EN **OXYGEN THERAPY THERAPY MASKS**
INSTRUCTIONS FOR USE

INDICATIONS
Therapeutic administration of oxygen.
NB: Disposable product - do not reuse.
The oxygen source must be in accordance to the regulations in force.
Devices must be connected and activated by qualified personnel.

PREPARATION AND CONNECTION
MODEL: OS/100 - OS/100P
MEDIUM CONCENTRATION MASK
Attach tubing connector to oxygen source. Attach other end to plastic output of mask. The mask has been designed to operate with a flow of between 5 and 10 LPM and to deliver oxygen flows of between 40% and 60%.

MODEL: OS6K - OS/60K - OS/62K - OS/70K - OS/72K
VARIABLE CONCENTRATION MASK WITH CUP
Connect prescribed diluter to corrugated tubing (for OS/62K - OS/72K select the concentration and check that the mobile part of the regulator is fully entered in its seat). Connect cup to diluter. Attach sure flow tubing to diluter. Attach other end to plastic output of mask. The recommended flows and relative percentages of the oxygen delivered are printed on the diluter or on the label.

MODEL: OS/50 - OS/50E - OS/50P
NON REBREATHING MASK WITH PLASTIC BAG AND CHECK VALVE
Flatten plastic bag. Attach tubing connector to oxygen source. Attach other end to plastic output of mask. Adjust the capacity in order to prevent the bag from ever deflating more than half during inspiration. The oxygen flow delivered is contained between 90% and 100%.

MODEL: OS/80 - OS/80P
AEROSOL MASK WITH NEBULIZER
Unscrew cap from base and add prescribed medication. Reassemble. Secure mask to top of nebulizer of opening provided. Attach one end of tubing to nebulizer output and the other end to oxygen or compressed air source. Verify that the connection is correct (as reported below).

For the duration of the administration follow the medical prescription. For an optimal nebulisation the recommended flow is between 6 and 9 LPM with a pressure of 3.44 bar (344 kPa, equivalent to 50 PSI). Efficient nebulisation is guaranteed up to a pressure of 1.73 bar (173 kPa, equivalent to 25 PSI).

ALL ABOVE MENTIONED MODELS: OXYGEN FLOW SETTING AND MASK DRESSING
Make sure tubing is safely fixed to oxygen source. Deliver oxygen and regulate the flow as prescribed by physician. Place mask on patient's face covering both mouth and nose. Pass elastic strap over patient's head and ears, on the neck. Adjust strap tension to hold mask in position by pulling. Model metal nose piece to patient's face.

MODEL: OS/110 - OS/110P- OS/110K – OS/110KP
FOR TRACHEOTOMY PATIENTS
OS/110 - OS/110P: connect aerosol tubing (not supplied with this package) between mask and gas source. Select correct liter flow at gas source and check for gas flow through mask device.
OS/110K or OS/110KP: Connect prescribed diluter to corrugated tubing. Connect cup to diluter. Attach sure flow tubing to diluter. Attach other end to plastic output of mask. The recommended flows and relative percentages of the oxygen delivered are printed on the diluter.
OS/110 - OS/110P - OS/110K - OS/110KP : position the elastic strap behind the neck and gently pull the end of the strap until the mask is secure. The mask inlet swivel is 360° to allow tubing to position itself for supine or upright patients. When using suction, loosen mask (by pulling strap in opposite direction or unsnapping one side of strap) and remove mask from suction area. Replace mask as previously noted. Warning: Be sure all connections are secure.

CONTRA-INDICATIONS
No contra-indications are described for oxygen therapy. For medicine administration refer to instructions supplied with medicine.

WARNINGS
If device is reused, contrarily to the present instructions, this may compromise following:
1. Not cleanliness of the device and possible presence of biological residues that might cause cross-infections.
2. Alteration of materials.
3. Loss of initial functional features of product.

- Before connecting to oxygen source verify its functioning.
- The accidental crushing of kinking of the connection tubing do not allow oxygen to flow properly and may cause the disjunction of the connector. It is therefore recommended that the users control carefully.
- An oxygen flow of more than 10 litres per minute may cause a disturbing noise in the system. Also possibly liquid, coming from the humidifier, can filtrate into the mixture that is sent to the patient.
- All above models are disposable and cannot be used for a continuous period of more than 30 days.

- This product contains phthalates (DEHP). Even if risks to human health are not confirmed, the use of the devices on pregnant / nursing or child should be evaluated by your doctor.

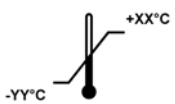
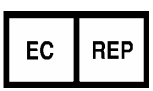
- The concentrated oxygen can ignite combustible materials. To avoid risk of fire or explosion keep away from possible sources of ignition, and refer to the precautions for use of the equipment used for the delivery of oxygen.

WASTE DISPOSAL
Waste coming from hospitals must be disposed of at thermal destruction only in authorised places. It is suggested to treat the waste coming from private houses with disinfectant solutions (Sodium hypo-chlorite, Chloro-oxidant, etc.) before disposal even though the regulations in force might not require this.

GUARANTEE-NOTICE
FIAB guarantees that the product complies with Directive 93/42/EEC and has been manufactured according to the procedures of FIAB Quality System certified ISO 13485. No responsibility may be ascribed to the producer who shall not be held liable for medical costs, direct or indirect damage due to lacking function or mis-function of above models, when used differently from the instructions for use. We recommend to report opportunely any malfunction or defect of the product to FIAB Quality Assurance Service.

CE 0123

IT Conformità Europea. Questo simbolo indica la conformità dei dispositivi medici alla Direttiva Europea 93/42/CEE. 0123: numero di identificazione dell'Organismo Notificato.
EN European Conformity. This symbol means that the device fully complies with European Directive 93/42/EEC. 0123: Notified Body identification number.
FR Conformité Européenne. Ce symbole indique la Conformité des dispositifs médicaux aux Directive Européenne 93/42/CEE. 0123 numéro d'identification de l'Organisme Notifié.
DE Europäische Konformität. Dieses Zeichen steht für die Konformität der medizinischen Geräte mit den EG-Richtlinien 93/42/EWG. 0123: Kennummer der benannten Stelle.
ES Conformidad Europea. Este símbolo indica la conformidad de los dispositivos médicos a las Normativa Europea 93/42/Cee. 0123: número de identificación del Organismo Notificado.
PL Zgodność z Dyrektywą Europejską. Symbol ten oznacza, że urządzenie jest w pełni zgodne z wymaganiami Dyrektywy Europejskiej 93/42/CEE. 0123: Numer identyfikacyjny Jednostki Notyfikującej.
RU Соответствие Европейскому Стандарту. Этот символ означает, что оборудование полностью выполнено в соответствии с Европейскими директивами 93/42/EEC. 0123:Зарегистрированный идентификационный номер.
PT Conformidade Europeia. Este símbolo indica a conformidade dos dispositivos médicos às Directiva Europeia 93/42/CEE. 0123: número de identificação do Organismo Notificado.

	**IT** Attenzione, leggere attentamente la documentazione allegata. **EN** Caution, consult accompanying documents. **FR** Attention, lire attentivement la documentation jointe. **DE** Achtung, beiliegende Dokumentation aufmerksam durchlesen. **ES** Atención, lea atentamente la documentación en anexo. **PL** Uwaga, zapoznaj się z dołączoną instrukcją. **RU** Предостережение, см.сопроводительный документ. **PT** Atenção, leia atentamente a informação inclusa.		**IT** Consultare le istruzioni d'uso **EN** Consult instructions for use **FR** Consulter les instructions **DE** Gebrauchsanweisung lesen **ES** Consulte las instrucciones de uso **PL** Skonsultuj instrukcje stosowania **RU** Обратитесь к инструкции по применению **PT** Consultar instruções de utilização
	**IT** Data di Produzione. **EN** Date of manufacture. **FR** Date de production. **DE** Herstellungsdatum. **ES** Fecha de Producción. **PL** Data produkcji **RU** Дата изготовления. **PT** Data de fabrico.		**IT** Usare entro il. **EN** Use by. **FR** Utiliser avant le. **DE** Verwendbar bis. **ES** Usarse antes del. **PL** Użyç przed. **RU** Использовать. **PT** Data de validade.
	**IT** Prodotto da **EN** Manufactured by **FR** Fabricant **DE** Hersteller **ES** Fabricante **RU** Производитель **PT** Fabricante		**IT** Numero pezzi per confezione **EN** Quantity of pieces per box **FR** Numéro de pièces **DE** Stückeanzahl **ES** Cantidad de piezas **RU** Количество штук **PT** Número de unidades
	**IT** Numero di Catalogo. **EN** Catalogue Number. **FR** Numéro de catalogne. **DE** Katalognummer. **ES** Número de Catálogo. **PL** Numer katalogowy. **RU** Каталожный номер **PT** Referência do catálogo.		**IT** Non riutilizzare. **EN** Do not re-use. **FR** Na pas réutiliser. **DE** Nicht wiederverwenden. **ES** No reutilizable. **PL** Do jednorazowego użytku. **RU** Не использовать повторно. **PT** Não reutilizar.
	**IT** Numero di Lotto **EN** Batch number **FR** Numéro de Lot **DE** Postennummer **ES** Número de Loto **PL** Numer partii. **RU** Номер партии. **PT** Número de Lote.		**IT** Non contiene LATTICE di gomma naturale. **EN** LATEX free. **FR** Ne contient pas de LATEX de caoutchouc naturel. **DE** Enthält kein LATEX aus Naturgummi. **ES** No contiene LÁTEX de goma natural. **PL** Nie zawiera LATEKSU. **RU** Не содержит латекс. **PT** Isento de látex.
	**IT** Limiti di Temperatura. **EN** Temperature limitation. **FR** Limites de température. **DE** Temperaturbereich. **ES** Límites de Temperatura. **PL** Temperatura przechowywania. **RU** Температурные ограничения **PT** Limites de temperatura.		**IT** Tenere al riparo dalla luce solare. **EN** Keep away from sunlight. **FR** Tenir à l'abri de la lumière du jour. **DE** Vor Sonneneinstrahlung schützen **ES** Proteger de la luz solar. **PL** Chronić przed światłem. **RU** Беречь от солнечных лучей. **PT** Proteger da luz solar.
	**IT** Limiti di Umidità. **EN** Humidity limitation. **FR** Limites d'humidité. **DE** Feuchtigkeitsbereich. **ES** Límites de Humedad. **PL** Zalecana wilgotność. **RU** Ограничения по влажности. **PT** Limites de humidade.		**IT** Contiene ftalati: DEHP. **EN** Contain phthalates: DEHP. **FR** Contient des phtalates: DEHP. **DE** Enthält Phthalate: DEHP. **ES** Contiene ftalatos: DEHP. **PL** Zawiera ftalany: DEHP **RU** Содержит фталаты: DEHP **PT** Contém ftalatos: DEHP
	**IT** Distributore **EN** Distributor **FR** Distributeur **DE** Verteiler **ES** Distribuidor **PL** Dystrybutor **RU** Распределитель **PT** Distribuidor		**IT** Rappresentante autorizzato nella Comunità Europea **EN** Authorised representative in the European Community **FR** Representant authorizé de la communauté Europeenne **DE** Autorisierter Verträter in der Europäischen Gemeinschaft **ES** Representante autorizado en la Comunidad Europea **PL** Autoryzowany przedstawiciel we Wspólnocie Europejskiej **RU** Уполномоченный представитель в Европейском сообществе **PT** Representante autorizado na Comunidade Europeia