Instruction Manual

Version 1.0.0

CE 0123

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Copyright

Caution

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

Note

Names of persons appearing in examples of the operating instructions are fictitious. Any resemblance to living or deceased persons is therefore purely coincidental and not intended.

This document is available electronically at: https://www.lothar-medtec.de/instructions-for-use/

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1 The Treatment Optimiser

The Treatment Optimiser is a medical device (software as a medical device; class IIa) consisting of a cloud-based software. It is a tool intended to quickly identify patients with a diagnosed respiratory disease who may benefit from a specialist review. The product provides a set of forms to collect information about a patient's current health status related to a respiratory disease. This information is analyzed according to recognized guidelines (e.g., GINA) and aggregated.

2 Indications for Use

Indications: Diagnosed asthma.

Contraindications: There are no contraindications.

3 Intended Purpose and Usability

The Treatment Optimiser is used to collect information about a patient's current health status related to a pre-diagnosed respiratory disease. The product then uses this information to provide decision support for general practitioners and their staff whether a patient would benefit from a specialist review. The Treatment Optimiser is used by general practitioners and their staff in the doctor's office. The Treatment Optimiser decision support is based on recognized guidelines for respiratory disease management.

The system is suitable for patients age 12 and older.

4 Pictograms and Safety Instructions in the Instruction Manual

Following the **ANSI** (American National Standards Institute) recommendations for safety instructions, the following pictograms have been used in this instruction manual:

Danger level	Definition
Danger	**DANGER** indicates an imminently hazardous situation which, if not avoided, could result in extremely serious injury or death. This signal word is reserved for extreme situations.
Warning	**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in extremely serious injury or death.
Caution	**CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. Also used to indicate unsafe procedures.

Additional pictograms shown in the instruction manual and/or in the user interface:

	Observe the instruction manual and accompanying documents.
Attention	Important operating instructions and useful information. No information that warns of a dangerous or critical situation.
Note	Tips, info, and operating instructions.

Attention: Please also observe the safety and operating instructions in section 13.

5 Data protection

For data protection please refer to the Data Privacy Policy available on the landing page of the Treatment Optimiser (e.g., www.asthma-optimiser.com)

6 Declaration of Conformity

LOTHAR MEDTEC declares that the product described herein has been designed and manufactured in accordance with the following specifications and standards: Medical Device Directive 2017/745.

This device, which complies with class IIa for continuous operation according to Annex IX of the Directive, also complies with the essential requirements according to EN ISO 13485:2016. medical devices - quality management systems - requirements for regulatory purposes.

Certification authority: TUEV SUED (CE0123)

Certificate numbers: G10 102194 0002 Rev. 1

7 Practical Hints

Before initial operation, you should make yourself familiar with safe handling of the medical application and with the examination procedure.

Warning: Modifications to the product endanger product safety and lead to the loss of the operating license! LOTHAR MEDTEC assumes no liability for modifications made by the customer.

8 Minimum Requirements

To use the Treatment Optimiser, you need computer system with internet access and a current common browser software application. The internet connectivity requires availability and bandwidth typical for medical care.

Internet access to the URL of the Treatment Optimiser must not be blocked or otherwise restricted by the configuration of the local IT infrastructure.

9 Access to the Software

Access to the Treatment Optimiser is restricted, credentials can be received from an administrator.

10 Product Information and Settings

The product information (Unique Device Identifier (UDI), product and software version, manufacturer’s contact etc.) and settings page (settings and profile details) are accessible after logging into the application.

11 Operating Instructions

After logging into the Treatment Optimiser, in a "Quick Tour" the main functions of the software are explained. The “Quick Tour” is also accessible from the settings page. To use the software, follow the explanations in the “Quick Tour” and the instructions on screen.

If you suspect malfunction, please contact LOTHAR MEDTEC immediately:

LOTHAR MEDTEC GmbH, Magdalene-Schoch-Str. 5, 97074 Wuerzburg, Germany,
Phone.: +49 931 6193816-0, E-Mail: support@lothar-medtec.de

12 Possible Sources of Error and Remedies

	Error	Error source	Remedy
1	User interface cannot be loaded or refreshed	No adequate internet connection available	Make sure the computer system you are using is connected to the internet. Restart the browser software.

13 Safety and Operating Instructions

This instruction manual describes the currently valid status of the product considering the essential requirements of MDR 2017/745. Strict adherence to the operating instructions is a prerequisite for the intended use of the Treatment Optimiser. Please follow the manufacturer's specifications (technical data, explanation and compliance with the pictograms and other information).

14 Deviation from the Intended Purpose

Any non-compliance of the procedures described in this instruction manual will result in a deviation from the intended purpose. In this case, the operator/user must provide proof of compliance with all applicable essential requirements. This is possible with the implementation of a corresponding conformity assessment procedure within the scope of in-house-manufacture (compare § 12, section 1, last sentence, Medical Product Law). The operator/user is responsible for the proper performance of the conformity assessment, and he also assumes the complete product liability - not only the liability for the application/use of the medical device changed by him.

LOTHAR MEDTEC guarantees the safety, reliability, and function only if the product is used in compliance with the instruction manual.

This instruction manual is considered part of the product and must be always kept accessible.

If any potentially serious harm to a patient occurs during use of the product, such an occurrence must be reported immediately to the manufacturer and to the appropriate national competent authorities.

15 Medical Responsibility

The Treatment Optimiser is not intended to give professional or medical advice. General practitioners and their staff who use this tool should exercise their own clinical judgement and take into account applicable guidelines when making treatment decisions for their patients.

16 CE notice

The CE 0123 symbol indicates that the Treatment Optimiser complies with the provisions of the Medical Device Regulation 2017/745 of the European Commission. It also indicates that the Treatment Optimiser meets or exceeds the requirements of the applicable technical standards.

17 Maintenance

In the event of malfunctions, LOTHAR MEDTEC support team will be happy to advise you and to take care for remedy.

18 Literature

The Treatment Optimiser implements applicable parts of the following published recognisced guidelines:

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023.

Available from www.ginasthma.org.

The Treatment Optimiser implements the following published reference models for calculation of patient-specific reference values:

Spirometry

Philip H. Quanjer, Sanja Stanojevic, Tim J. Cole, Xaver Baur, Graham L. Hall, Bruce H. Culver, Paul L. Enright, John L. Hankinson, Mary S.M. Ip, Jinping Zheng, Janet Stocks and the ERS Global Lung Function Initiative, Multi-ethnic reference values for spirometry for the 3–95-yr age range: the global lung function 2012 equations, Eur Respir J, 2012; 40.

Peak flow

Sterk PJ, Fabbri LM, Quanjer PH, Cockcroft DW, O'Byrne PM, Anderson SD, Juniper EF, Malo JL., Airway responsiveness. Standardized challenge testing with pharmacological, physical and sensitizing stimuli in adults. Report Working Party Standardization of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. Eur Respir J Suppl. 1993; 16.

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