



GENERAL INFORMATION

On Product Ordering and Management for NOVALUNG® HEART AND LUNG THERAPY



General Information

All orders shall be subject to the terms and conditions of this policy, and the sale of any **PRODUCTS** sold by Fresenius USA Marketing, Inc. ("FUSA") is expressly conditioned on Customer's agreement to these Terms and Conditions. Any additional or different terms proposed by the Customer, in a purchase order or otherwise, are expressly rejected and will not be binding upon FUSA unless agreed to in writing. Except for the quantities specified in such instrument, the terms, conditions, or provisions of any instrument, including purchase orders or order confirmation, shall not apply. Furthermore, any oral or written representation, warranty, course of dealing, or trade usage not contained in these Terms and Conditions shall not be binding on either party. Any order for **PRODUCTS** or FUSA's delivery of **PRODUCTS** shall constitute agreement to these Terms and Conditions.

PRODUCT(S) shall mean **EQUIPMENT** and **DISPOSABLES**.

DISPOSABLES shall mean any extracorporeal membrane oxygenation ("**ECMO**") product other than **EQUIPMENT**.

EQUIPMENT shall mean **ECMO** machines and other related equipment.

CUSTOMER shall mean a person or entity who is legally authorized to purchase **PRODUCT(S)** from **FUSA**, and either purchases **PRODUCT(S)** directly from **FUSA**, or from a **FUSA** authorized distributor.

PRODUCTS sold are not for resale.

Pricing. **PRODUCTS** are priced at the amount indicated for the selling unit of measure ordered. Prices and specifications are subject to change without notice. All items are priced at the current price as of the invoice date. **EQUIPMENT** service will be performed during normal business hours at a standard labor rate. **EQUIPMENT** service performed after normal business hours, on weekends, and holidays will be charged at a premium labor rate. Travel and other expenses may apply. Published prices are exclusive of all taxes. **CUSTOMER** shall be responsible for payment of all applicable state and local sales, use, and/or gross receipt tax resulting from transactions with FUSA regardless of placement of liability for the tax by the law.

Tax Exempt Status. A **CUSTOMER** that is exempt from taxation is required to provide appropriate certification to FUSAs' [Finance Department](#).

Payment Terms. Payment terms shall be contingent upon FUSA's review of **CUSTOMER**'s credit standing and subsequent approval. Invoices that are not paid pursuant to the approved terms may be subject to a late payment charge of one and one-half percent (1.5%) per month. Additionally, FUSA, in addition to all other rights available to it, reserves the right to require payment in advance of shipment in the event that **CUSTOMER** is delinquent in its payment for past purchases. To the extent that an agreement provides for rebate or discounts, failure to pay an invoice within the specified payment terms may result in disqualification of the items listed on the invoice from the rebate or discount calculation. Except where prohibited by law, FUSA imposes a convenience fee of two percent (2.0%) on all credit card purchases.

Financials. Upon request, **CUSTOMER** shall provide FUSA with adequate assurance of financial condition. Satisfactory assurance may include but is not restricted to **CUSTOMER** providing the most updated credit

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information. This information will be held confidentially within FUSA's Credit Department and will be used for the sole purpose of credit evaluation.

Invoices. PRODUCT is billed after it is shipped. The invoice reflects the product code, description, price, and, if applicable, freight, handling, and tax. The invoice number, date, and remittance address are located on the invoice.

Statements. Statements of account are issued monthly. Statements identify all open items. All past due balances not in dispute must be remitted immediately.

Credit/ Disputes. Only amounts which are disputed in good faith may be withheld pending resolution. Any portion of an invoice not in dispute must be remitted within the terms of the sale. Invoices in dispute must be resolved with the [Accounts Receivable Department](#).

Discount Disclosure. Prices invoiced for the goods purchased reflect any negotiated discounts, and rebates may apply to purchases. Any discounts, rebates or deductions from FUSAs' list price or other concessions received by CUSTOMER from FUSA are "Discounts or Other Reductions in Price" under 42 U.S.C. § 1320a-7b(b)(3)(A). The parties shall comply with all laws and regulations (including 42 C.F.R. 1001.952[h]) regarding reporting of any discount, rebate, or other concession in the fiscal year of the CUSTOMER in which it was earned or the year after, and report any discount, rebate, or other concession, consistent with applicable rules. FUSA shall provide additional information requested by the applicable Medicare or state health care program to assist CUSTOMER in meeting its reporting requirement.

Drug and Service State Licensing Requirements. CUSTOMER agree to obtain and maintain all state-mandated licenses and/or permits required for the purpose of purchase, use, and distribution of FUSA (a division of Fresenius Medical Care) PRODUCT(S). CUSTOMERS shall provide all applicable licenses and permit information to FUSA upon request.

Force Majeure. FUSA shall use commercially reasonable efforts to fill orders, but FUSA shall not be liable for non-performance or delays caused by a supply shortage of raw materials, manufacturing problems, delivery or labor problems, acts of regulatory agencies, discontinuation of a product line, acts of God, or causes beyond its control. CUSTOMERS agree that in such events, FUSA may allocate PRODUCTS among all CUSTOMERS without liability.

LIMITATION OF LIABILITY. THE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY IN CONTRACT, TORT OR UNDER ANY OTHER THEORY AGAINST FUSA WITH RESPECT TO FUSA PRODUCTS AND THEIR USE, SHALL BE THE REPLACEMENT OR REPAIR OF THE PRODUCTS AND NO OTHER REMEDY (INCLUDING, WITHOUT LIMITATION, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES) SHALL BE AVAILABLE TO CUSTOMER. FUSA SHALL HAVE NO FURTHER OBLIGATION OR LIABILITY WITH RESPECT TO THE PRODUCTS AND PARTS, OR THEIR SALE, OPERATION AND USE, AND FUSA NEITHER ASSUMES, NOR AUTHORIZES THE ASSUMPTION OF, ANY OBLIGATION OR LIABILITY IN CONNECTION WITH SUCH PRODUCTS AND PARTS.

Confidential Information. All information relating to pricing and payment terms is confidential. CUSTOMER shall not disclose any such information to any third party without FUSA's prior written consent. However, FUSA hereby consents to PURCHASER disclosing such information to CUSTOMER's third-party consultants and financial and legal advisors, provided they are bound by a non-disclosure and confidentiality agreement with CUSTOMER prohibiting the disclosure of such information. Each party agrees to keep

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confidential any non-public information of the other party received in any form, including without limitation, these Terms and Conditions, any PRODUCT instructions for use or documentation, and any line-item PRODUCT pricing and discounts. Each party will treat confidential information with the same degree of care as it keeps its own confidential information, but in no event with less than reasonable care. If the disclosure of the other party's confidential information is required by law, the party required to make such disclosure shall provide sufficient notice to the other party to allow such party time to take legal or other action to prevent or obtain confidential treatment of such disclosure.

Debarment. Each party warrants that it is not, nor will it hire, retain or use any individual or entity that is excluded, debarred, suspended or otherwise ineligible to participate in (collectively, "debarred") federal or state health care programs, or federal or state procurement or non-procurement programs in connection with the obligations set forth in these Terms and Conditions, including without limitation persons or entities listed on the HHS/OIG List of Excluded Individuals/Entities (<http://exclusions.oig.hhs.gov/search.aspx>) or the SAM exclusion database: (<https://www.sam.gov/portal/public/SAM>), or persons or entities debarred by the FDA. Each party further represents that, to the best of its knowledge, it is not aware of any investigation or circumstances which might result in it or any of its employees, agents, or subcontractors being debarred or proposed to be debarred. Either party shall have the right to terminate any pending transactions made pursuant to these Terms and Conditions immediately without further obligation in the event that the other party becomes debarred or hires, retains, or uses an individual or entity that is debarred.

Shared Values. As stated in the Fresenius Medical Care Code of Ethics and Business Conduct, FUSA upholds the values of integrity and lawful conduct, especially with regard to anti-bribery and anti-corruption. Fresenius Medical Care upholds these values in its own operations, as well as in its relationships with business partners. FUSA's continued success and reputation depends on a common commitment to act accordingly. Together with FUSA, the CUSTOMER is committed to uphold these fundamental values by adherence to applicable laws and regulations.

Waiver. Either parties' failure to insist on performance of any of the Terms or Conditions herein, or to exercise any right, or privilege, or FUSA'S waiver of any breach hereunder shall not thereafter waive any other term, condition, right, or privilege.

Severability. If any provision of the Terms and Conditions is held to be invalid or unenforceable, the remaining provisions will remain in full force and effect.

Survival. All provisions of these Terms and Conditions that by their nature should survive the performance of the transactions made hereunder shall do so, subject to the limitations contained herein.

Warranties. FUSA warrants that the PRODUCT(S) marketed and sold by FUSA when used in accordance with the directions on the labeling, is fit for the purposes and indications described on the labeling. The applicable manufacturer under the manufacturer's warranty will cover PRODUCT(S) not manufactured by FUSA, and FUSA provides no warranty for PRODUCT(S) not manufactured by FUSA.

The Warranty does not apply to any PRODUCT(S) that is misused, abused, neglected, tampered with, or damaged by accident, flood, fire, or other hazard. If the PRODUCT(S) is not used in accordance with manufacturer's instructions, the product warranties are void and of no effect.

All warranties in this Policy shall be construed to comply with the Warranty Safe Harbor found at 42 C.F.R. 1001.952(g).

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FUSA warrants to CUSTOMER that EQUIPMENT delivered is free from defects in material or workmanship for the periods specified in the appropriate Operator's Manual (which outlines the complete warranty), provided the EQUIPMENT is used and maintained in accordance with the manufacturer's operating instructions. Parts installed which have been purchased from vendors other than FUSA shall void all applicable warranties.

The Warranty does not apply to any EQUIPMENT that is misused, abused, neglected, tampered with, damaged by accident, flood, water, fire, or other hazard, subjected to abnormal or unusual electrical or fluid stress, improperly installed or operated, or not maintained in accordance with the routine maintenance schedule set forth in the Operator's and Technician's manual for the equipment. Periodic preventative maintenance required to maintain proper machine operation is not covered under the Warranty. The Warranty does not provide replacement XLung Kits or any other compensation during the period that CUSTOMER'S equipment is inoperative.

FUSA shall repair or replace, at its option, using new or reconditioned parts and/or subassemblies, any parts subject to this warranty that are proven defective in materials or workmanship. Such repair or replacement shall be made without cost to CUSTOMER and FUSA reserves the right to determine the location at which the repair or replacement will be accomplished.

THE WARRANTY IN THIS SECTION SHALL BE IN LIEU OF ANY OTHER WARRANTY EXPRESSED, IMPLIED OR STATUTORY, RESPECTING PRODUCTS, AND FUSA MAKES NO IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Delivery Terms. All PRODUCT(S) shall be sold FOB Origin. Published prices for PRODUCT(S) do not include freight and distribution charges. PRODUCT(S) will be shipped via regular ground delivery unless otherwise specified by CUSTOMER when placing the purchase order. These charges shall be arranged and billed separately. CUSTOMER is responsible for all freight and distribution charges for all PRODUCTS, unless specifically provided in these Terms and Conditions. All shipments are considered "contiguous USA only" unless otherwise mutually agreed to in writing by CUSTOMER and FUSA.

Orders. Orders may be placed by telephone or fax. Upon request, all originators of faxed orders shall receive a faxed Sales Order Confirmation.

Inspection; Acceptance. Due to the nature of FUSA PRODUCTS, the contents are subject to damage in transit to CUSTOMER. All orders must be counted and inspected for damages or shortages prior to acceptance of delivery from the carrier. Any exception should be noted on CUSTOMERS' copy of the carrier's freight bill, and the driver must countersign the freight bill. Exceptions must be reported within ten (10) business days to the designated [Customer Service](#) representative in order to receive all authorized credits or to have PRODUCT(S) replaced without incurring delivery charges. After the ten (10) business day period, standard return goods policies are in effect. It is incumbent upon the CUSTOMER to verify their deliveries to ensure that all items ordered and shipped are received.

Returns. All returns must be arranged through FUSA' [Customer Service Department](#). Requests for return from CUSTOMERS must include an accurate count of product and batch number being returned and must be accompanied by matching FUSA documentation (i.e., a counter signed carrier's freight bill or invoice). CUSTOMERS must ensure that Products are packed for shipment. All PRODUCTS returned to FUSA must

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have a Returned Goods Authorization (RGA) number. Any PRODUCT returned to FUSA without a corresponding RGA number shall not be credited.

Disposables

Prior notification and approval by FUSA are required to return any DISPOSABLES. Credit shall not be issued without prior notification of the return and unless returned in accordance with this policy. Approval to return DISPOSABLES does not guarantee credit. FUSA does not assume liability for DISPOSABLES returned without prior notification.

DISPOSABLES must be returned in the original, unopened carton. DISPOSABLES that have not been stored in a sanitary manner or in accordance with PRODUCT(S) storage statements cannot be returned or credited. Verification of proper storage may be required for credit.

DISPOSABLES provided at no charge are not eligible for credit but are still subject to the terms of this Policy.

All DISPOSABLES returned to FUSA may be subject to restocking/processing fee of seventy-five dollars (\$75) per return shipment, plus two hundred dollars (\$200) per refused shipment, and/or one hundred dollars (\$100) per redelivery.

The only exception to the restocking fee is DISPOSABLES shipped in error by FUSA, provided the CUSTOMER reports the error within ten (10) business days of delivery. All returns must be arranged through FUSA's [Customer Service Department](#). CUSTOMERS must ensure that DISPOSABLES are packed for shipping.

DISPOSABLES shipped in error by FUSA must be reported within ten (10) business days and returned within thirty (30) days of shipment to receive one hundred percent (100%) credit.

Equipment/Spare Parts

Purchased EQUIPMENT is not returnable unless SHIPPED IN ERROR BY FUSA or ORDERED IN ERROR BY A CUSTOMER. Rental, trade-in, and/ or evaluation equipment may be returned as governed by the terms of this policy.

All EQUIPMENT returns are at CUSTOMER'S expense, and EQUIPMENT must be in the same condition as when delivered to CUSTOMER, normal wear and tear excepted. A CUSTOMER shall make the EQUIPMENT available to a representative of FUSA for packing prior to delivery to such place or on board such carrier, as FUSA may specify. CUSTOMER is fully responsible for return of EQUIPMENT including all associated charges with the exception of return due to EQUIPMENT shipped in error by FUSA. CUSTOMER shall give FUSA prior written notice that it is returning EQUIPMENT. Any/all credits are subject to final credit approval of FUSA.

Warranty Parts: Defective parts must be returned to FUSA within thirty (30) days of CUSTOMER'S receipt of replacement part to receive proper credit. To place an order for a replacement part under parts warranty, CUSTOMER must supply the serial number of the machine, purchase order number, invoice number, or order number under which the part was originally purchased at the time the order is placed. An RGA shall be issued at the time the order is placed for the defective part. If the defective part is not returned within thirty (30) days from the date of the RGA, CUSTOMER agrees to pay for the replaced part at list price.

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Returned parts that are not actually under warranty, based on the manufacture date, shall also be invoiced at list price. All warranties in this policy shall be construed to comply with the Warranty Safe Harbor found at 42 C.F.R. 1001.952(g).

Each part returned to FUSA must have a corresponding Material Travel Tag completed and attached securely to the part. If either the Material Travel Tag or the RGA form is not enclosed with the replacement part(s), CUSTOMER must contact the Parts Customer Service Department to obtain the RGA number to be recorded on the Material Traveler Tag.

Spare parts ordered by CUSTOMER may be subject to a restocking fee of twenty percent (20%). Return freight charges are the responsibility of CUSTOMER. CUSTOMER must request an RGA from the Parts Customer Service Department to return items.

Damaged or Lost EQUIPMENT (Rentals/ Evaluations). CUSTOMERS assume the entire risk of loss of or damage to the EQUIPMENT. In such cases, the CUSTOMER will be invoiced at the current FUSA list price for the EQUIPMENT to cover the costs of such a loss. In the event the EQUIPMENT is not returned according to FUSA' Order/Delivery Policy within thirty (30) days of rental term, the fee shall be invoiced and be payable to FUSA immediately. A pickup charge of five hundred dollars (\$500) will apply for EQUIPMENT rental returns.

Proof of Delivery. The FUSA invoice and packing list must be retained as proof of delivery. Subject to availability and within three (3) months following the date of shipment, requests for additional documentation of delivery (e.g., carrier delivery logs) may be subject to a service charge of thirty-five dollars (\$35).

Important Telephone Numbers

Customer Service/Order Entry

Address: 101 Waukegan Road, Suite 100 Lake Bluff, IL 60044

Telephone: **1-800-405-1321**

Email: acuteorders@freseniusmedicalcare.com

When ordering, please include the following information:

1. **Account Number**
2. **Hospital or Center Name**
3. **Complete Delivery Address**
4. **Requested Delivery Date**

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5. **Purchase Order Number**
6. **Contact Name and Contact Telephone Number**

Technical Service – Repairs, Technical Support and Training Inquiries

Address: 4040 Nelson Avenue Concord, CA 94520

Telephone: **1-800-405-1321**

When ordering, please include the following information:

1. **Account Number**
2. **Hospital or Center Name**
3. **Complete Delivery Address**
4. **Requested Delivery Date**
5. **Purchase Order Number**
6. **Contact Name and Telephone Number**

Accounts Receivable & Credit Inquiries (Includes invoice and statement inquiries.)

Email: AccountsReceivable@fmc-na.com

RTG.Credit@fmc-na.com



Indications for use of the NOVALUNG® System: The NOVALUNG® System is indicated for long-term (> 6 hours) respiratory/ cardiopulmonary support that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation and CO₂ removal) of the patient's blood in adults with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

These may include:

- Failure to wean from cardiopulmonary bypass following cardiac surgery in adult patients.
- ECMO-assisted cardiopulmonary resuscitation in adults.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Fresenius USA Marketing, Inc., a subsidiary of Fresenius Medical Care North America
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Customer Service: 1-800-405-1321 Technical Support: 1-800-405-1321

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