IKARIA®

INOmax DS IR®

(Delivery System)

Operation Manual

(800 ppm INOMAX® (nitric oxide) for inhalation)

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User Responsibility

This Product will perform in conformity with the description contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked prior to use following the Pre-Use Checkout procedure described in section 3, and periodically as required. A defective Product should not be used. Parts that are broken, missing, visably worn, distorted or contaminated should be replaced immediately.

Should such repair or replacement become necessary, INO Therapeutics LLC d/b/a Ikaria® recommends that a telephone request for service advice be made to the nearest Field Technical Service Support Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ikaria. The Product must not be altered without the prior written approval of Ikaria Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ikaria.

Caution: U. S. Federal and Canadian law restrict this device to sale by or on the order of a licensed medical practitioner. Outside the U. S. A. and Canada, check local laws for any restrictions that may apply.

Inhaled Nitric Oxide mixtures must be handled and stored in compliance with federal, state and local regulations.

Ikaria products have unit serial numbers with coded logic which indicates the year of manufacture and a sequential unit number for identification.

20051234	The first four numeric digits indicate the year of product manufacture, and the next 4 digits are the sequential unit number produced.
10007	INOmax DS_{IR}® part number

Open Source Software

A CD-ROM is available upon request containing the full source code to the open source software used within this product.

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No license is conveyed, either expressed or implied, with the purchase hereof under U.S. Patent 5,485,827 and U.S. Patent 5,427,729 and their foreign equivalents.

U.S. Patent 5,558,083 and foreign equivalents.

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