten und dessen korrekte Funktionsweise sicherstellen, wobei die Gebrauchsanweisung des elektromedizinischen Geräts zu berücksichtigen ist.

ANWENDUNG:

ALLGEMEINE BEDINGUNGEN
Die **SpO_2-Schnittstellenkabel von Nissha Medical Technologies** können unter folgenden Bedingungen verwendet werden:
- Umgebungstemperatur: 10 to 50 °C- 50 to 122 °F

BESONDERE BEDINGUNGEN
- **Keine SpO_2-Kabel verwenden, die ein Risiko für den Patienten darstellen (beschädigte Isolierung zum Beispiel).**

VORBEUGENDE WARTUNG
Die Lebensdauer des **SpO_2-Schnittstellenkabels** hängt von einer Reihe von Parametern ab. Zum Beispiel:
- Der Anzahl der Anwendungen
- Der Einhaltung der vorbeugenden Wartung
- Der Aufrechterhaltung eines guten hygienischen Zustands

Bei einer regelmäßigen Sichtkontrolle und elektrischen Kontrolle der Kabel wird festgestellt, ob der Austausch des **SpO_2-Schnittstellenkabels** notwendig ist.

WARNUNG:
⚠ **Wenn ein Kabel zur Wartung oder für eine Begutachtung aus der Abteilung entfernt wird, ist die entsprechende Abteilung des Anwenders dafür verantwortlich das Produkt zu reinigen und zu desinfizieren, bevor es verschickt oder entfernt wird.**

KORRIGIERENDE WARTUNG
- Für dieses Produkt gibt es keine korrigierende Wartung.

HYGIENE

ACHTUNG:
Darauf achten, dass keine Flüssigkeit in das Innere der verschiedenen Steckverbinder des Schnittstellenkabels gelangt.

Reinigen Sie das SpO_2-Schnittstellenkabel von Nissha Medical Technologies und seine Ableitungskabel regelmäßig gemäß dem nachfolgend beschriebenen Verfahren.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
CAUTION	When cleaning or disinfecting the cables make sure that the plugs at the end of the cables do not become immersed in any liquid to avoid any electrical problems
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

DE DEUTSCH

Automatic cleaning:	Is strictly not applicable
Reinigung:	• Reinigung des **SpO_2-Schnittstellenkabels** von Nissha Medical Technologies (einschließlich Steckverbinder) mit einem mit Seifenwasser getränkten Lappen.
Desinfektion:	**(Entnommen aus der Studie des Laboratoriums ANIOS, Nr. 6416.94/0387)** **Verfahren** • ein Einweichgefäß mit einer Lösung aus 0,5% HEXANIOS G+R füllen • das Kabel teilweise untertauchen, so dass die Enden geschützt sind, um jegliche elektrischen Probleme an den Steckverbindern zu vermeiden • eine Einwirkzeit von 15 Minuten einhalten • das Kabel abspülen • das Kabel mit saugfähigem Papier abtrocknen • während der Einweichzeit die Enden des Kabels mit einem Desinfektionstuch „LINGET ANIOS" abreiben **(Die Lösung alle 48 Stunden erneuern)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Please follow the standard protocol of packaging of your institution before sterilization
Sterilisation : ⚠	• Sterilisationszeit: 22 Stunden, davon 20 Stunden Einwirkzeit des Gases • Sterilisationsmittel: Kohlendioxid + Ethylenoxid (80/20%). • Anfangsvakuum: -70 kPa • Relative Luftfeuchtigkeit: >60% • Temperatur: 50°C • Ethylenoxid-Konzentration: 530 g/m3. • Druck: 120 kPa • Abschlussvakuum: -70 kPa • Abspülen **(Prüfbericht 001 : Sterilisationsversuch / SpO2-Kabel – RE/IP/BPF – Überarbeitung 0 vom 26.02.98)**
Achtung:	**Die Kabel und das Zubehör niemals im Autoklav mit Dampf oder kochendem Wasser sterilisieren.**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

DE DEUTSCH

V. GARANTIE / HAFTUNG

Nissha Medical Technologies gewährt ein Jahr Garantie auf jedes **SpO_2-Schnittstellen-Kabel von Nissha Medical Technologies**, das noch nicht gebraucht ist, in seiner Originalverpackung aufbewahrt wurde und keinen offensichtlichen Schaden davongetragen hat.

Nissha Medical Technologies garantiert, dass die Vorrichtung die Bestimmungen der derzeit in Bezug auf die Vorrichtung geltenden Sicherheits- und Funktionsnormen erfüllt.

ACHTUNG:
Die Schutzklasse und der Schutztyp gegen elektrische Schläge sind auch von der Schutzklasse und dem Typ des elektromedizinischen Geräts (Pulsoximeter), an das der Sensor und sein Kabel angeschlossen werden, abhängig.

Vor der Inbetriebnahme der Vorrichtung die Gebrauchsanweisung des betreffenden Geräts und der angeschlossenen Zubehörteile lesen.

Nissha Medical Technologies haftet nicht für Schäden, die aufgrund einer Verletzung der in dieser Gebrauchsanweisung angegebenen Installations- und Anwendungsregeln entstehen.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

MANUAL DE INSTRUCCIONES

CABLE DE INTERFAZ para captadores SpO_2

- **TEMPERATURE LIMITS**
- **PROTECT FROM MOISTURE**
- **LOT CODE**
- **QUANTITY**
- **EXPIRY**
- **MEDICAL DEVICE**
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE**
- **MANUFACTURER**
- **LATEX FREE**
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE**
- **EC ACCORDING TO EU MDR 2017/745**

De acuerdo con las reglas de clasificación de la EU MDR 2017/745 y con el uso al que se destina, **el cable de la interfaz SpO_2** es de la **clase I.**

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

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ES ESPAÑOL

CABLE DE INTERFAZ para captadores SpO_2

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. IDENTIFICACIÓN / CAMPO DE APLICACIÓN

IDENTIFICACIÓN
El **cable de la interfaz SpO_2,** diseñado por Nissha Medical Technologies es el **elemento** que conecta el **captador SpO_2 de medición no invasiva** y de manera continua de la **saturación arterial de oxígeno y** el aparato electromédico.

El **cable de la interfaz** puede utilizarse únicamente con el aparato electromédico (oxímetro de pulso) para el cual se diseñó. Indicación ofrecida en el dispositivo o bien en el embalaje. Los dispositivos (captadores, medios de fijación, etc.) compatibles aparecen en el catálogo comercial de Nissha Medical Technologies (COMM/DOCU001/018) que puede consultarse y descargarse en su sitio en Internet: www.NisshaMedical.com.

CAMPO DE APLICACIÓN
El **cable de la interfaz SpO_2 Nissha Medical Technologies** se puede utilizar en todos aquellos casos en los que se requiera una saturación arterial de oxígeno mediante el método no invasivo.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES
The envelopes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Nissha Medical Technologies ofrece una gama completa de **cables de interfaz SpO_2.**

En sus pedidos posteriores, utilice el número de código que figuran en el cable de la interfaz SpO_2 Nissha Medical Technologies o en su embalaje.

NISSHA MEDICAL TECHNOLOGIES

Para más información acerca de este producto, póngase en contacto con Nissha Medical Technologies o consulte su sitio en Internet: www.NisshaMedical.com.

II. ALMACENAMIENTO / ENVASADO / SÍMBOLOS

ALMACENAMIENTO

Las condiciones de **almacenamiento de los cables de la interfaz SpO_2** son las siguientes:

- Temperatura ambiente: 10 to 50 °C- 50 to 122 °F

ENVASADO

Los **cables de la interfaz SpO_2 Nissha Medical Technologies** se envasan de manera individualizada.

Cuando no se esté utilizando el **cable de la interfaz SpO_2 Nissha Medical Technologies**, éste deberá almacenarse en su envase original con el fin de evitar cualquier deterioro que pueda reducir su fecha de caducidad, sus resultados, así como su nivel de seguridad.

III. RESULTADOS/ FIABILIDAD / SEGURIDAD / COMPATIBILIDAD / INTEGRIDAD MECÁNICA y ELÉCTRICA / SÍMBOLOS / ÍNDICE DE ALERGIAS

RESULTADOS / FIABILIDAD

Los **cables de interfaz SpO_2 Nissha Medical Technologies** se controlan durante y al final del proceso de fabricación, aplicando protocolos técnicos elaborados de acuerdo con lo dispuesto en la normativa y en los reglamentos actualmente en vigor para este tipo de productos. El resultado final de las pruebas realizadas en un grupo de tipos representativos de acuerdo con un protocolo técnico elaborado por Nissha Medical Technologies ha sido certificado por un Laboratorio homologado.

(Informe técnico del Gmed núm.º5358010/1T)

Han sido además objeto de pruebas y evaluaciones clínicas.

SEGURIDAD

Los **cables de interfaz SpO_2 Nissha Medical Technologies** se han diseñado y fabricado de acuerdo con lo establecido en las especificaciones generales y específicas de las normas nacionales, europeas y/o internacionales, aplicables en este campo y actualmente vigentes.

(Normas IEC 60601-1/NF EN ISO 9919…)

Los cables de interfaz SpO_2 Nissha Medical Technologies forman parte de la "parte aplicada" al paciente tal y como se establece en la norma europea de seguridad IEC 60601-1.

La clase de seguridad, el tipo de protección (BF, CF) y el grado de protección contra las descargas eléctricas del cable de interfaz SpO_2 están íntimamente relacionados con el aparato electromédico al que se conecta.

Las corrientes de fuga de baja frecuencia, medidas de acuerdo con las recomendaciones establecidas en las normas actualmente vigentes y aplicables a este producto presentan valores inferiores a los autorizados para el nivel más elevado de seguridad.

ADVERTENCIA

⚠
- Consultar el manual de instrucciones del aparato electromédico antes de instalar el cable de interfaz SpO_2.
- Alejar el **cable de interfaz SpO_2** de las fuentes de radiación electromagnética.
- Asegurarse de que en la sala de operaciones el **cable de interfaz SpO_2** (total o parcialmente) se encuentra fuera del campo operatorio.
- Actuar de forma que ningún líquido pueda mojar los contactos de los conectores.

ATENCIÓN

⚠ **Nissha Medical Technologies no podrá considerarse responsable de los accidentes que le sucedan al paciente, al usuario y a las demás personas y que se ocasionen debido a la presencia de corrientes eléctricas peligrosas procedentes del aparato electromédico en caso de existir algún defecto.**

COMPATIBILIDAD

Nissha Medical Technologies pone a disposición de sus clientes a través de su sitio web (www.NisshaMedical.com), un documento que se puede descargar y en el que se incluyen las informaciones relacionadas con la compatibilidad del dispositivo, así como las informaciones técnicas pertinentes.

ES ESPAÑOL

INTEGRIDAD MECÁNICA Y ELÉCTRICA

Para garantizar una buena resistencia mecánica del cable SpO_2, frente a la tracción y a la flexión, y disminuir las corrientes de fuga que puedan circular a través del cliente, Nissha Medical Technologies ha utilizado materiales de alta calidad para la fabricación del dispositivo. Los conectores premontados están equipados con manguitos flexibles que minimizan el riesgo de rotura del cable en este lugar.

La superficie de contacto de las agujas de los conectores se trata de modo que se pueda reducir al máximo la resistencia de contacto entre dos agujas, incuso tras un considerable número de conexiones y desconexiones

(Informe de pruebas núm. CPB1097 – CPB1897/CPB2897)

Los cables de interfaz SpO_2, Nissha Medical Technologies pueden soportar descargas de desfibrilación repetidas. No existe en ellos ninguna parte metálica que sea accesible.

Cuando no se esté utilizando un **cable**, éste deberá almacenarse en su envase original con el fin de evitar cualquier deterioro intempestivo en su funda aislante y de sus conductores y mantener su fecha de caducidad, sus resultados y/o su grado de seguridad.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:

 or 

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ÍNDICE DE ALERGIAS

Los materiales aislantes utilizados en la fabricación de los **cables de interfaz SpO_2 Nissha Medical Technologies** han sido objeto de pruebas para determinar posibles alergias. Estas pruebas no han puesto de manifiesto la existencia de productos que pudiesen desencadenar una reacción alérgica de intolerancia.

IV. INSTALACIÓN / UTILIZACIÓN / MANTENIMIENTO / HIGIENE / ESTERILIZACIÓN

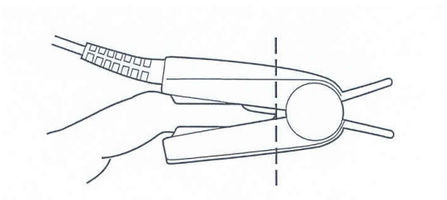
INSTALACIÓN

Para una instalación y un uso adecuados del **cable de interfaz SpO_2**, síganse las siguientes instrucciones:

(Véase asimismo el manual de instrucciones del aparato electromédico correspondiente)

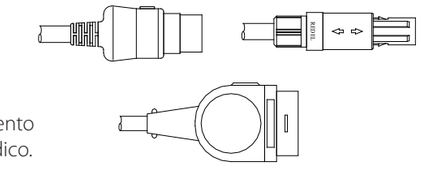
En el lado del paciente:

- Conectar en primer lugar el **cable de interfaz SpO_2** adecuado.
- Colocar el **captador SpO_2** en el lugar del paciente que se haya seleccionado y que sea el más adecuado para efectuar la medición, respetando las instrucciones dadas en el manual del aparato médico correspondiente).
  Ejemplos de colocación del captador en el dedo:



No insertar el dedo demasiado a fondo

Ejemplos de fichas:



En relación con el aparato:

- Conectar **el cable de interfaz SpO_2** al aparato (oxímetro de pulso) adecuado.
- Poner en marcha el aparato y asegurarse de que su funcionamiento consultando el manual de instrucciones del aparato electromédico.

UTILIZACIÓN:

CONDICIONES GENERALES
Las condiciones de uso del **cable de interfaz SpO_2 Nissha Medical Technologies** son las siguientes:
- Temperatura ambiente: 10 to 50 °C- 50 to 122 °F

CONDICIONES PARTICULARES
- **No utilizar un cable de interfaz SpO_2 que presente riesgos para el paciente (por ejemplo, un aislante deteriorado).**

MANTENIMIENTO PREVENTIVO
La fecha de caducidad del **cable de interfaz SpO_2** depende de un considerable número de parámetros. Por ejemplo:
- El número de aplicaciones
- Del cumplimiento del mantenimiento preventivo
- Del mantenimiento en un buen estado de higiene

El **cable de interfaz SpO_2** deberá sustituirse cuando se realice un control regular, visual y eléctrico de los conductores que así lo aconseje.

ADVERTENCIA:
⚠ **En caso de que se deje fuera de servicio un cable, o bien cuando se le someta a un mantenimiento o evaluación, será responsabilidad del usuario limpiar y desinfectar el producto antes de despacharlo o transferirlo.**

MANTENIMIENTO CORRECTIVO
- No existe un mantenimiento correctivo para este producto.

HIGIENE

ATENCIÓN:
No dejar que penetre líquido en el interior de los conectores del cable de interfaz.

Deberá realizarse una limpieza regular del cable de interfaz SpO_2 Nissha Medical Technologies y de sus conductores de derivación, de acuerdo con el método que se describe a continuación.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
CAUTION	No dejar que penetre líquido en el interior de los conectores del cable de interfaz.
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

Automatic cleaning:	Is strictly not applicable
Limpieza :	• Limpieza del cable de interfaz SpO_2 Nissha Medical Technologies (conector incluido) con un paño humedecido con agua jabonosa.
Desinfección :	**(Sacado del estudio del Laboratorio ANIOS, núm. 6416.94/0387)** **Procedimiento** • Llenar una bandeja para remojo con una solución de HEXANIOS G+R al 0,5%. • sumergir parcialmente el cable protegiendo las extremidades con el fin de evitar cualquier problema eléctrico en los conectores • respetar un tiempo de contacto de 15 minutos • aclarar el cable • secar el cable con un papel absorbente • Durante la inmersión, frotar las extremidades del cable con ayuda de una toallita ANIOS (impregnada en una solución libre de haldeados y sin derivados clorados). **(Renovar la solución cada 48 horas)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Si se utiliza un cable de interfaz SpO_2 Nissha Medical Technologies en una sala estéril podría ser necesario aplicar un procedimiento de esterilización. Nissha Medical Technologies recomienda utilizar los métodos de desinfección y/o de esterilización que se describen a continuación.
Esterilización: ⚠	• Tiempo de esterilización: 22 horas, 20 de las cuales se harán mediante exposición al gas. • Agente esterilizante: Dióxido de carbono + Óxido de etileno (80/20%) • Vacío inicial: -70 kPa • Humedad relativa: >60% • Temperatura: 50°C • Concentración en óxido de etileno: 530 g/m3 • Presión: 120 kPa • Vacío final: -70 kPa • Aclarado **(Informe de prueba 001: prueba de esterilización/cables SpO2-RE/IP/BPF – revisión 0 del 26/02/98)**
ATENCIÓN:	**No esterilizar nunca los cables y los accesorios en autoclave con vapor o agua hirviendo.**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

ES ESPAÑOL

V. GARANTÍA / RESPONSABILIDAD

Cualquier **cable de interfaz SpO_2** que no se haya utilizado y que se haya conservado en su envase original sin presentar ningún deterioro aparente está garantizado por Nissha Medical Technologies durante un año.

Nissha Medical Technologies garantiza la conformidad del dispositivo de acuerdo con las especificaciones contenidas en las normas de seguridad y de resultados que le son aplicables y que se encuentran actualmente vigentes.

ATENCIÓN:

La clase y el tipo de protección contra las descargas eléctricas están relacionadas con las del aparato electromédico (oxímetro de pulso) al cual se conectan el captador y su cable.

Consultar el manual de instrucciones del aparato correspondiente y de los accesorios anejos antes de poner en servicio el dispositivo.

Nissha Medical Technologies no podrá responsabilizarse de los accidentes que se produzcan en caso de que no se respeten las normas de instalación y de uso que se mencionan en el presente manual de instrucciones.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

ΚΑΛΩΔΙΟ ΔΙΑΣΥΝΔΕΣΗΣ για αισθητήρες SpO_2

- **TEMPERATURE LIMITS**
- **PROTECT FROM MOISTURE**
- **LOT CODE**
- **QUANTITY**
- **EXPIRY**
- **MEDICAL DEVICE**
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE**
- **MANUFACTURER**
- **LATEX FREE**
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE**
- **EC ACCORDING TO EU MDR 2017/745**

Σύμφωνα με τους κανόνες ταξινόμησης της EU MDR 2017/745 και τον προορισμό της, το καλώδιο **διασύνδεσης SpO_2 ανήκει στη κατηγορία I.**

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

ISO 13485:2016
HS.NisshaMedical.com/IFU

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EL ΕΛΛΗΝΙΚΑ

ΚΑΛΩΔΙΟ ΔΙΑΣΥΝΔΕΣΗΣ ΓΙΑ ΑΙΣΘΗΤΗΡΕΣ SPO_2

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. ΣΤΟΙΧΕΙΑ ΑΝΑΓΝΩΡΙΣΗΣ/ΠΕΔΙΟ ΕΦΑΡΜΟΓΗΣ

ΣΤΟΙΧΕΙΑ ΑΝΑΓΝΩΡΙΣΗΣ
Το **καλώδιο διασύνδεσης SpO_2, το οποίο σχεδιάστηκε από την Nissha Medical Technologies** είναι **το στοιχείο** που συνδέει **τον αισθητήρα SpO_2 της μη επεμβατικής** και συνεχούς **μέτρησης του κορεσμού οξυγόνου στο αρτηριακό αίμα** και την ηλεκτροϊατρική συσκευή.

Το **καλώδιο διασύνδεσης** μπορεί να χρησιμοποιηθεί αποκλειστικά με την ηλεκτροϊατρική συσκευή (οξύμετρο σφυγμού) για την οποία σχεδιάστηκε. Παρέχονται οδηγίες επάνω στη συσκευή ή τη συσκευασία της. Οι συμβατές συσκευές (αισθητήρες, μέσα στερέωσης,…) παρατίθενται στον εμπορικό κατάλογο της Nissha Medical Technologies **(COMM/DOCU001/018)** τον οποίο μπορείτε να συμβουλευτείτε και να κατεβάσετε από την ιστοσελίδα της: www.NisshaMedical.com.

ΠΕΔΙΟ ΕΦΑΡΜΟΓΗΣ
Το **καλώδιο διασύνδεσης SpO_2 της Nissha Medical Technologies** μπορεί να χρησιμοποιηθεί παντού όπου απαιτείται μέτρηση του αρτηριακού κορεσμού σε οξυγόνο με μη επεμβατική μέθοδο.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES
The enveloppes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Η Nissha Medical Technologies προσφέρει μια πλήρη γκάμα καλωδίων διασύνδεσης SpO_2.

Για μετέπειτα παραγγελία σας, χρησιμοποιήστε τον κωδικό που αναγράφεται στο καλώδιο διασύνδεσης SpO2 Nissha Medical

Technologies ή στην συσκευασία του:
Για συμπληρωματικές πληροφορίες σχετικά με αυτό το προϊόν, επικοινωνήστε με την Nissha Medical Technologies ή επισκεφθείτε την ιστοσελίδα της: www.NisshaMedical.com.

II. ΑΠΟΘΗΚΕΥΣΗ/ΣΥΣΚΕΥΑΣΙΑ/ΣΥΜΒΟΛΑ

ΑΠΟΘΗΚΕΥΣΗ

Οι συνθήκες αποθήκευσης των καλωδίων διασύνδεσης SpO_2 είναι οι ακόλουθες.

- Θερμοκρασία περιβάλλοντος: 10 to 50 °C- 50 to 122 °F

ΣΥΣΚΕΥΑΣΙΑ

Τα **καλώδια διασύνδεσης SpO_2 Nissha Medical Technologies** συσκευάζονται ανά τεμάχιο.
Το **καλώδιο διασύνδεσης SpO_2 Nissha Medical Technologies** πρέπει να αποθηκεύεται, έως ότου χρησιμοποιηθεί, στην αρχική του συσκευασία για να αποφευχθεί οποιαδήποτε φθορά η οποία ενδέχεται να μειώσει το χρόνο ζωής του, την απόδοσή του και/ή το επίπεδο ασφάλειάς του.

III. ΕΠΙΔΟΣΕΙΣ/ΑΞΙΟΠΙΣΤΙΑ/ΑΣΦΑΛΕΙΑ/ΣΥΜΒΑΤΟΤΗΤΑ/ΜΗΧΑΝΙΚΗ & ΗΛΕΚΤΡΙΚΗ ΑΚΕΡΑΙΟΤΗΤΑ ΑΚΕΡΑΙΟΤΗΤΑ/ ΣΥΜΒΟΛΑ/ΑΛΛΕΡΓΙΚΟΤΗΤΑ

ΕΠΙΔΟΣΕΙΣ/ΑΞΙΟΠΙΣΤΙΑ

Τα καλώδια **διασύνδεσης SpO_2 Nissha Medical Technologies** ελέγχονται κατά τη διάρκεια και στο τέλος της κατασκευής σύμφωνα με τεχνικά πρωτόκολλα που εκπονούνται σύμφωνα με τις προδιαγραφές και τους κανονισμούς που ισχύουν για αυτόν τον τύπο προϊόντος.
Το τελικό αποτέλεσμα των δοκιμών που έγιναν σε ομάδα αντιπροσωπευτικών τύπων, με βάση τεχνικό πρωτόκολλο που εκπονήθηκε από την **Nissha Medical Technologies**, επιβεβαιώθηκε από εγκεκριμένο Εργαστήριο.

(Τεχνική Έκθεση του Gmed αρ.5358010/1T)

Επίσης, αποτέλεσαν αντικείμενο δοκιμών και κλινικής αξιολόγησης.

ΑΣΦΑΛΕΙΑ

Τα **καλώδια διασύνδεσης SpO_2 Nissha Medical Technologies** έχουν σχεδιαστεί και υλοποιηθεί σύμφωνα με τις γενικές και ειδικές ισχύουσες προδιαγραφές των εθνικών, ευρωπαϊκών και/ή διεθνών προτύπων που τα αφορούν:

(Πρότυπα IEC 60601-1/NF EN ISO 9919…)

Τα **καλώδια διασύνδεσης SpO_2 Nissha Medical Technologies** ανήκουν στην κατηγορία του «τμήματος που εφαρμόζεται» στον ασθενή όπως ορίζεται από το ευρωπαϊκό πρότυπο ασφάλειας IEC 60601-1.

Η **κατηγορία ασφάλειας**, ο **τύπος προστασίας (BF, CF)**, ο **βαθμός προστασίας** από τις ηλεκτρικές εκκενώσεις του **καλωδίου διασύνδεσης SpO_2** εξαρτώνται στενά από τα αντίστοιχα της ηλεκτροϊατρικής συσκευής με την οποία συνδέεται.

Το ρεύμα διαρροής χαμηλής συχνότητας, το οποίο έχει μετρηθεί σύμφωνα με τις συστάσεις που περιλαμβάνονται στα πρότυπα που είναι σήμερα σε ισχύ, έχει τιμές χαμηλότερες από τις τιμές που επιτρέπονται από το ανώτερο επίπεδο ασφάλειας

Προειδοποίηση

- Συμβουλευτείτε τις οδηγίες χρήσης της ηλεκτροϊατρικής συσκευής πριν να προβείτε στην εφαρμογή του **καλωδίου διασύνδεσης SpO_2**.
- Απομακρύνετε το **καλώδιο διασύνδεσης SpO_2** από πηγές ηλεκτρομαγνητικής ακτινοβολίας.
- Στο χειρουργείο πρέπει να διασφαλιστεί ότι το **καλώδιο διασύνδεσης SpO_2** (στο σύνολό του ή μέρος αυτού) βρίσκεται εκτός του χειρουργικού πεδίου.
- Φροντίστε τα σημεία επαφής των συνδετών να μην έρχονται σε επαφή με κανένα υγρό.

ΠΡΟΣΟΧΗ

Η Nissha Medical Technologies δεν μπορεί να θεωρηθεί υπεύθυνη για οποιοδήποτε συμβάν που ενδέχεται να προκύψει στον ασθενή, στο χρήστη ή σε άλλα άτομα και το οποίο θα οφείλεται στην παρουσία επικίνδυνων ηλεκτρικών ρευμάτων που προέρχονται από την ηλεκτροϊατρική συσκευή σε περίπτωση ελαττώματος.

ΣΥΜΒΑΤΟΤΗΤΑ

Η Nissha Medical Technologies θέτει στη διάθεση των πελατών της, στην ιστοσελίδα της στο Διαδίκτυο (www.NisshaMedical.com), ένα έγγραφο με πληροφορίες σχετικά με τη συμβατότητα της συσκευής καθώς και τεχνικά στοιχεία που την αφορούν.

ΜΗΧΑΝΙΚΗ ΚΑΙ ΗΛΕΚΤΡΙΚΗ ΑΚΕΡΑΙΟΤΗΤΑ

Για να διασφαλιστεί η ικανοποιητική μηχανική αντοχή των καλωδίων διασύνδεσης SpO_2 κατά την έλξη ή την κάμψη και για να μειωθεί ο κίνδυνος πρόκλησης βλάβης κατά τη χρήση, η Nissha Medical Technologies χρησιμοποίησε υλικά υψηλής ποιότητας και υψηλής αξιοπιστίας.

Οι συνδέτες που έχουν κατασκευασθεί εκ των προτέρων είναι εφοδιασμένοι με μαλακούς δακτυλίους προστασίας που ελαχιστοποιούν τον κίνδυνο τραυματισμού του καλωδίου σε αυτό το σημείο. Η επιφάνεια επαφής των βυσμάτων των συνδετών έχει υποστεί κατάλληλη επεξεργασία ώστε να εξασφαλίζεται, στο μέγιστο δυνατό βαθμό, η καλή επαφή μεταξύ των βυσμάτων ακόμη και μετά από μεγάλο αριθμό συνδέσεων και αποσυνδέσεων.

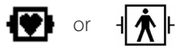
(΄΄Έκθεση δοκιμών αρ. CPB1097 – CPB1897/CPB2897)

Τα **καλώδια διασύνδεσης SpO_2 Nissha Medical Technologies** μπορούν να αντέξουν επανειλημμένες εκκενώσεις απινίδωσης. Δεν περιλαμβάνουν κανένα μεταλλικό τμήμα στο οποίο να παρέχεται πρόσβαση.

Το καλώδιο πρέπει να αποθηκεύεται, έως ότου χρησιμοποιηθεί, στην αρχική του συσκευασία για να αποφευχθεί οποιαδήποτε τυχαία ζημιά του προστατευτικού του περιβλήματος και των αγωγών του, η οποία ενδέχεται να μειώσει το χρόνο ζωής του, την απόδοσή του και/ή το επίπεδο ασφάλειάς του.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:



or

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ΑΛΛΕΡΓΙΚΟΤΗΤΑ

Τα υλικά που χρησιμοποιούνται για την κατασκευή των **καλωδίων διασύνδεσης SpO_2 Nissha Medical Technologies** αποτελέσαν αντικείμενο μελετών αλλεργικότητας. Αυτές οι δοκιμές δεν κατέδειξαν τυχόν παρουσία προϊόντων που θα μπορούσαν να προκαλέσουν αλλεργική αντίδραση και δυσανεξία.

IV. ΕΓΚΑΤΑΣΤΑΣΗ/ΧΡΗΣΗ/ΣΥΝΤΗΡΗΣΗ/ΥΓΙΕΙΝΗ/ΑΠΟΣΤΕΙΡΩΣΗ

ΕΓΚΑΤΑΣΤΑΣΗ

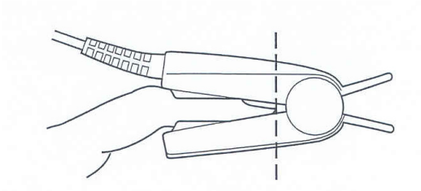
Για τη σωστή εγκατάσταση και χρήση του **καλωδίου διασύνδεσης SpO_2**, ακολουθήστε τις παρακάτω οδηγίες:

(Βλέπε, επίσης, τις οδηγίες χρήσης της ηλεκτροϊατρικής συσκευής).

Ενέργειες του/της ασθενούς:

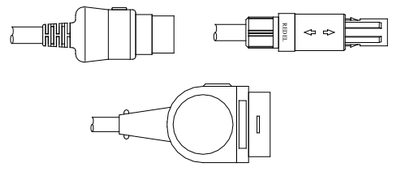
- Κατ'α ρχήν συνδέστε το καλώδιο της διασύνδεσης με τον **κατάλληλο αισθητήρα SpO_2.**
- Τοποθετείστε τον **αισθητήρα SpO_2** στο επιλεγμένο σημείο του σώματος του/της ασθενούς και το οποίο είναι κατάλληλο για τη μέτρηση σύμφωνα με τις οδηγίες του εγχειριδίου χρήσης της αντίστοιχης ηλεκτροϊατρικής συσκευής.

Παραδείγματα τοποθέτησης του αισθητήρα επί του δακτύλου:



Μην εισάγετε το δάκτυλο σε υπερβολικά μεγάλο βάθος

Παραδείγματα βύσματος:



Πλευρά που συνδέεται με τη συσκευή:

- Συνδέστε το καλώδιο διασύνδεσης SpO_2 με την κατάλληλη συσκευή (οξύμετρο παλμών).
- Θέστε σε λειτουργία τη συσκευή και ελέγξτε την καλή λειτουργία του ανατρέχοντας στις οδηγίες χρήσης της ηλεκτροϊατρικής συσκευής.

ΧΡΗΣΗ:

ΓΕΝΙΚΕΣ ΣΥΝΘΗΚΕΣ

Οι συνθήκες χρήσης του καλωδίου διασύνδεσης SpO_2 Nissha Medical Technologies είναι οι ακόλουθες.

- Θερμοκρασία περιβάλλοντος: 10 to 50 °C- 50 to 122 °F

ΕΙΔΙΚΕΣ ΣΥΝΘΗΚΕΣ

- **Μην χρησιμοποιείτε ένα καλώδιο διασύνδεσης SpO_2 που εγκυμονεί κίνδυνο για τον ασθενή (π.χ. φθαρμένο μονωτικό υλικό)**

ΠΡΟΛΗΠΤΙΚΗ ΣΥΝΤΗΡΗΣΗ

Η διάρκεια ζωής του κ**αλωδίου διασύνδεσης SpO_2** εξαρτάται από αρκετές παραμέτρους. Παραδείγματος χάριν:

- Ο αριθμός των χρήσεων
- Η εφαρμογή προληπτικής συντήρησης
- Η τήρηση ικανοποιητικών συνθηκών υγιεινής

Ο τακτικός έλεγχος, οπτικός και ηλεκτρονικός του **καλωδίου διασύνδεσης SpO_2**, θα καθορίσει εάν πρέπει να αλλαχθεί.

ΠΡΟΕΙΔΟΠΟΙΗΣΗ:

⚠ **Σε περίπτωση μεταφοράς ενός καλωδίου εκτός τμήματος για συντήρηση ή πραγματογνωμοσύνη, η καθαριότητα και η απολύμανση του προϊόντος πριν την αποστολή ή τη μεταφορά του είναι ευθύνη του τμήματος που το χρησιμοποιεί.**

ΔΙΟΡΘΩΤΙΚΗ ΣΥΣΝΤΗΡΗΣΗ

- Δεν υπάρχει διορθωτική συντήρηση για το παρόν προϊόν.

ΥΓΙΕΙΝΗ

PLEASE NOTE:
Do not allow any liquid to get inside the various connectors on the interface cable.

Καθαρίζετε τακτικά το καλώδιο διασύνδεσης SpO_2 Nissha Medical Technologies και των αγωγών απαγωγών του σύμφωνα με τη μέθοδο που περιγράφεται πιο κάτω.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
Προσοχή	Δεν πρέπει να διεισδύσει υγρό στο εσωτερικό των διαφόρων συνδετών του καλωδίου διασύνδεσης.
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

Automatic cleaning:	Is strictly not applicable
Καθαρισμός	• Καθαρισμός του καλωδίου διασύνδεσης SpO2 INTEGRAL PROCESS (συμπεριλαμβανομένου του συνδέτη) με μαλακό ύφασμα εμποτισμένο με νερό και σαπούνι.
Απολύμανση του	**(προερχόμενη από τη μελέτη του Εργαστηρίου ANIOS, αρ. 6416.94/0387)** **Διαδικασία** • Γεμίστε μια λεκάνη εμποτισμού με διάλυμα 0,5% HEXANIOS G+R • Βυθίστε μερικώς το καλώδιο προστατεύοντας τα άκρα για να αποφευχθεί οποιοδήποτε πρόβλημα ηλεκτρικής φύσης στους συνδέτες • Τηρείστε χρόνο επαφής 15 λεπτών • Ξεπλύντε το καλώδιο • Στεγνώστε το καλώδιο με απορροφητικό χαρτί • Κατά την εμβύθιση τρίψτε τα άκρα του καλωδίου χρησιμοποιώντας LINGET ANIOS. **(Ανανεώστε το διάλυμα κάθε 48 ώρες)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Η χρήση του καλωδίου διασύνδεσης SpO2 INTEGRAL PROCESS σε αποστειρωμένη αίθουσα ενδέχεται να καταστήσει αναγκαία την εφαρμογή διαδικασίας αποστείρωσης. Η Nissha Medical Technologies συνιστά την εφαρμογή των μεθόδων απολύμανσης και/ή αποστείρωσης που περιγράφονται πιο κάτω.
Απολύμανση : ⚠	• Χρόνος αποστείρωσης: 22 ώρες εκ των οποίων 20 ώρες έκθεσης σε αέριο. • Παράγοντας αποστείρωσης: Διοξείδιο του άνθρακα + Οξείδιο του Αιθυλενίου (80/20%). • Αρχικό κενό: -70 kPa. • Σχετική υγρασία: >60% • Θερμοκρασία: 50°C. • Συγκέντρωση Οξειδίου του Αιθυλενίου: 530 g/m3. • Πίεση: 120 kPa. • Τελικό κενό: -70 kPa. • Έκπλυση **(Έκθεση της δοκιμής 001: Δοκιμή αποστείρωσης/καλώδια ΗΚΓ-– RE/IP/BPF – Αναθεώρηση 0 της 26/02/98)**
ΠΡΟΣΟΧΗ:	**Μην αποστειρώνετε ποτέ τα «καλώδια και εξαρτήματα σε κλίβανο» με ατμό ή βραστό νερό.**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

EL ΕΛΛΗΝΙΚΑ

V. ΕΓΓΥΗΣΗ/ΕΥΘΥΝΗ

Κάθε **καλώδιο διασύνδεσης Spo$_2$** που δεν χρησιμοποιείται και διατηρείται στην αρχική του συσκευασία και το οποίο δεν έχει υποστεί καμία εμφανή βλάβη καλύπτεται με εγγύηση ενός έτους από την Nissha Medical Technologies.

Η Nissha Medical Technologies εγγυάται τη συμμόρφωση της συσκευής με τις προδιαγραφές των προτύπων ασφάλειας και επιδόσεων που είναι σε ισχύ και εφαρμόζονται σχετικά με αυτό.

ΠΡΟΣΟΧΗ:

Η κατηγορία και ο τύπος προστασίας από τις ηλεκτρικές εκκενώσεις εξαρτώνται επίσης από την κατηγορία και τον τύπο προστασίας της ηλεκτροϊατρικής συσκευής (οξύμετρο σφυγμών) με την οποία μπορεί να συνδεθεί.

Συμβουλευτείτε τις οδηγίες χρήσης της εκάστοτε συσκευής και των διασυνδεδεμένων με αυτήν εξαρτημάτων, πριν την εφαρμογή των συσκευών.

Η Nissha Medical Technologies δεν θεωρείται υπεύθυνη για οποιοδήποτε συμβάν που θα οφείλεται σε μη τήρηση των κανόνων εγκατάστασης και χρήσης που περιλαμβάνονται στο παρόν εγχειρίδιο.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

ISTRUZIONI PER L'USO

CAVO INTERFACCIA PER SENSORI SpO_2

- **TEMPERATURE LIMITS** (10°C 50°F – 50°C 122°F)
- **PROTECT FROM MOISTURE**
- **LOT CODE** (LOT)
- **QUANTITY** (QTY)
- **EXPIRY** (Use By)
- **MEDICAL DEVICE** (MD)
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE** (NON STERILE)
- **MANUFACTURER**
- **LATEX FREE** (Not made with natural rubber latex)
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE** (REF)
- **EC ACCORDING TO EU MDR 2017/745** (CE)

Secondo le regole di classificazione della EU MDR 2017/745 e la sua destinazione, il cavo interfaccia SpO2 è di classe I.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

ISO 13485:2016
HS.NisshaMedical.com/IFU

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IT ITALIANO

CAVO INTERFACCIA PER SENSORI SpO2

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. IDENTIFICAZIONE/CAMPO DI APPLICAZIONE

IDENTIFICAZIONE
Il cavo interfaccia SpO_2 progettato da Nissha Medical Technologies è **l'elemento** che collega il s**ensore SpO_2** per la **misurazione non invasiva** continua della **saturazione d'ossigeno arteriosa** e l'apparecchio elettromedicale.

Il **cavo interfaccia** è utilizzabile unicamente con l'apparecchio elettromedicale (pulsossimetro) per il quale è stato progettato. L'indicazione in proposito viene fornita sul dispositivo o sul suo imballaggio. I dispositivi (sensori, mezzi di fissaggio,…) compatibili sono elencati nel catalogo commerciale Nissha Medical Technologies ***(COMM/DOCU001/018)*** consultabile e scaricabile sul suo sito Internet: HS.Nisshamedical.com/ifu.

CAMPO DI APPLICAZIONE
Il **cavo interfaccia SpO_2 Nissha Medical Technologies** è utilizzabile in tutte quelle situazioni in cui sia necessaria la misurazione della saturazione d'ossigeno arteriosa tramite metodo non invasivo.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES
The enveloppes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Nissha Medical Technologies propone una gamma completa di **cavi interfaccia SpO_2.**

Per i vostri ordini ulteriori, utilizzate il numero di codice indicato sul cavo interfaccia SpO2 Nissha Medical Technologies o sul suo imballaggio.

NISSHA MEDICAL TECHNOLOGIES

Per avere un supplemento di informazioni su questo prodotto, contattare Nissha Medical Technologies o consultare il suo sito Internet: www.NisshaMedical.com.

II. IMMAGAZZINAMENTO / CONFEZIONAMENTO / SIMBOLI

IMMAGAZZINAMENTO

Le condizioni di **immagazzinamento** dei **cavi interfaccia SpO_2** sono le seguenti:

- Temperatura ambiente: 10 to 50 °C- 50 a 122 °F

CONFEZIONAMENTO

I cavi interfaccia SpO_2 Nissha Medical Technologies vengono confezionati singolarmente.

Il cavo interfaccia SpO_2 Nissha Medical Technologies in attesa di utilizzazione, deve essere immagazzinato nel suo imballaggio originale al fine di evitare qualsiasi deterioramento suscettibile di ridurne la durata di vita, le prestazioni e/o il livello di sicurezza.

III. PRESTAZIONI / AFFIDABILITÀ / SICUREZZA / COMPATIBILITÀ / INTEGRITÀ MECCANICA ed ELETTRICA / SIMBOLI / ALLERGENICITÀ

PRESTAZIONI / AFFIDABILITÀ

I **cavi interfaccia SpO_2 Nissha Medical Technologies** sono controllati in corso di fabbricazione, e alla fine di essa, secondo protocolli stabiliti conformemente alle specifiche delle norme e regolamentazioni pertinenti.
Il risultato finale dei test praticati su un gruppo di tipi rappresentativi secondo un protocollo tecnico stabilito da **Nissha Medical Technologies**, è stato confermato da un laboratorio certificato.

(Rapporto tecnico Gmed n°5358010/1T)

Essi sono stati inoltre sottoposti a test e valutazioni in ambito clinico.

SICUREZZA

I **cavi interfaccia SpO_2 Nissha Medical Technologies** sono progettati e realizzati conformemente alle specifiche generali e particolari delle norme europee, nazionali e internazionali a riguardo attualmente in vigore.

(Norme IEC 60601-1/NF EN ISO 9919…)

I **cavi interfaccia SpO_2 Nissha Medical Technologies** costituiscono parte integrante della «parte applicata» al paziente, come definita dalla norma europea di sicurezza IEC 60601-1.

La **classe di sicurezza**, il **tipo di protezione (BF, CF)**, il **grado di protezione** contro le scosse elettriche del cavo interfaccia SpO_2 sono strettamente legati a quelli dell'apparecchio elettromedicale sul quale esso è connesso.

Le correnti di dispersione in bassa frequenza, misurate in conformità alle raccomandazioni delle norme attualmente in vigore e applicabili a questo prodotto hanno valori inferiori a quelli autorizzati per il livello di sicurezza più alto.

ATTENZIONE

⚠
- Consultare le istruzioni dell'apparecchio elettromedicale prima di qualsiasi utilizzo del cavo interfaccia SpO_2.
- Allontanare il cavo interfaccia SpO_2 dalle sorgenti elettromagnetiche.
- In sala operatoria, assicurarsi che il cavo interfaccia SpO_2 (in tutto o in parte) si trovi al di fuori del campo operatorio.
- Fare in modo che nessun liquido possa entrare in contatto coi connettori.

ATTENZIONE

⚠ Nissha Medical Technologies non potrà essere ritenuta responsabile di incidenti occorsi al paziente, all'utilizzatore e ad altre persone, causati dalla presenza di correnti elettriche pericolose provenienti dall'apparecchio elettromedicale in caso di guasto.

COMPATIBILITÀ

Nissha Medical Technologies mette a disposizione della propria clientela, sul proprio sito internet (www.NisshaMedical.com), un documento scaricabile contenente informazioni sulla compatibilità del dispositivo nonché informazioni tecniche che lo riguardano.

IT ITALIANO

INTEGRITÀ MECCANICA ED ELETTRICA

Per assicurare una buona resistenza meccanica del cavo interfaccia SpO_2 alla trazione, alla flessione e ridurre le correnti di dispersione che potrebbero circolare attraverso il paziente, INTEGRAL PROCESS utilizza materiali di alta qualità per la fabbricazione del dispositivo.

I connettori pressofusi sono dotati di manicotti flessibili che minimizzano il rischio di rottura del cavo a questo livello.
La superficie di contatto dei maschi dei connettori è trattata in modo da ridurre per quanto possibile la resistenza di contatto anche dopo un numero considerevole di connessioni e disconnessioni.

(Rapporto test n°CPB1097 – CPB1897/CPB2897)

I **cavi interfaccia SpO_2 Nissha Medical Technologies** possono sopportare scariche di defibrillazione ripetute. Essi non possiedono alcuna parte metallica accessibile.

Un cavo, in attesa di utilizzazione, deve essere immagazzinato nel suo imballaggio di origine al fine di evitare qualsiasi deterioramento precoce della sua guaina isolante e dei suoi conduttori che possa ridurne la durata di vita, le prestazioni e/o il livello di sicurezza.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:

 or 

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ALLERGENICITÀ

I materiali isolanti utilizzati nella fabbricazione dei cavi interfaccia SpO_2 Nissha Medical Technologies sono stati sottoposti a test di allergenicità. Questi test non hanno messo in evidenza la presenza di prodotti in grado di scatenare una reazione allergica intollerabile.

IV. INSTALLAZIONE / UTILIZZAZIONE / MANUTENZIONE / IGIENE / STERILIZZAZIONE

INSTALLAZIONE

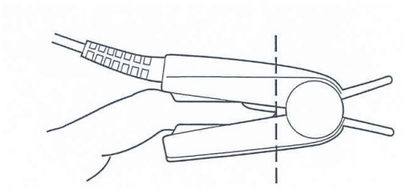
Per una installazione e una utilizzazione appropriate del **cavo interfaccia SpO_2**, seguire le seguenti istruzioni:

(vedere anche le istruzioni per l'uso dell'apparecchio elettromedicale in questione)

Lato paziente:

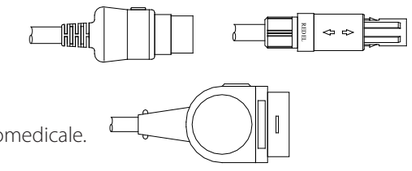
- Connettere per prima cosa il cavo interfaccia al sensore SpO_2 appropriato.
- Posizionare il sensore SpO_2 sul sito paziente scelto di misura adatta, facendo riferimento alle istruzioni dell'apparecchio elettromedicale in questione)

Esempi di posizionamento del sensore sul dito:



Non inserire il dito troppo a fondo

Esempi di spina:



Lato apparecchio:

- Connettere il **cavo interfaccia SpO_2** all'apparecchio (pulsossimetro) appropriato.
- Mettere in funzione l'apparecchio e assicurarsi del suo funzionamento, consultando le istruzioni dell'apparecchio elettromedicale.

UTILIZZAZIONE:

CONDIZIONI GENERALI
Le condizioni di utilizzazione del cavo interfaccia SpO2 INTEGRAL PROCESS sono le seguenti:
- Temperatura ambiente 10 to 50 °C- 50 a 122 °F

CONDIZIONI PARTICOLARI
- **Non utilizzare un cavo interfaccia SpO_2 che presenti un rischio per il paziente (isolante deteriorato, per esempio).**

MANUTENZIONE PREVENTIVA
La durata di vita del **cavo interfaccia SpO_2** è in funzione di un numero importante di parametri. Per esempio:
- Il numero di applicazioni
- Il rispetto della manutenzione preventiva
- Il mantenimento in buono stato di igiene

Un controllo regolare, visivo ed elettrico, dei conduttori determinerà se sia da effettuare la sostituzione del **cavo interfaccia SpO_2.**

ATTENZIONE:
⚠ **In caso di trasferimento di un cavo fuori reparto per manutenzione o esame, è responsabilità del reparto utilizzatore pulire e disinfettare il prodotto prima di spedirlo o trasferirlo.**

MANUTENZIONE CORRETTIVA
- Non è prevista manutenzione correttiva per questo prodotto.

IGIENE

ATTENZIONE
Non fare penetrare liquido all'interno dei connettori del cavo interfaccia.

Procedere a una pulitura regolare del cavo interfaccia SpO_2 Nissha Medical Technologies e dei suoi conduttori di derivazione secondo il metodo descritto qui di seguito.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
CAUTION	When cleaning or disinfecting the cables make sure that the plugs at the end of the cables do not become immersed in any liquid to avoid any electrical problems
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

IT ITALIANO

Automatic cleaning:	Is strictly not applicable
Pulitura :	• Pulitura del cavo interfaccia SpO_2 Nissha Medical Technologies (connettore compreso) con un panno imbevuto di acqua saponata
Disinfezione :	**(Tratto dallo studio di Laboratorio ANIOS, n° 6416.94/0387)** **Procedimento** • riempire una bacinella con una soluzione allo 0,5% di HEXANIOS G+R • immergere parzialmente il cavo proteggendone le estremità per evitare qualsiasi problema elettrico sui connettori • rispettare un tempo di immersione di 15 minuti • risciacquare il cavo • asciugare il cavo con carta assorbente • durante l'immersione, strofinare le estremità del cavo con l'aiuto di una PEZZUOLA ANIOS. **(Rinnovare la soluzione ogni 48 ore)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Please follow the standard protocol of packaging of your institution before sterilization
Sterilizzazione: ⚠	• Tempo di sterilizzazione: 22 ore, di cui 20 ore di esposizione al gas • Agente sterilizzaznte: Diossido di Carbonio + Ossido di Etilene (80/20%) • Vuoto iniziale: -70 kPa • Umidità relativa: >60% • Temperatura: 50°C • Concentrazione in Ossido di Etilene: 530 g/m3 • Pressione: 120 kPa • Vuoto finale: -70 kPa • Risciacquo **(Rapporto di test 001: test di sterilizzazione/cavi SpO2-RE/IP/BPF – revisione 0 del 26/02/98)**
Attenzione:	**Non sterilizzare mai i cavi e sensori in autoclave esponendoli al vapore o all'acqua bollente**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

IT ITALIANO

V. GARANZIA / RESPONSABILITÀ

Ogni **cavo interfaccia SpO_2** non utilizzato e conservato nel suo imballaggio di origine, e che non abbia subito alcun danno apparente, è garantito per un anno da **Nissha Medical Technologies**.

Nissha Medical Technologies garantisce la conformità del dispositivo alle specifiche di norme di sicurezza e di prestazioni che sono a esso applicabili e attualmente in vigore.

ATTENZIONE:

La classe e il tipo di protezione contro le scosse elettriche sono legati a quelli dell'apparecchio elettromedicale (pulsossimetro) sul quale il sensore e il suo cavo sono connessi.

Consultare le istruzioni per l'uso dell'apparecchio interessato e degli accessori annessi prima di ogni messa in funzione del dispositivo.

Nissha Medical Technologies non potrà essere ritenuta responsabile di incidenti occorsi in caso di mancato rispetto delle regole di installazione e di utilizzazione menzionate in queste istruzioni per l'uso.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

GEBRUIKSAANWIJZING

INTERFACEKABEL voor SpO_2 sensoren

- **TEMPERATURE LIMITS**
- **PROTECT FROM MOISTURE**
- **LOT CODE**
- **QUANTITY**
- **EXPIRY**
- **MEDICAL DEVICE**
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE**
- **MANUFACTURER**
- **LATEX FREE**
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE**
- **EC ACCORDING TO EU MDR 2017/745**

Overeenkomstig het classificatiesysteem gegeven in de **EU MDR 2017/745** en overeenkomstig zijn gebruik, behoort de **SpO_2 interfacekabel** tot **klasse I**.

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

ISO 13485:2016
HS.NisshaMedical.com/IFU

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COMM-DOCU 810/002
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INTERFACEKABEL VOOR SPO_2 SENSOREN

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. CLASSIFICATIE / TOEPASSINGSGEBIED

CLASSIFICATIE

De **SpO_2 interfacekabel** die werd ontwikkeld door **Nissha Medical Technologies** verzorgt de verbinding tussen het elektromedische apparaat en de **SpO_2 sensor voor metingen, niet-invasief en continu, van de arteriële zuurstofverzadiging**.

De **interfacekabel** is enkel bruikbaar met het elektromedische apparaat (oximeter van puls) waarvoor hij werd ontwikkeld. Aanwijzingen worden gegeven op het toestel of de verpakking. Het compatibele materieel (sensoren, bevestigingsmiddelen, …) wordt vermeld in een lijst in de commerciële catalogus ***(COMM/DOCU 001/018)*** die geraadpleegd en gedownload kan worden op de internetsite : **HS.Nisshamedical.com/ifu.**

TOEPASSINGSGEBIED

De Nissha Medical Technologies SpO_2 interfacekabel is overal bruikbaar waar een niet-invasieve meting van de arteriële zuurstofverzadiging gevraagd wordt.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES

The enveloppes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

Nissha Medical Technologies biedt een compleet gamma aan van **SpO_2 interfacekabels.**

Gebruik voor uw volgende bestelling het codenummer dat op de Nissha Medical Technologies SpO_2 interfacekabel of op de verpakking staat.

Voor meer informatie over dit product, contacteer dan Nissha Medical Technologies of raadpleeg de internetsite : www.NisshaMedical.com

II. OPSLAG / VERPAKKING / SYMBOLEN

OPSLAG

De **Nissha Medical Technologies SpO_2 interfacekabels** dienen onder de volgende voorwaarden opgeslagen te worden :

- **Omgevingstemperatuur : 10 à 50 °C- 50 à 122 °F**

VERPAKKING

De **Nissha Medical Technologies SpO_2 interfacekabels** worden per stuk verpakt. De **Nissha Medical Technologies SpO_2 interfacekabels** dienen in afwachting van ingebruikneming opgeslagen te worden in de oorspronkelijke verpakking om elke beschadiging te vermijden die de houdbaarheid, het prestatievermogen en/of de veiligheid kan doen afnemen.

III. PRESTATIES / BETROUWBAARHEID / VEILIGHEID / COMPATIBILITEIT / MECHANISCHE INTEGRITEIT / SYMBOLEN / ALLERGIEËN

PRESTATIES / BETROUWBAARHEID

De **Nissha Medical Technologies SpO_2 interfacekabels** worden tijdens en na de fabricatie gecontroleerd overeenkomstig een technisch protocol dat werd opgemaakt in overeenstemming met de normen en reglementeringen die thans van kracht zijn betreffende dit type product. Het eindresultaat van de tests, die werden uitgevoerd op een groep representatieve types volgens een technisch protocol dat door Nissha Medical Technologies werd opgemaakt, is door een officieel erkend Laboratorium voor echt verklaard.

(Technisch Rapport Gmed nr. 5358010/1T)

De kabels werden eveneens aan klinische tests en evaluaties onderworpen.

VEILIGHEID

De **Nissha Medical Technologies SpO_2 interfacekabels** zijn ontworpen en geproduceerd in overeenstemming met de algemene en bijzondere specificaties uit nationale, Europese en/of internationale normen die thans van kracht zijn m.b.t. deze producten.

(Standards EN IEC 60601-1 / EN ISO 9919, etc.)

De **Nissha Medical Technologies SpO_2 interfacekabels** maken deel uit van « het gedeelte dat op de patiënt wordt aangebracht » zoals dat gedefinieerd werd in de Europese veiligheidsnorm **IEC 60601-1.** De **veiligheidsklasse**, het **beveiligingssysteem (BF, CF)** en de **beveiligingsgraad** van de **SpO_2 interfacekabel** tegen elektrische schokken zijn nauw verbonden met die van het elektromedische apparaat waarop de kabel is aangesloten.

De lekstromen met lage frequentie, die gemeten werden in overeenstemming met de aanbevelingen van de normen die thans op dit product van kracht en van toepassing zijn, hebben lagere waarden dan de toegestane waarden in het hoogste veiligheidsniveau.

WAARSCHUWING

- Instructieblad van het elektromedische apparaat raadplegen voor elke ingebruikneming van de SpO_2 interfacekabel.
- De SpO_2 interfacekabel uit de buurt van elektromagnetische stralingsbronnen houden.
- Men moet zich er in de operatiekamer van vergewissen dat de SpO_2 interfacekabel zich (volledig of gedeeltelijk) buiten het operatieveld bevindt.
- Ervoor zorgen dat geen enkele vloeistof de contacten van de schakelaars kan aantasten.

OPGELET

Nissha Medical Technologies kan niet aansprakelijk gesteld worden bij incidenten met de patiënt, de gebruiker of andere personen die veroorzaakt worden door de aanwezigheid van gevaarlijke elektrische stromingen afkomstig van het elektromedische apparaat in geval van een defect.

COMPATIBILITEIT

Nissha Medical Technologies stelt op zijn internetsite (www.NisshaMedical.com) een document ter beschikking van de klanten dat men kan downloaden en dat informatie bevat over de compatibiliteit van het toestel, alsook technisch advies hieromtrent.

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MECHANISCHE EN ELEKTRISCHE INTEGRITEIT

Om een goede weerstand te garanderen van de Nissha Medical Technologies SpO^2 interfacekabels tegen tractie en doorbuigen, alsook om het risico op beschadiging tijdens het gebruik te verminderen, heeft Nissha Medical Technologies materialen van hoge kwaliteit gebruikt bij de fabricatie van het toestel. De afgewerkte schakelaars zijn uitgerust met buigzame moffen die het risico op het breken van de kabel op die plaats tot een minimum herleiden.

Het contactoppervlak van de pennen van de schakelaars werd behandeld om de contactweerstand tussen twee pennen tot een minimum te herleiden, zelfs na een aanzienlijk aantal koppelingen en ontkoppelingen.

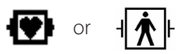
(Technisch Rapport nr. CPB1097-CPB1897/CPB2897)

De Nissha Medical Technologies SpO_2 interfacekabels kunnen herhaalde schokken bij defibrillatie doorstaan. Ze bevatten geen enkel toegankelijk metalen onderdeel.

Een kabel dient in afwachting van ingebruikneming opgeslagen te worden in de oorspronkelijke verpakking om elke onbedoelde beschadiging te vermijden aan de isolerende bescherming en de geleiders die de houdbaarheid, het prestatievermogen en/of de veiligheid kan doen afnemen.

SAFETY SYMBOLS

Explanation of the symbols used on the electromedical device:



or

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ALLERGIEËN

De materialen gebruikt tijdens de fabricatie van de **Nissha Medical Technologies SpO_2 interfacekabels** die op de patiënt worden aangebracht werden aan allergietests onderworpen. Deze tests hebben de aanwezigheid van producten die een ondraaglijke allergische reactie kunnen teweegbrengen niet kunnen bewijzen.

IV. INSTALLATIE / GEBRUIK / ONDERHOUD / HYGIËNE / STERILISEREN

INSTALLATIE

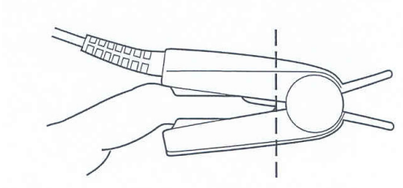
Voor een gepaste installatie en goed gebruik van de Nissha Medical Technologies SpO_2 interfacekabel de volgende instructies in acht nemen:

(zie ook de gebruiksaanwijzing van het elektromedische apparaat)

Kant van de patiënt:

- Eerst de interfacekabel verbinden met de gepaste **SpO_2 sensor.**
- De **SpO_2 sensor** plaatsen op de gekozen plek bij de patiënt en daarbij de instructies in de handleiding van het betreffende elektromedische apparaat naleven.

Voorbeeld plaatsing sensor op de vinger:

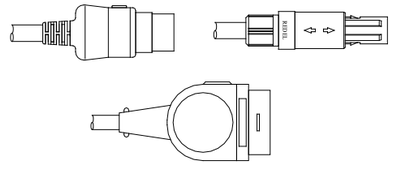


Vinger niet te diep inbrengen

Kant van het apparaat:

- De Nissha Medical Technologies SpO_2 interfacekabel verbinden met het gepaste apparaat (oximeter van pols).
- Het apparaat aanzetten en zich ervan vergewissen dat het goed werkt door het instructieblad van het elektromedische apparaat te raadplegen.

Voorbeelden plug:



GEBRUIK:

ALGEMENE VOORWAARDEN
De gebruiksvoorwaarden voor de Nissha Medical Technologies SpO_2 interfacekabel zien er als volgt:
- Omgevingstemperatuur: 10 à 50 °C- 50 à 122 °F

BIJZONDERE VOORWAARDEN
- **Geen SpO_2 interfacekabel gebruiken die een risico inhoudt voor de patiënt (beschadiging van isolatiemateriaal bijvoorbeeld).**

PREVENTIEF ONDERHOUD
De houdbaarheid van de SpO_2 interfacekabel wordt door een aanzienlijk aantal parameters bepaald. Bijvoorbeeld:
- het aantal ingebruiknemingen
- het naleven van het preventief onderhoud
- het onderhoud en de goede hygiënische staat

Een regelmatige visuele en elektrische controle van de geleiders zal bepalen of de interfacekabel vervangen dient te worden.

WAARSCHUWING:
⚠ **Bij een overplaatsing van de kabel buiten de afdeling voor onderhoud of onderzoek, is het de verantwoordelijkheid van de dienst die het product gebruikt om het te reinigen en te ontsmetten alvorens het te verzenden of over te brengen.**

HERSTELLEND ONDERHOUD
- Voor dit product is er geen herstellend onderhoud .

HYGIËNE

PLEASE NOTE:
Do not allow any liquid to get inside the various connectors on the interface cable.

Overgaan tot een regelmatige reiniging van de Nissha Medical Technologies SpO_2 interfacekabel en zijn geleiders volgens de hierop volgende methode.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: SpO_2 Cables	
CAUTION	Ervoor zorgen dat er geen vloeistoffen binnendringen in de verschillende schakelaars van de verbindingskabel.
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

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Automatic cleaning:	Is strictly not applicable
Manual cleaning:	• Reiniging van de Nissha Medical Technologies SpO_2 interfacekabel (schakelaar inbegrepen) met een in zeepwater gedrenkte doek.
Ontsmetten:	**(gebaseerd op de studie van Laboratorium ANIOS, nr. 6416.94/0387)** **Methode** • een dompelbak vullen met een oplossing die 0,5% HEXIANOS G+R bevat • de kabel gedeeltelijk onderdompelen waarbij de uiteinden beschermd worden om elk elektrisch probleem met de schakelaars te voorkomen • de kabel gedurende 15 minuten in de oplossing laten rusten • de kabel afspoelen • de kabel droogmaken met absorberend papier • tijdens het onderdompelen over de uiteinden van de kabel wrijven met een ANIOS LINGET **(De oplossing om de 48 uur vervangen)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Nissha Medical Technologies raadt de volgende methodes aan wat ontsmetten en steriliseren betreft
Steriliseren : ⚠	• Steriliseringstijd : 22 uren waarvan 20 voor blootstelling aan gas • Agens voor steriliseren : koolstofdioxide + ethyleenoxide (80/20%) • Beginvacuüm : -70 kPa • Relatieve vochtigheid : > 60% • Temperatuur : 50°C • Ethyleenoxideconcentratie : 530 g/m3 • Druk : 120 kPa • Eindvacuüm : -70 kPa • Afspoelen **(Testrapport 001 : steriliseringsproef / SpO_2 kabels-RE/IP/BPF-Aanpassing 0 van 26/02/98)**
OPGELET:	**Nooit de kabels en hun accessoires steriliseren met stoom of kokend water in de autoclaaf.**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

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V. GARANTIE / AANSPRAKELIJKHEID

Voor elke SpO_2 kabel die niet werd gebruikt, in de oorspronkelijke verpakking zit en geen zichtbare schade heeft opgelopen, biedt Nissha Medical Technologies één jaar garantie aan.

Nissha Medical Technologies garandeert dat de toestellen in overeenstemming zijn met de specificaties van de veiligheid- en gebruiksnormen die thans van kracht en toepasbaar zijn op dit product.

OPGELET:

De veiligheidsklasse en het beveiligingssysteem tegen elektrische schokken worden bepaald door het elektromedische apparaat (oximeter van puls) waarop de sensor en diens kabel aangesloten worden.

Raadpleeg voor elke ingebruikneming van het toestel de gebruiksaanwijzing van het betreffende toestel, alsook die van de te gebruiken hulpstukken.

Nissha Medical Technologies kan niet aansprakelijk gesteld worden als de installatie- en gebruiksregels die vermeld worden in deze gebruiksaanwijzing niet werden nageleefd.

NISSHA MEDICAL TECHNOLOGIES

INTEGRAL PROCESS Cables & Leadwires

MODO DE EMPREGO

CABO DE INTERFACE para sensores de SpO_2

- **TEMPERATURE LIMITS**
- **PROTECT FROM MOISTURE**
- **LOT CODE**
- **QUANTITY**
- **EXPIRY**
- **MEDICAL DEVICE**
- **SEPARATE COLLECTION AS WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT**
- **CAUTION**
- **NON-STERILE**
- **MANUFACTURER**
- **LATEX FREE**
- **READ INSTRUCTIONS FOR USE**
- **REFERENCE**
- **EC ACCORDING TO EU MDR 2017/745**

Consoante as regras de classificação da EU MDR 2017/745 e o respectivo uso a que se destina, o cabo de interface SpO2 é da classe I.

- The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)
- Please always read the instruction leaflet for the electromedical device before using the SpO_2 interface cable.
- Remove the SpO_2 interface cable to a safe distance from any sources of electromagnetic radiation.
- In the operating room, ensure that all or part of the SpO_2 interface cable is outside of the operating area.
- Ensure that no liquid can reach the connectors' contacts.
- Do not use a cable or part of a cable if there is any risk to the patient (e.g. damaged insulating material).
- The Nissha Medical Technologies SpO_2 interface cable has not been designed to be used in MRI environment.
- If you need to take a cable out of the department for maintenance or verification, this becomes the responsibility of the user department to clean and disinfect the product before shipping or transportation.
- Do not allow any liquid to get inside the various connectors on the interface cable.
- The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the SpO_2 interface cable is connected.
- Always read the instruction manual for the particular device and any accessories to be used before placing the device into service.
- Nissha Medical Technologies may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

ISO 13485:2016
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CABO DE INTERFACE PARA SENSORES DE SPO_2

Please carefully read the following instructions:
Failure to observe these precautions for use may lead to undesirable medical consequences.

Important note:
This insert is designed to provide guidance for the use and handling of the SpO_2 interface cable which connects the **SpO_2 sensor** used for the **non-invasive** and continuous **measurement of arterial oxygen saturation**, to the electromedical device.

No reference is made to a specific medical technique. The manufacturer declines any responsibility for problems resulting from improper use of the product.

I. IDENTIFICAÇÃO / ÂMBITO DE APLICAÇÃO

IDENTIFICAÇÃO

O **cabo de interface SpO_2**, concebido pela Nissha Medical Technologies é o elemento que estabelece a ligação entre o sensor de SpO2 de medição não invasiva e em contínuo da saturação arterial em oxigénio e o aparelho electromédico.

O cabo de interface pode apenas ser utilizado com o aparelho electromédico (oxímetro de pulso) para o qual foi especialmente concebido. A leitura é dada no dispositivo ou na respectiva embalagem. Os dispositivos (sensores, meios de fixação,…..) compatíveis estão indicados no catálogo comercial da Nissha Medical Technologies ***(COMM/DOCU001/018)*** que pode ser consultado e descarregado no site da Internet: www.NisshaMedical.com.

ÂMBITO DE APLICAÇÃO

O cabo de interface SpO_2 Nissha Medical Technologies pode ser utilizado sempre que se pretenda a leitura da saturação arterial em oxigénio, medida pelo método não invasivo.

The user has to make sure that the SpO_2 sensor connected to the SpO_2 interface cable suits the electromedical device and the type of patients (adult, infant, neonates)

ANTIBACTERIAL QUALITIES

The enveloppes of the medical bioactive **Nissha Medical Technologies** cables carry an additional chemical compost of non toxic material which gives them a slightly acid surface like the human skin pH neighbour 5. Almost all the pathogenic agents responsible for the nosocomial sicknesses are destroyed in this environment.

A Nissha Medical Technologies propõe uma gama completa de cabos de interface SpO_2.

Para os seus pedidos posteriores, utilize o número de código que se encontra no cabo de interface SpO_2 Nissha Medical Technologies ou na respectiva embalagem.

Para mais informações sobre este produto, contacte a Nissha Medical Technologies ou consulte o site da Internet: www.NisshaMedical.com

II. ARMAZENAGEM / ACONDICIONAMENTO / SÍMBOLOS

ARMAZENAGEM
As condições de armazenagem dos cabos de interface SpO_2 são as seguintes:
- Temperatura ambiente: 10 to 50 °C- 50 to 122 °F

ACONDICIONAMENTO
Os **cabos de interface SpO_2** são acondicionados unitariamente.

Um cabo de interface SpO_2 que aguarda a respectiva utilização deve ser guardado na respectiva embalagem original, a fim de evitar qualquer deterioração intempestiva, susceptível de diminuir a sua vida útil , o seu desempenho e/ou o seu nível de segurança.

III. DESEMPENHO / FIABILIDADE / SEGURANÇA / COMPATIBILIDADE / INTEGRIDADE MECÂNICA / SÍMBOLOS / ALERGENICIDADE

DESEMPENHO / FIABILIDADE
Os cabos de interface SpO_2 Nissha Medical Technologies são controlados durante e no final do seu ciclo de fabrico, ao abrigo dos protocolos técnicos estabelecidos em conformidade com as normas e directivas actualmente em vigor e a eles respeitantes. O resultado final dos ensaios efectuados com um grupo de tipos representativos, segundo um protocolo técnico estabelecido pela Nissha Medical Technologies, foi confirmado por um Laboratório devidamente aprovado.

(Relatório técnico do LNE n°53558010/1T)

Foram igualmente objecto de ensaios e de uma avaliação clínica.

SEGURANÇA
Os **cabos de interface SpO_2 Nissha Medical Technologies** são concebidos e fabricados em conformidade com as especificações gerais e especiais das normas nacionais, europeias, e/ou internacionais actualmente em vigor e a eles respeitantes:

(Normas europeias IEC 60601-1/NF EN ISO 9919...)

Os **cabos de interface SpO_2 Nissha Medical Technologies** pertencem à «parte aplicada» ao doente, conforme definido pela norma europeia de segurança IEC 60601-1.

A **classe de segurança, o tipo de protecção (BF, CF, …)**, e o **grau de protecção** contra os choques eléctricos do **cabo de interface SpO_2** estão intimamente ligados aos do aparelho electromédico a que está ligado.

As correntes de fuga de baixa frequência, medidas de acordo com as recomendações das normas actualmente em vigor e aplicáveis a este produto têm valores inferiores aos autorizados para o nível de segurança mais elevado.

ATENÇÃO
⚠
- Consultar o manual de instruções do aparelho electromédico antes da utilização de qualquer cabo de interface SpO_2.
- Afastar o cabo de interface SpO_2 de quaisquer fontes de radiação electromagnética.
- Na sala de cirurgia certificar-se de que o cabo de interface SpO_2 (na totalidade ou em parte) se encontra fora do campo operatório.
- Agir de modo a que nenhum líquido possa atingir os contactos dos conectores.

ATENÇÃO
⚠ A Nissha Medical Technologies não poderá ser responsabilizada em caso de ocorrência de quaisquer incidentes que sobrevenham para o doente, o utilizador e outras pessoas e que sejam causados pela presença de correntes eléctricas perigosas provenientes do aparelho electromédico em caso de deficiência deste.

COMPATIBILIDADE
A Nissha Medical Technologies coloca à disposição dos seus clientes, através do seu site na Internet (www.NisshaMedical.com), um documento descarregável, que inclui informações sobre a compatibilidade do dispositivo, assim como informações técnicas sobre o mesmo.

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INTEGRIDADE MECÂNICA e ELÉCTRICA
De modo a assegurar uma boa resistência mecânica do cabo de interface SpO_2 à tracção e à flexão e a diminuir as correntes de fuga que podem circular através do doente, a Nissha Medical Technologies utiliza materiais de elevada qualidade no fabrico do dispositivo. Os conectores moldados sobre uma peça base, estão equipados de mangas flexíveis, que minimizam o risco de ruptura do cabo neste ponto.

A superfície de contacto dos pernos dos conectores é tratada de modo a diminuir ao máximo a resistência de contacto entre dois pernos, mesmo após um número significativo de conexões e desconexões.

(Relatório dos ensaios nº CPB1097 – CPB1897/CPB2897)

Os **cabos de interface SpO_2 Nissha Medical Technologies** conseguem suportar choques de desfibrilhação repetidos. Não apresentam qualquer peça metálica acessível.

Um cabo que aguarda aplicação deve ser guardado na respectiva embalagem de origem, a fim de evitar qualquer tipo de deterioração intempestiva do respectivo revestimento isolante e dos seus condutores, podendo diminuir o seu tempo de vida útil, os seus desempenhos e/ou o seu nível de segurança.

SAFETY SYMBOLS
Explanation of the symbols used on the electromedical device:

 or 

Shows that the SpO_2 cables and accessories are fitted with special protection against electric shocks (including admissible leakage currents) and defibrillation shocks.

The class and type of protection (BF, CF) against electrical shocks are defined by the type of electromedical device to which the Nissha Medical Technologies ECG cable is connected to.

ALERGENICIDADE
Os materiais utilizados no fabrico dos **cabos de interface SpO_2 Nissha Medical Technologies** foram submetidos a ensaios de alergenicidade. Estes ensaios não evidenciaram a presença de produtos potencialmente desencadeadores de uma reacção alérgica intolerável.

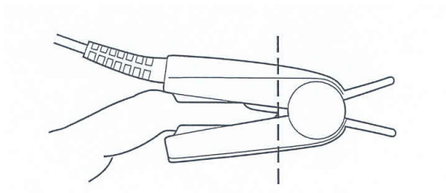
IV. INSTALAÇÃO / UTILIZAÇÃO / MANUTENÇÃO / HIGIENE / ESTERILIZAÇÃO

INSTALAÇÃO
Para uma instalação adequada do **cabo de interface SpO_2**, seguir as instruções abaixo:

(ver igualmente o modo de emprego do aparelho electromédico em causa)

Do lado do doente:
- Ligar primeiro o cabo de interface ao **sensor de SpO_2** adequado.
- Colocar o sensor de SpO_2 no doente, no ponto escolhido e adequado, à medida que consulta as instruções da nota informativa do aparelho electromédico em causa)

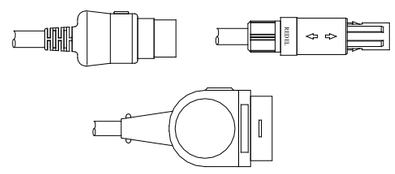
Exemplos da colocação do sensor no dedo::



Não introduzir o dedo demasiado para dentro do aparelho

Do lado do aparelho:
- Ligar o cabo de interface SpO_2 ao aparelho (oxímetro de pulso) adequado.
- Colocar o aparelho em funcionamento e certificar-se de que está a funcionar, consultando o manual de instruções do aparelho electromédico.

Examples of plugs:



UTILIZAÇÃO:

CONDIÇÕES GERAIS

As condições de utilização do **cabo de interface SpO_2 Nissha Medical Technologies** são as seguintes:

- Temperatura ambiente: 10 a 50 °C- 50 a 122 °F

CONDIÇÕES ESPECÍFICAS

- **Não utilizar um cabo de interface SpO_2 que apresente qualquer risco para o doente (isolante deteriorado, por exemplo).**

MANUTENÇÃO PREVENTIVA

O tempo de vida útil do cabo de interface SpO_2 depende de uma série de parâmetros importantes. Por exemplo:

- Número de utilizações
- Respeito pela manutenção preventiva
- Manutenção de um bom estado de limpeza

Um controlo regular, visual e eléctrico, dos condutores determinará a necessidade de substituição do cabo de interface SpO_2.

ATENÇÃO:

⚠ **Se for retirado um cabo, fora de serviço, para manutenção ou peritagem, cabe ao serviço utilizador do aparelho a limpeza e desinfecção do produto antes de voltar a enviá-lo para o serviço.**

MANUTENÇÃO CORRECTIVA

- Este produto não necessita de manutenção correctiva.

HIGIENE

Proceder a uma limpeza regular do cabo de interface SpO_2 Nissha Medical Technologies e dos respectivos condutores de derivação, segundo o método descrito abaixo.

A utilização de um cabo de interface SpO_2 Nissha Medical Technologies em ambiente esterilizado pode implicar a aplicação de um processo de esterilização.

A Nissha Medical Technologies preconiza a aplicação dos métodos de desinfecção e ou de esterilização a seguir descritos.

RE-PROCESSING INSTRUCTIONS OF SpO_2 INTERFACE CABLES (Acc. to EN ISO 17664:2004)

Manufactured by: Nissha Medical Technologies	
Devices: cabo de interface SpO_2	
Atenção	Não fazer com que o líquido penetre no interior dos conectores do cabo de interface.
Re-processing limits	Nissha Medical Technologies SpO_2 interface cables are designed to support repetitive defibrillation shocks and cleaning and disinfection cycles. Any misuse of the cable may shorten its lifetime.
INSTRUCTIONS	
In the place of use:	Remove any stains or dirt with a soft disposable cloth
Isolation and transportation:	Remember to always reprocess the device after use
Cleaning preparation:	No specific requirement

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Automatic cleaning:	Is strictly not applicable
Limpeza :	• Limpeza do cabo de interface SpO_2 Nissha Medical Technologies (incluindo o conector) com um pano embebido em água e sabão.
Desinfecção :	**(Extraída do estudo do Laboratório ANIOS, n° 6416.94/0387)** **Processo** • Encher um recipiente de lavagem com uma solução de HEXANIOS G+R a 0,5% em água • Mergulhar parcialmente o cabo, protegendo as extremidades, a fim de evitar qualquer problema eléctrico nos conectores • Respeitar um tempo de contacto de 15 minutos • Enxaguar o cabo • Secar o cabo com papel absorvente • Durante a imersão, esfregar as extremidades do cabo com o auxílio de um LINGET ANIOS. **(Substituir a solução a cada 48 horas)** **(Taken from the study by the ANIOS Laboratory, no. 14496.02/052)** **Method B (new cold method)** • fill a dip tank with an ANIOXYDE 1000 activated preparation • but do not use before 30 minutes • partially immerse the cable protecting the ends in order to avoid any electrical problems on the connectors • allow a contact time of 10 to 30 minutes depending upon the required level of disinfection • regularly check the peracetic acid content using a test strip • and afterwards rinse with ANIOS mains water (pH = 7.3; TH = 48°f)
Drying:	Dry the cable with absorbent paper
Maintenance, control and tests:	Please check visually that the cable is in working order
Conditionment	Please follow the standard protocol of packaging of your institution before sterilization
Esterilização : ⚠	• Tempo de esterilização: 22 horas, das quais 20 de exposição ao gás • Agente de esterilização: Dióxido de Carbono + Óxido de Etileno (80/20%) • Vazio inicial: -70 kPa • Humidade relativa: >60% • Temperatura: 50°C • Concentração em Óxido de Etileno: 530 g/m^3 • Pressão: 120 kPa • Vazio final: -70 kPa • Lavagem **(Relatório de ensaio 001: ensaio de esterilização / cabos SpO2-RE/IP/BPF – revisão 0 de 26/02/98)**
ATENÇÃO	**Nunca esterilizar os cabos e acessórios em autoclave a vapor ou com água a ferver.**
Preservation:	**Please read the conditions of storage in this document**

Complementary information:	The above methods have been validated and are strongly advisable. Particularly we advise you strongly to use the recommended or equivalent products above and not to exceed the indicated time of application or immersion; otherwise the life time of the cable might be reduced.
Contact the manufacturer:	See below or visit the website www.NisshaMedical.com

V. GARANTIA / RESPONSABILIDADE

Qualquer **cabo de interface SpO_2** não utilizado e conservado na respectiva embalagem original, que não tenha suportado qualquer dano aparente, tem uma garantia de um ano da Nissha Medical Technologies.

A Nissha Medical Technologies garante a conformidade do dispositivo com as especificações das normas de segurança e desempenho que lhe são aplicáveis e que estão actualmente em vigor.

ATENÇÃO :

A classe e o tipo de protecção contra choques eléctricos dependem dos do aparelho electromédico (oxímetro de pulso) a que o sensor e o respectivo cabo se encontram ligados.

Consultar o modo de emprego do aparelho em causa e o dos acessórios anexos, antes de colocar o dispositivo em funcionamento.

A Nissha medical Technologies não poderá ser responsabilizada por quaisquer incidentes ocorridos em caso de desrespeito das regras de instalação e utilização mencionadas neste modo de emprego.