

LOTHAR MEDTEC

Instruction Manual

Ambulatory Lung Diagnosis System

ALDS

Version 2021.08

REF: ALDS-MAN



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Caution

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This document is available electronically at: <https://alds.health/>

Subject to technical changes.

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1. Spirometry and oscillometry

The **spirometry** measurement is based on the performance of resting breathing followed by forced inhalation and exhalation and is used to determine respiratory volumes. For this purpose, the patient must perform and, if necessary, repeat the respective breathing maneuvers required for such measurements, as instructed by the user. Predefined criteria (published by the European Respiratory Society (ERS) and the American Thoracic Society (ATS)) are used to determine the quality of a measurement.

Measurement of airway resistance can be performed by using oscillometric methods (**oscillometry**). In this examination one or more pressure waves, which are delivered to the lungs via the trachea, are generated during the patient's resting breath. No special breathing maneuvers are necessary for this.

For both spirometry and oscillometry standard values exist that are used to evaluate the measurement results.

In addition, there are generally accepted decision criteria to define or distinguish pulmonary diseases and to help physicians decide which diseases are likely to be existent in their patients.

2. Structure of the ALDS

The ALDS (Ambulatory Lung Diagnostic System) is a medical device (class IIa) consisting of the diagnostic software in the cloud and the accessories (pressure-flow-sensor and pressure-impulse-actuator) described below (see figure 1).

The Workflow App (WFA), which is also included in the accessories, is described on page 9

The measurements on the patient required to prepare the diagnostic suggestion are recorded by using a pressure-flow-sensor while the patient is breathing into the ALDS. Optionally, the patient's respiratory system is stimulated by a pressure-impulse-actuator during the examination. At the end of the measurement, the data are transferred via the Workflow App to the cloud-based data processor for evaluation and preparation of a diagnostic proposal. The result can be managed by the user in the Workflow App and transferred to the physician information system of the doctor's office.

A commercially available filter with mouthpiece, which has its own approval as a medical device, is provided as the patient interface. Besides, an elbow and nose clips are included in the delivery.

The Workflow App is a software (Windows, iOS) that has to be installed on the customer's own system (PC, notebook, smartphone).

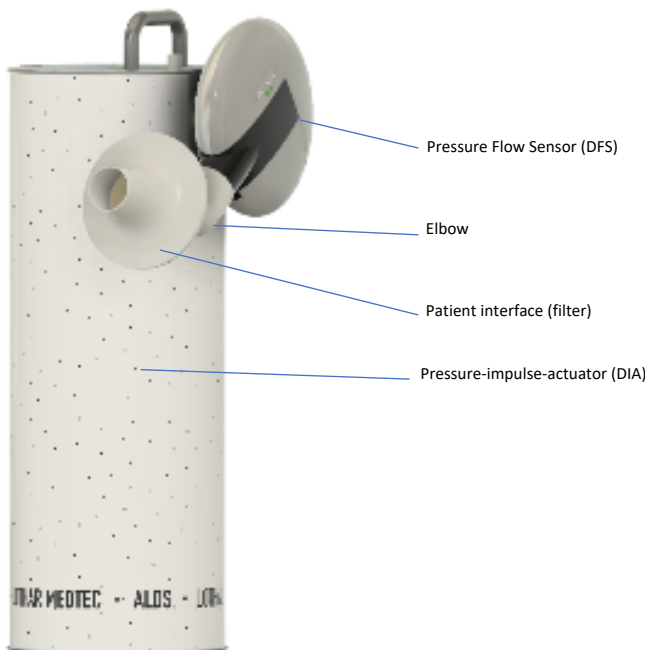


Figure 1: Structure of the ALDS

The pressure-flow-sensor can be disassembled for cleaning purposes and consists of the components shown in Figure 2.



Figure 2: Individual components of the pressure-flow-sensor

3. Indications for use

Spirometry as well as oscillometry are fundamental examinations in the assessment of respiratory health. Spirometry and oscillometry enable measuring the effect of a disease to the lung function, assessing airway responsiveness, monitoring disease course or the result of therapeutic interventions, assessing preoperative risks and determining a prognosis for many pulmonary diseases. Spirometry and oscillometry are valuable tools that provide important information to the physicians which are used together with other diagnostic findings, symptoms and the patient's medical history to establish a diagnosis.

Common indications for spirometry and oscillometry are:

Diagnosis:

- To evaluate symptoms, indications or abnormal laboratory test results
- To measure the physiologic effects of a disease or disorder
- To screen individuals at risk of having pulmonary diseases
- To assess preoperative risks
- To assess the prognosis

Monitoring:

- To assess response to therapeutic intervention
- To monitor the course of disease
- To monitor patients for exacerbations of disease and recovery from exacerbations
- To monitor people for adverse effects of exposure to injurious agents
- To watch for adverse reactions to drugs with known pulmonary toxicity

Evaluation of disability/impairment:

- To assess patients as part of a rehabilitation program
- To assess risks as part of an insurance evaluation
- To assess individuals for legal reasons

Other

- Research and clinical trials
- Epidemiological surveys
- Derivation of reference equations
- Preemployment and lung health monitoring for at-risk occupations
- To assess health status before beginning at-risk physical activities

4. Contraindications

In general spirometry and oscillometry shall be avoided

- if the patient is not spontaneously breathing
- if the patient cannot breathe through a mouthpiece with a filter
- if the patient cannot breathe on the mouthpiece for at least 60 seconds.

Performing spirometry can be physically demanding. The forced expiratory maneuver used in spirometry increases intrathoracic, intraabdominal and intracranial pressures. Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure and expansion of the chest wall and the lungs. The physical effort required can increase myocardial stress. Caution must be used for patients with diseases that could be adversely affected by these physiological consequences:

- Increases in myocardial stress or changes in blood pressure
 - Acute myocardial infarction within one week
 - Systemic hypotension or severe hypertension
 - Significant atrial/ventricular arrhythmia
 - Noncompensated heart failure
 - Uncontrolled pulmonary hypertension
 - Acute cor pulmonale

- Clinically unstable pulmonary embolism
 - Medical history of syncope related to forced expiration/cough
- Increased intracranial/intraocular pressure
 - Cerebral aneurysm
 - Brain surgery within four weeks
 - Recent concussion with continuing symptoms
 - Eye surgery within one week
- Increases in sinus and middle ear pressures
 - Sinus surgery or middle ear surgery or infection within one week
- Increases in intrathoracic and intraabdominal pressure
 - Presence of pneumothorax
 - Thoracic surgery within four weeks
 - Abdominal surgery within four weeks
 - Late-term pregnancy
- Infection control issues
 - Active or suspected transmissible respiratory or systemic infection, including tuberculosis
 - Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleedings

Although such risks are likely to be minimal for spirometry with most patients, the potential risks associated with testing should always be weighed against the benefit of obtaining information about lung function. Spirometry should be discontinued if the patient experiences pain during the maneuver. Patients with potential contraindications that would prevent testing in the primary care setting may be tested in a pulmonary function laboratory where operators are more experienced and there may be access to emergency care if needed. Furthermore, because spirometry requires the active participation of the patient, inability to understand directions or unwillingness to follow the directions of the operator will usually lead to submaximal test results.

Performing oscillometry is not physically demanding. Oscillometry does not significantly increase intrathoracic, intraabdominal, and intracranial pressures. Caution must be used for patients with diseases that could adversely be affected by these physiological consequences:

- Infection control issues
 - Active or suspected transmissible respiratory or systemic infection, including tuberculosis
 - Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding


5. Intended purpose and usability

The ambulatory lung diagnosis system (ALDS) is used to determine forced spirometry parameters and oscillatory airway resistances. It uses this information together with data from patient anamnesis to make physiological interpretations in spontaneously breathing patients. The ALDS is used by general practitioners, pediatricians or pulmonologists and their staff in the doctor's office or in hospitals. The ALDS cloud-based diagnostic system (DS) is based on published concepts for physiological interpretation of obstructive and restrictive limitations. The ALDS shall be easy to use by general practitioners, pediatricians, pulmonologists and their staff, so that it is possible to screen and diagnose multiple patients per day efficiently. The typical duration of use with the patient is one minute per measurement.








The system is suitable for patients aged two and older.














6. 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	Use with:
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 on the device:

	Observe the instruction manual and accompanying documents.
Attention or 	Important operating instructions and useful information. No information that warns of a dangerous or critical situation.
Note	Tips, infos and operating instructions.
	Date of manufacture and manufacturer
	Identification name of components
	Serial number
	Application part type B
	The device must be taken to a collection point for hazardous waste for disposal. This device must not be disposed of with unsorted general trash.

	Charging voltage DC
	Charging current
	Charging power
	Class II device
QTY	Number of devices in the package
	Fragile, please handle with care
	Store dry
	Store protected from light
	Storage temperature
	Limitation of humidity during storage
	Limitation of air pressure during storage
	Lithium-ion-batteries
	Combustible if damaged
	UDI label
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician

Attention: Please also observe the safety and operating instructions on page 63.

7. Data protection

Compliance with European and German data protection regulations is ensured by an ALDS-specific data protection concept.

8. 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 2a 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.

For Canada only: LOTHAR MEDTEC declares that the product described herein has been designed and manufactured in accordance with the following specifications and standards: Canadian Medical Device Regulation (SOR/98-282). This device also complies with the safety and effectiveness requirements.

Certification authority: TUEV SUED (CE0123)

Certificate numbers: G10 102194 0002 Rev. 1

9. Practical hints

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

The ALDS is operated wirelessly. The supplied cable may be used exclusively for charging. No cable must be plugged in during measurement operation.

Attention: The ALDS operates wirelessly via radio. When selecting the installation site, make sure that the radio transmission cannot be influenced by other devices emitting electromagnetic energy.

The ALDS does not have an on/off switch, as the measurement function is controlled via the associated app and the device starts on its own as soon as someone breathes into the device.

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

Note: The device can be disconnected from the mains supply at any time by removing the charging cable from the device.

Guidance of the patient:

Most patients are performing a spirometry or oscillometry for the first time. These patients, as well as experienced patients, may be excited and nervous. You should explain the purpose and performance of the measurement in detail to the patient in order to achieve a good result. Special attention should be paid to the correct use of the filter.

On the device, the pressure-flow-sensor, together with the filter, can be adjusted to the size of the patient as described on page 13 This is important in order to obtain a correct measurement result. Make sure that the patient is sitting upright and can take the mouthpiece of the filter into his mouth in such a way that he is not sitting with his head tilted upwards or downwards. You can adjust the pressure-flow-sensor to the size of the patient in an infinitely variable way.

10. Minimum requirements

To operate the ALDS you need an end device for operation and display with internet access. This device requires at least Windows 7 or iOS 13. The end device must have an internet connectivity typical for medical care.

Internet access to the URL of the ALDS must not be restrained by the configuration of the IT infrastructure of the doctor's office.

11. Scope of delivery

ALDS components	Quantity
Pressure-flow-sensor (DFS)	1
Pressure-impulse-actuator (DIA)	1
Elbow	1
Nose clip	3
Filter with mouthpiece (filter)	5
Charger	1
Charging cable	1
Instruction manual	1
CE Declaration of Conformity	1
Packaging	1
PC-adapter for Windows end devices	1
Reference resistor	1

Optional accessories for the ALDS	Quantity
Calibration pump	1

12. Starting up with the device and login

Check the packaging of the ALDS for any damage. In case of packaging damages, please contact LOTHAR MEDTEC immediately and do not use the device.

Unpack the ALDS with all its accessories and place the pressure-impulse-actuator in the designated location.

Note: The device must be placed on a level surface to prevent tipping.

Note: Please observe the operating conditions in chapter 27 and select the installation site accordingly.

Attention: The ALDS operates wirelessly via radio. When selecting the installation site, make sure that the radio transmission cannot be influenced by other devices emitting electromagnetic energy.

Caution: Position the device in a way that the charger is freely accessible when charging.

Plug the pressure-flow-sensor into the main connector of the pressure-impulse-actuator (see figure 1 and 2) while pressing down the release button on the pressure-impulse-actuator. Attach the supplied elbow to the pressure-flow-sensor.

Caution: Danger of pinching fingers during assembly!

Make sure that the display device to be used has an internet connection. For the installation on Windows do the following: Insert the supplied PC-adapter (see figure 3) into a free USB port of the display device.

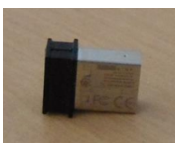


Figure 3: PC Adapter for Windows display device

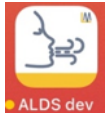
Start the Internet Explorer, start the page www.lothar-medtec.de/downloads and enter your customer data Afterwards you will find a webpage from where you can [download the app](#). After that, you start the download of the file "workflow app". Follow the instructions on the screen.

For the installation on iOS do the following:

Open the app-store and insert "ALDS" into the search box. Start the installation of the ALDS-app then.

After completing the installation, start the Workflow App. The app establishes a connection to the diagnostic system via the internet connection of your display device. In addition, the Workflow App connects itself to the device.

The Workflow App is presented as follows:



The ALDS is now ready for operation.

Note: Before use, please check whether the accumulators of the ALDS are sufficiently charged.

Caution: If the device is not charged regularly, the batteries may become deeply discharged and the device will stop working.

Caution: Extreme heat, humidity or high altitude may falsify the measurement. Please observe the operating conditions in chapter 27.

Caution: Do not operate the ALDS with systems (e. g. computer, monitor, keyboard, mouse, network) having been damaged or impacted in terms of their performance.

Attention: Make sure that your display system is sufficiently protected by passwords to prevent data misuse. Also observe the guidelines in accordance with the General Data Protection Regulation in this context.

Login

As soon as the Workflow App has been installed, you may log in:

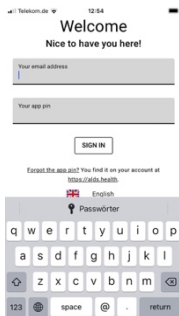



Figure 4: Login Screen of the Workflow App

Enter your email address into the field "Your email address" – take the one you have used for registering in your customer account with Lothar Medtec. You'll find your App-PIN" in your customer account if you go to "alds.health". Having entered this information, please click on the icon  to finalize your login.

13. Operating displays, operating states and operating elements of the ALDS

Note: The ALDS is operated wirelessly. The supplied cable may exclusively be used for charging. No cable may be plugged in during measurement operation.

Note: The ALDS does not have an on/off switch, as the measurement function is controlled via the associated app and the device switches itself on as soon as someone breathes into the device.

Note: When restarting the workflow app, an update of the software is performed automatically from time to time.

Operating displays and operating states:

The ALDS uses multiple LEDs to indicate operating conditions and battery charge levels (see figure 5):

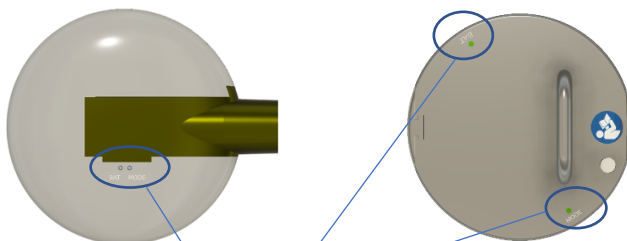


Figure 5: Status displays of the DFS and DIA

Battery state of charge: (Figure 5: Status displays of the DFS and DIA)

Both the pressure-flow-sensor and the pressure-impulse-actuator have indicators for the battery-charge-status (LED labeled BAT, "BAT LED" for short).

The following battery charge levels are displayed:

- Off: Accumulator is empty
- Green: Fully charged - more than ten typical measurement runs possible
- Orange: Charging needed soon - less than ten, but more than two typical measurement runs possible

During charging, the battery status indicator of the ALDS flashes.

Operating status: (see figure 5)

Both the pressure-flow-sensor and the pressure-impulse-actuator have indicators for the operating status (LED labeled MODE, "MOD-LED" for short).

The following operating states are displayed:

- Off: Device is off
- Green: Device is available
- Orange: Device is not available

The light indicators of the operating status are used during the measurement to signal the measurement progress and result. The function of the status indicators is described in chapters 15 and 16.

Operational controls

Acoustic signal:

The acoustic signal in the pressure-flow-sensor sends an audio signal to make clear when a measurement starts and when it ends.

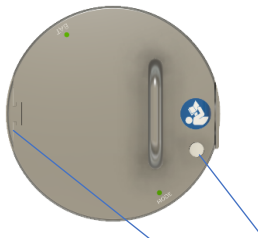


Figure 6: Charging connector and release button

Release button: (Figure 6: Charging connector and release button)

The release button on the pressure-impulse-actuator is used to release the pressure-flow-sensor from the pressure-impulse-actuator. If the pressure-flow-sensor is not attached to the pressure-impulse-actuator the charging socket for charging the batteries opens by pressing the release button.

Charging connector for pressure-flow-sensor: (Figure 6: Charging connector and release button)

A charging connector for the pressure-flow-sensor is located on the pressure-impulse-actuator. This charging connector is used to charge the battery of the pressure-flow-sensor.

Charging cover for the charging connector of the pressure-flow-sensor: (see figure 6)

The charging cover for the charging connector of the pressure-flow-sensor can be attached to the pressure-impulse-actuator to cover the charging contacts. This cover must be inserted during measurement!

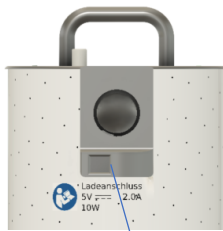


Figure 7: Charging connector

Charging connector (concealed): (Figure 7: Charging connector)

A charging connector for charging the batteries is located on the pressure-impulse-actuator. The connector is covered by the release button during measurement, and it becomes visible and applicable after removing the pressure-flow-sensor and pressing the release button.

14. Operation of the Workflow App

Attention: Please check conscientiously the use of the correct patient information. If the patient information is incorrect, the result may otherwise be a misdiagnosis!

Attention: When entering the personal data, the criteria "male" or "female" must be entered, since the calculation of the standard values is based on these distinctions. Unfortunately, the setting as "divers" is not provided for the standard values.

The Workflow App is used to enter information about the patient and to handle the measurements. When starting, the Workflow App shows the following:

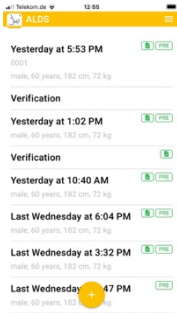


Figure 8: Display of the Workflow App on the display device

The initial display comprises all information on visits or device checks existing in the Workflow App. One visit or device check each is presented per line, as explained in detail below.

Additionally, the essential patient information are presented together with each entry to realize quickly to which patient the visit belongs.

If a new visit or device check has been generated, there won't be any green icons in the respective line. As soon as there are measurements in the context of a visit or a device check, the following icons appear:



PRE indicates that one or several measurements exist and that a report may be retrieved. In case that provocation/dilatation has been carried out, there will be the icon POST.

By clicking on the icon PRE you may transfer a copy of the report into the AIS/KIS via drag and drop (see chapter 18).

Device information:

In the Workflow App data related to the device can be retrieved by clicking on the icon in the upper right corner with the left mouse button. The following window then appears:

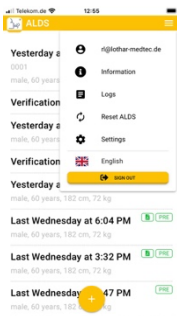


Figure 9: Retrieval of device specific data

The following information can be retrieved:

User name:

The entry ri@lothar-medtec.de shows the user name you have currently taken to log in the Workflow App.

Information:

If you click on the entry Information you will get the following display:

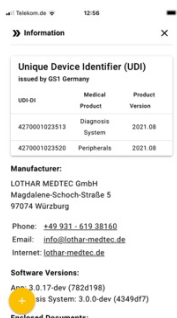




Figure 10: Display of the information on your device


This display provides you with information on the delivery status of your device. The information given there help you to name your ALDS exactly. They include the Unique Device Identifier (UDI) required by law as well as the version of the Workflow App and the system. You will also find the manufacturer's contact data here as well as a reference to the instruction manual (this document).

You may leave this window by clicking on the icon  at the upper right edge.

Logs:


By clicking on the entry  you may retrieve technical information which help to carry out a quick analysis in case of error.

Reset the ALDS:


You may reset the ALDS by means of the icon  .

Attention: If measurement data are still available, they get deleted now!


Settings:

Clicking on the entry  , you may find out the serial number of the ALDS which is connected with your Workflow App.

Language:

Clicking on the entry  , you may change between the various released languages.

Sign out:

The function  is intended to log out the current user in the Workflow App.

Entering patient information and environmental conditions

The initial screen displays the following:

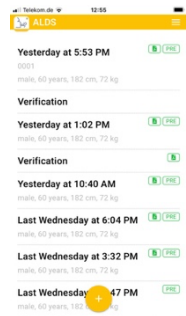


Figure 11: Initial screen of the Workflow App

Click on the  for entering patient data and environmental conditions. The following window opens:

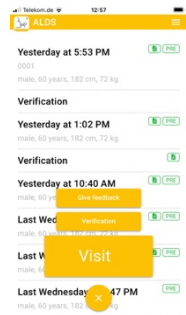


Figure 12: Selection screen of the Workflow App

The following entries of the dialogue are explained in detail here:

Visit

The ALDS manages one visit for each patient. This visit summarizes all information on this patient and includes:

- Patient information and
- all measurements

having been carried out during one visit.

Measurements mean spirometry and oscillometry as explained in chapter 15 and 16. These may comprise several measurements in series (see chapter 17)

On each start of a measurement, you may also determine if a measurement is to take place before or after provocation/dilatation.


Clicking on the icon  you see the following on your screen:



Figure 13: Entering patient data

You may enter a patient ID here if you want – you may freely choose this ID. This ID is optional and is no longer used in the ALDS. However, it is seen on the report if you have chosen one.

Enter the patient's sex, date of birth, ethnicity, height and weight.

If the environmental conditions cannot be retrieved automatically, you have to enter the fields for the environmental conditions.

After that you may press **SAVE**. Now you may carry out a measurement.

If you click on the icon **Verification** a device check can be processed. This check is described in detail in chapter 22.

If you click on the icon **Give feedback** you may provide your feedback directly to the manufacturer as described in chapter 23. Having saved the data you see the following:

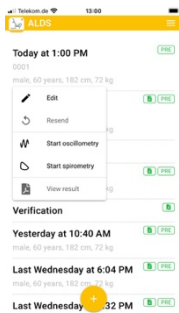


Figure 14: Selection of measurements after entering patient data

The patient data especially serve as a basis for calculating the standard values.

Note: Due to data protection regulations, patient names are not used in the Workflow App. If you want to enter the patient's name, you can rename the report with the patient's name at the end of the measurement when transferring the results to the doctor's information system.

Warning: Make sure that the information is entered correctly, because otherwise incorrect standard values will be used for assessment and misdiagnoses are possible!

Selection of existing examinations

If measurements for a patient have already been carried out during a visit, you may execute further measurements for this patient by clicking on the visit already existing:

The data entered for the patient to be examined become visible.

If you click on an existing visit or after having entered data for a new visit, you will see the following menu:

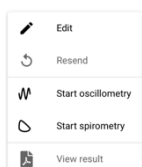




Figure 15: Selection menu for a visit

Here you may select by clicking,

- if you want to edit the patient data of this visit, e. g. in case of faulty input. Thus, you return to the entry mask for the patient data
- if you want to resend the measurement to the diagnosis system for getting another appraisal; e. g. in case of modified patient data or if the connection to the internet had been interrupted
- if you want to start an oscillometry; see chapter 16 for further information

- if you want to start a spirometry; see chapter 15 for further information; or
- if you want to view the results or if you want to transfer them to your AIS (= doctor's information system) or KIS (=hospital information system); see chapter 18 for further information

If several measurements are to be performed, a further measurement can be carried out within the same visit by clicking on the icons  Start spirometry or

 Start oscillometry

15. Measuring spirometry

Note: The ALDS is operated wirelessly. The supplied cable must exclusively be used for charging. No cable may be plugged in during measurement.

Note: The ALDS does not have an on/off switch, as the measurement function is controlled via the associated app and the device switches on automatically as soon as someone breathes into the device.

Caution: No maintenance or service may be performed on the device during operation!

Attention: Only use filters approved by Lothar Medtec. Non-approved filters can lead to incorrect measurement results!

Note: A measurement can only be performed if the pressure-flow-sensor is not connected to the pressure-impulse-actuator. During a measurement loading of the ALDS is not possible!

Note: The charging cover for the charging guide of the pressure-flow-sensor must be plugged on!

Note: The accumulator of the pressure-flow-sensor must be sufficiently charged. Please check the charge status at the BAT LED. If the LED is orange, the accumulator must be charged urgently!

Note: The data memory of the ALDS must be empty. If there is still a measurement of a patient in the ALDS, the MOD LED lights up orange. In this case, the existing measurement must first be transferred to the Workflow App before a new measurement can be taken.

Note: Most patients are performing a spirometry for the first time. These patients, as well as experienced patients, may be excited and nervous. You should explain the purpose and performance of the measurement in detail to the patient to achieve a good result. Special attention should be paid to the correct use of the filter and the nose clip.

Note: The user should position himself in a way that he or she has a good view of the patient and the ALDS.

Note: Never plug the filter into the main connector of the pressure-impulse-actuator.

Note: All output volume measurement values are BTPS-corrected according to ISO26782.

Attention: Observe the contraindications in chapter 4 before and when performing a measurement!

Attention: To avoid cross-infection from one patient to another, a new, unused filter must be used for each patient.


Attention: There might be faulty measurements in case of improper use of the nose clip or if no nose clip at all is used!

The patient has to inhale and exhale sufficiently, because otherwise the recording does not start as described here. If this is the case, ask the patient to breathe more strongly.

Attention: The device starts automatically recording the measurement as soon as the patient breathes. If the patient starts breathing at the device before having started the measurement via the Workflow App, there won't be an evaluation.


Attention: If the patient coughs or spits during the measurement, the measuring results might get falsified. In this case, please repeat the measurement.

Enter the information on the patient in the Workflow App and select a visit as described in chapter 14.

Select the icon  Start spirometry from the selection menu and after that follow the instructions carrying out a measurement on the screen.

After the diagnosis has been generated the associated report appears on the display.

If you now click "Done", you see again:

The green icons  indicate that a measurement has been carried out and that a report has been generated.

If several spirometry measurements are to be performed for the same patient, please repeat the measurement using the same procedure. To get a high quality of the evaluation, you should perform at least three measurements for one patient.

If a provocation/dilatation is to be carried out, you may select upon starting the measurement if the measurement should take place before or after the provocation/dilatation.

Having finalized the measurement, you should instruct the patient to get away from the filter and remove the nose clip.

Remove the filter from the pressure-flow-sensor and clean those parts of the device having been touched by the patient. The device switches off automatically.

16. Measuring oscillometry

Attention: No maintenance or service may be performed on the device during operation!

Attention: Only use filters approved by Lothar Medtec. Non-approved filters can lead to incorrect measurement results!

Note: A measurement can only be carried out if the pressure-flow-sensor is connected to the pressure-impulse-actuator. In this case, loading of the ALDS is not possible!

Note: The charging cover for the charging connector of the pressure-flow-sensor must be plugged on!

Note: The accumulator of the pressure-flow-sensor and that of the pressure-impulse-actuator must be sufficiently charged. Please check the charge status at the BAT LED. If it is orange, the accumulator must be charged urgently!

Note: The data memory of the ALDS must be empty. If there is still a patient's measurement in the ALDS, the MOD LED lights up orange. In this case, the existing measurement must first be transferred to the Workflow App before a new measurement can be taken.

Note: For most of the patients it is the first time to have an oscillometry. These patients, but also experienced patients, may be excited and nervous. You should explain the purpose and the performance of the measurement to the patient in detail to achieve a good result. Special attention should be paid to the correct use of the filter and the nose clip.

Note: Advise the patient that some discomfort might occur as a result of the measurement.

Note: The user positions himself in a way that he has a good view of the patient and the ALDS.

Note: Never plug the filter into the main connector of the pressure-impulse-actuator.

Note: All output volume measurement values are BTPS-corrected according to ISO26782.

Attention: To avoid cross-infection from one patient to another, a new, unused filter must be used for each patient.

Attention: Non-use or improper use of the nose clip may result into incorrect measurements!

Attention: The device automatically starts recording the measurement as soon as the patient is breathing. If the patient starts breathing on the device before the measurement is started via the workflow app, no evaluation takes place!


Note: The patient must inhale and exhale sufficiently, because otherwise the recording will not start as described here. If he doesn't do this, ask the patient to breathe more strongly.

Attention: If the patient coughs or spits during the measurement, the measuring results might get falsified. In this case repeat the measurement.

Enter the information on the patient in the Workflow App or select a visit as described in chapter 14.

Now select the icon START OSCILLOMETRY from the selection menu and follow the instructions on the execution of a measurement to be seen on the screen.

After the diagnosis has been generated, the report can be seen on the screen which you can close by clicking on "Done".

The green icons  in the main menu show that a measurement has been carried out, and that a diagnosis has been generated.

If it is intended to carry out several oscillometry measurements with the same patient, repeat the measurement according to the same process. For getting a good quality of evaluation/analysis you should do at least three measurements with one patient.

If it is intended to carry out a provocation/dilatation, you have the possibility at each start of measurement to select if the measurement should take place before or after the provocation/dilatation.

After having finished the measurement, instruct the patient to remove from the filter and to take off the noseclip.

Remove the filter from the pressure-flow-sensor and clean the device in case that the patient has touched parts of it. The device switches off automatically.

17. Measuring oscillometry and spirometry

If you want to measure both oscillometry and spirometry with a patient, it is best to start with oscillometry. This is performed during resting breathing and does not require the patient's cooperation.


Proceed as described in chapter 16. As soon as you have completed as many measurements as needed for oscillometry, you may go on with the spirometry. You may leave the filter, used for the oscillometry, at the device. Follow the instructions of chapter 15, however, you need not create a new examination, but start the measurement right away.


If a provocation/dilatation is to be carried out, you always have the possibility when starting a measurement to select if the measurement takes place before or after the provocation/dilatation.

18. Managing and displaying measurement

The results of a measurement are displayed in the Workflow App as described above.

The measurement results are automatically transferred to the cloud and evaluated there. The evaluation is transferred to the Workflow App and displayed as described above.

The green icons  indicate that a measurement has been carried out and that a report has been generated:

If a visit is selected, the result of the measurement(s) can be displayed in a report presenting all measurements belonging to this visit by clicking on  View result .

19. Charging of the device

Note: The device may only be charged if no measurement is taking place and no patient is connected to the device.

Note: The charging plug is only visible in case the pressure-flow-sensor is removed and the release button is pressed down.

Note: Charge the device once a day, if possible, preferably overnight. Observe the battery status indicators at the pressure-flow-sensor and at the pressure-impulse-actuator.

Attention: If the device is not charged regularly, the batteries may become deeply discharged and the device will stop working.

Attention: Position the device in a way that the charger is freely accessible when charging.

Remove any filters that may still be on the unit.



Figure 16: Disconnect DFS from DIA via the release button

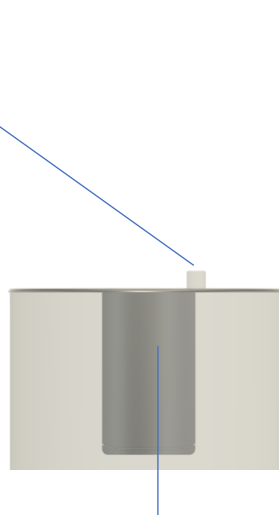


Figure 17: Charging cover at the DIA

Remove the pressure-flow-sensor from the pressure-impulse-actuator by pressing the release button at the pressure-impulse-actuator and pulling off the pressure-flow-sensor. (Figure 16).

Remove the charging cover for the pressure-flow-sensor located on the pressure-impulse- actuator. (Figure 17)

Remove the air channel together with the air channel support from the pressure-flow- sensor. (Figure 18)

Attention: When disassembling, cleaning and reassembling, please make sure that the membrane of the DFS (figure 24) is not being damaged. Any damage may lead to incorrect measurements!

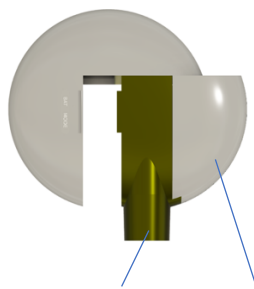
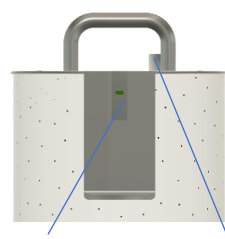


Figure 18: Air channel and air channel support of the DFS

Insert the electronic housing of the pressure-flow-sensor into the provided charging connector of the pressure-impulse-actuator. (Figure 19 and Figure 20)



Figure 19: Charging connector of the DIA



charging socket and release button of the DIA

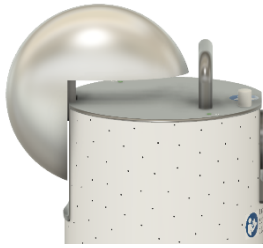


Figure 20: Attaching the DFS to the DIA for charging

Plug the charging cable into the charging socket of the pressure-impulse-actuator by pressing the release button completely down. (Figure 19)

Make sure that the plug is inserted in the correct position.



Figure 21: Position of the charging plug in the charging socket

Attention: Improper insertion may result in damage of the charging socket!

Plug the charger into the socket and connect it to the charging cable. The battery status indicator of the pressure-impulse-actuator starts flashing.

Note: Only use standard charging cables and chargers approved by LOTHAR MEDTEC.

Note: Pay attention to possible damages to the charging cable and the charger. If there is any damage, these damaged parts must not be used under any circumstances!

The device charges and displays the charge status (Figure 22). The battery status indicator flashes during charging.

As soon as the device is fully charged, the battery status indicator lights up green continuously. Remove the charging cable from the pressure-impulse-actuator and unplug the charger from the socket.



Figure 22: Plugged-on DFS during charging with battery status display

Assemble air channel and air channel support and remove the electronics housing from the charging connector of the pressure-impulse-actuator to connect it to the remaining components of the pressure-flow-sensor.

Note: When plugging together, make sure that the individual parts are positioned correctly!

Caution: Danger of pinching fingers during assembly!

Insert the charging cover into the charging connector at the pressure-impulse-actuator.

Plug the pressure-flow-sensor into the pressure-impulse-actuator while pressing down the release button at the pressure-impulse-actuator.

20. Software-update

This instruction manual describes version 2021.08 of the ALDS.

The following table shows which software versions of the components are compatible with version 2 of the ALDS:

ALDS version	Software version of the component			
	DS	WFA	DFS Firmware	DIA Firmware
2021.08	3.0.y	3.0.y	1.x.y	1.x.y

From time to time, updates of the software for the ALDS are automatically installed when restarting the Workflow App. Make sure that you restart the workflow app regularly. If necessary, follow the instructions on the screen.

The Workflow App automatically restarts after the download is complete, and it reconnects to the diagnostic system via the internet connection. In addition, the workflow app connects to the device.

Attention: After an update, please download the latest version of this instruction manual at https://www.lothar-medtec.de/assets/ALDS_Gebrauchsanweisung.pdf.

The ALDS is thus ready for operation again.

21. Cleaning of surface and disinfection

Note: Cleaning and disinfection may only be performed when the device is not being charged. The charging cable and charger must be removed from the device!

Remove the filter that might still be at the device.

Remove the elbow from the pressure-flow-sensor.

Carrying out cleaning and disinfection

Attention: To avoid cross-infection from one patient to another, a new, unused filter must be used for each patient. It is recommended to clean and disinfect the housings of the pressure-flow-sensor, the pressure-impulse-actuator as well as the air channel of the pressure-flow-sensor regularly according to the guidelines individually defined by the operator within his own quality management system.

Attention: The cleaning frequency depends on the individual risk assessment by the operator and the frequency of use. However, the device should be cleaned at least once a month.

Attention: The air channel must be replaced if damaged.

Clean the individual parts as described in the table below by using the materials and appropriate cleaning/disinfection methods:

Part	Material	*Disinfecting	Autoclaving possible?	Recommended Disinfectants
DFS housing outside	PC-HT	disinfecting	no	Wipe all external parts with a cloth soaked with 70 % isopropyl alcohol. Make sure that all housing parts are well-humidified. Note: Make sure that the isopropyl alcohol does not get into the sensor openings or the opening of the main connection of the DIA or into the air channel of the DFS.
DIA housing outside	PET, PPS, PA, ABS	disinfecting	no	
Air channel,	PC-HT, stainless steel	disinfecting	no	Disinfect by complete immersion in Descoton Forte at 4% concentration for 30 minutes. Then rinse the air channel with running water.
Elbow	PC	disinfecting	no	
Filter	PP	single use	single use	No disinfection; disposal according to manufacturer's specification
Nose clip	PP	single use	single use	

Depending on the country, the availability of the recommended cleaning and disinfection agents may be limited.

Attention: Make sure that all outer surfaces of the pressure-flow-sensor and the pressure-pulse-actuator are sufficiently humidified with the wiping fluid.

Attention: Check that the air channel and elbow are completely immersed in the disinfectant solution.

Note: Before using a cleaning agent for DFS and DIA, check whether it is suitable for surface disinfection of plastic housings.

Attention: Follow the instructions of the detergent manufacturer regarding the use of the products.

Using the above table, you can assess and select the cleaning and disinfection agents and procedures optionally available in your practice with regard to their suitability. When using cleaning and disinfection agents other than those recommended above, it is essential to observe the suitability, application and safety instructions of the manufacturer.

Make sure that the housings of the DFS and the DIA are dry after cleaning and that there is no more contamination. Otherwise, repeat the cleaning procedure.

Allow the air channel and elbow to air-dry overnight before reassembling.

Before reassembling, check that the air channel and elbow are dry and that there is no more contamination. Otherwise, repeat the cleaning procedure.

Reassemble the air channel and air channel support after cleaning and remove the electronic housing from the charging connector of the pressure-impulse-actuator to connect it to the remaining pressure-flow-sensor components.

Attention: When disassembling, cleaning and reassembling, please make sure that the membrane of the DFS (figure 24) is not damaged. Damage may lead to incorrect measurements!

Plug the pressure-flow-sensor into the pressure-impulse-actuator while pressing down the release button on the pressure-impulse-actuator.

Attach the elbow to the pressure-flow-sensor.

Check the function of the ALDS using a test measurement, e. g. by using the calibration pump.

Note: When plugging together, make sure that the individual parts are fitted correctly!

Caution: Danger of pinching fingers during assembly!

Caution: After cleaning, check the function of the ALDS by means of a test measurement, e. g. by using the calibration pump. Especially after cleaning the air channel, make sure that it is completely dried out, otherwise incorrect measurements will occur!

Attention: Observe the instructions of the original manufacturer with regard to the disposal of the products. This applies in particular to disposable products such as filters.

Disinfection of the air channel and the elbow (in case of special contamination)

In case that disinfection of the air channel and/or the elbow is necessary, please proceed as follows:

Remove the pressure-flow-sensor from the pressure-impulse-actuator by pressing the release button at the pressure-impulse-actuator and remove the pressure-flow-sensor (see figure 20).

Remove the air channel including the air channel support from the pressure-flow-sensor (see figure 18).

Separate air channel and air channel support by compressing the two levers (mark 1) and pulling out the air channel at the same time (mark 2), (figure 23).

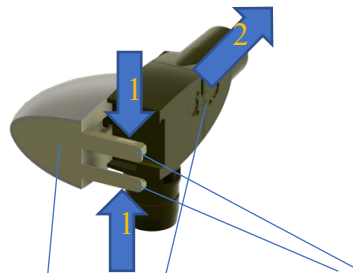


Figure 23: Air channel carrier and air channel of the DFS and the levers

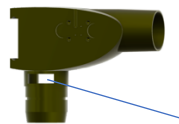


Figure 24: Air channel of the DFS with membrane

The air channel (figure 24) and the elbow may additionally be cleaned and must be dried sufficiently afterwards. Please note the specifications in the above shown table.

Attention: When disassembling, cleaning and reassembling, make sure that the membrane of the DFS (figure 24) does not get damaged. A damage may result into false measurements!

22. Device check

Regularly check the function of the ALDS to ensure the correctness of the measurements. At first the following display appears:

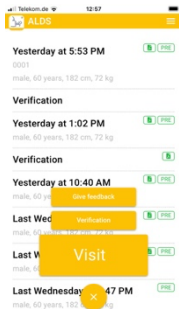


Figure 25: Selecting device check

If you click on the icon  the following display appears:

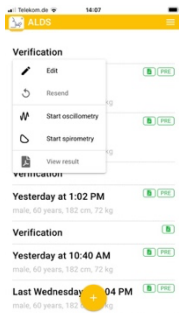




Figure 26: Selection menu for device check

Afterwards, you may select in the display if you want to start a flow check or a pressure check. For this, you may click on the icons  Start spirometry or  Start oscillometry.

Remove any remaining filters from the ALDS and follow the instructions to be seen on the screen.

After the examination the result is transferred and displayed automatically.

If the results presented in the report are not within the acceptable range, contact the manufacturer immediately via the following contact:


LOTHAR MEDTEC GmbH

Magdalene-Schoch-Str. 5
97074 Wuerzburg, Germany
Tel: +49 931 6193816-0
E-Mail: info@lothar-medtec.de

Warning: If the device check shows that the device is faulty, it must in no case be used any longer! Inform the manufacturer's service immediately.

23. Possible sources of error and remedies; feedback

Note: In general, the device can be reset by plugging the charging cable into the charging plug as described in chapter 19.



Note: The device may also be reset by clicking on the icon  Reset ALDS in the menu Device Information.

Note: A measurement having been carried out directly before resetting the device might get lost.

No.	Error	Error source	Remedy
1	device does not start; no LED lights up	battery empty	charging, see chapter "Charging the device"
2	there are no impulses for oscillometry	DIA was not switched on	measuring, see chapter "Measuring oscillometry".
3	there are no impulses for oscillometry	battery of the DIA is empty	charging, see chapter "Charging device"
4	the Workflow App does not receive data	battery of the DFS is empty	charging, see chapter "Charging device"
5	the Workflow App does not receive any data	measurement not finished or quality of measurement is insufficient	repeat measurement, see chapter "Measuring spirometry" or "Measuring oscillometry".
6	the Workflow App does not receive data	Workflow App has not started	start or activate Workflow App
7	the MOD LED of the DFS lights up orange	a measurement of the previous patient is still available	transfer the measurement in the WFA, see chapter "Managing measurement".

8	no diagnosis suggestion appears in the Workflow App despite successful measurement	no internet connection	check the internet connection
9	the BAT LED of the DFS lights up orange	Accumulator of the DFS is empty	charging according to chapter "Charging of the device"
10	the BAT LED of the DIA lights up orange	Accumulator of the DIA is empty	charging according to chapter "Charging of the device"
11	the measurement does not start	Accumulator of the DFS is empty	charging according to chapter "Charging of the device"
12	the measurement does not start	the air channel of the DFS is blocked	cleaning, see chapter "Cleaning of surface and disinfection".
13	there are no impulses for oscillometry	the air channel of the DFS is blocked	cleaning, see chapter "Cleaning of surface and disinfection".
14	the measurement is not transferred to the Workflow App	measurement has not been performed correctly	repeat measurement, see chapter "Measuring spirometry" or "Measuring oscillometry".
15	measurement does not start	there is still an old measurement available in the DFS	establish connection to the workflow app see chapter "Manage measurement".
16	charging does not start	defective charger or charging cable	use a different charger or charging cable specified in the chapter "Technical data"
17	The ALDS no longer responds	Accumulator empty or connection interrupted	charging, see chapter "Charging of the device"
18	The Workflow App no longer responds	Windows or iOS error	close the app via the Task Manager
19	The filter has accidentally not been changed Attention: Inform the responsible hygiene officer immediately	operator error	immediately disinfect the air channel and the elbow as described in the chapter "Cleaning of surface and disinfection".

Feedback:

After clicking on the icon  in the main menu you may forward important information to Lothar Medtec via clicking on the icon . By providing this feedback especially information on the device and further specific data are forwarded which are necessary for finding out the cause of potential errors. Please fill in the fields precisely:

24. Safety and operating instructions

This instruction manual describes the currently valid status of the device/system, including software and accessories, taking into account the essential requirements of MDR 2017/745.

Strict adherence to the operating instructions is a prerequisite for the intended use of the ALDS.

Please observe the manufacturer's specifications (technical data, explanation and compliance with the pictograms and other information).

Deviation from the intended purpose

Any disregard of the procedures described in this instruction manual (measuring arrangements and methods, disinfection procedures, use of accessories and spare parts, etc.) will result in a deviation from the intended purpose.

In the event of a deviation from the intended purpose, 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.

Accessories and consumables with a limited shelf life must be disposed of after expiration of the shelf life.

LOTHAR MEDTEC guarantees the safety, reliability and function of its equipment only if:

- The installation is carried out in accordance with the specifications in this instruction manual
- The installation site corresponds to the environmental conditions of the device/system (as specified in this instruction manual, chapter 12).
- The device is used in accordance with the instruction manual.

Remove the device from the packaging and check it for damage. If the device is damaged, do not use it, and return it to LOTHAR MEDTEC for replacement.

This instruction manual is considered part of the device/system and must be kept accessible at all times.

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

Electrical safety

Warning: Do not perform any measurement during the charging process.

Patient safety according to EN 60601-1

The safety requirements for leakage current according to EN 60601-1 are met during measurement.

Interference radiation

The medical device complies with the regulations of EN 60601-1-2 with regard to interference emission and interference immission.

The device operates with radio communication which may be disturbed by sources of electromagnetic energy.

Environmental conditions

The medical device must not be used in rooms with or in the presence of flammable mixtures of anesthetics with air or flammable mixtures of anesthetics with oxygen or nitrous oxide.

When using gases and pharmacological substances (aerosol), ensure good ventilation!

The medical device is intended for operation in rooms in which only non-conductive contamination occurs. Occasionally, however, short-term conductivity is possible due to condensation. The medical device is intended for operation in rooms used for medical purposes.

The medical device must especially be protected from exposure to moisture.

When operating the device, do not hold the air channel to your ear.

Electrical connection when charging the batteries

Before connecting a device/system to the supply mains for charging the batteries, the nameplate data informing about the permissible mains voltage and mains frequency must be compared to the local characteristic data. Connection only if those data are matching!
Mains connection cables must be visually inspected before use. Damaged lines and plug devices must be replaced immediately.
In case of smell of burning or discoloration or deformation of the device or its components, do not touch these components. Remove the charger from the socket if necessary and contact the manufacturer immediately.


Medical responsibility

To prevent cross-infection from one patient to another, a new, unused filter must be used for each patient.
A qualified physician must re-evaluate all recordings. A diagnosis suggestion by the device is only significant if considered in the context of other clinical findings. It must be reviewed again by the physician.

If you suspect equipment malfunction, please contact LOTHAR MEDTEC immediately:

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

CE notice

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

Maintenance

Only use accessories and spare parts approved by LOTHAR MEDTEC for this medical device.
If applied parts have been subjected to extreme mechanical stress, a function test must be performed. Defective parts have to be discarded. Damaged plug connections, lines and cables must be replaced immediately. In case of an unauthorized opening of the device, the warranty claims expire.
In the event of malfunctions, the LOTHAR MEDTEC support team will be happy to advise you and to take care for remedy.

Keep consumables, accessories, packaging materials as well as cleaning and disinfecting agents out of the reach of children or mentally impaired persons. Comply with the regional guidelines for disposal.

The packaging material or parts of it may not be swallowed or put over one's head – this may lead to death by suffocation.

Maintenance and repairs are to be carried out exclusively by LOTHAR MEDTEC.

Recycling/disposal

When disposing of the medical device and its accessories, the legal regulations must be observed. Please send the entire device to LOTHAR MEDTEC for disposal. The accessories (filters) must be disposed of in accordance with the manufacturer's instructions.

25. Literature

The ALDS implements the following published concepts for the physiological interpretation:

- King GG, Bates J, Berger Kl, et al. Technical standards for respiratory oscillometry, Eur Respir J 2020.
Brian L. Graham, et al. Standardization of Spirometry 2019 Update, American Journal of Respiratory and Critical Care Medicine 2019.
Stanojevic S, Kaminsky DA, Miller M, et al. ERS/ATS technical standard on interpretive strategies for routine lung function tests, Eur Respir J 2021.
Marcin Bednarek, Marcin Grabicki, Tomasz Piorunek, Halina Batura-Gabryel, Current place of impulse oscillometry in the assessment of pulmonary diseases, Respiratory Medicine 2020.
Lennart K. A. Lundblad, Salman Siddiqui, Ynuq Bossé, Ronald J. Dandurand, Applications of oscillometry in clinical research and practice, Canadian Journal of Respiratory, Critical Care, and Sleep Medicine 2019.
R.L. Dellaca, P.P. Pompilio, P.P. Walker, N. Duffy, A. Pedotti and P.M.A. Calverle, Effect of bronchodilation on expiratory flow limitation and resting lung mechanics in COPD, Eur Respir J 2009.
Noemi Porojan-Suppini, Ovidiu Fira-Mladinescu, Monica Marc, Emanuela Tudorache, Cristian Oancea, Lung Function Assessment by Impulse Oscillometry in Adults, Therapeutics and Clinical Risk Management 2020.

Reference Models

The ALDS implements the following published reference models for calculation of patient-specific reference values.

Spirometry

All ages
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.

Oscillometry

Children Aged 2–13 Years:
Claudia Calogero, Shannon J. Simpson, Enrico Lombardi, Niccolo Parri, Barbara Cuomo, Massimo Palumbo, Maurizio de Martino, Claire Shackleton, Maureen Verheggen, Tania Gavidia, Peter J. Franklin, Merci M.H. Kusel, Judy Park, Peter D. Sly, Graham L Hall, Respiratory Impedance and Bronchodilator Responsiveness in Healthy Children Aged 2–13 Years, Pediatric Pulmonology, 2013, 48.

Adolescents 14–17 Years:
Bozena Nowowiejska, Waldemar Tomalak, Jakub Radlinski, Grzegorz Siergiejo, Wojciech Latawiec, Maciej Kaczmarek, Transient Reference Values for Impulse Oscillometry for Children Aged 3–18 Years, Pediatric Pulmonology, 2008, 43.

Adults 18 and older
Ellie Oostveen, Krisztina Boda, Chris P.M. van der Grinten, Alan L. James, Sally Young, Hans Nieland and Zoltan Hantos, Respiratory impedance in healthy subjects: baseline values and bronchodilator response, Eur Respir J, 2013, 42.

26. Order numbers of consumables, spare parts and accessories

Components of ALDS	Order no.
Pressure-flow-sensor complete	ALDS-DFS
Pressure-impulse-actuator complete	ALDS-DIA

Elbow	ALDS-ELB
Nose clip	ALDS-NOS
Filter with mouthpiece	ALDS-PI
Charger	ALDS-CHA
Charging cable	ALDS-CAB
Instruction manual	ALDS-MAN
PC adapter for Windows devices	ALDS-DON
Calibration pump	ALDS-CAL
Reference resistor	ALDSRRE

The supply of filters and nose clips usually takes place automatically according to your consumption. You are welcome to order spare parts and accessories via

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

27. Technical data

All measured values are provided as BTPS values.
 The ALDS meets the requirements of ISO26782:2009.

Flow/Volume

Measuring range: Flow: 0-14l/s; Volume: >8l
 Resolution: flow: better than 200ml/s; volume: better than 50ml/s
 Accuracy: Flow: better than +-3% related to the measuring range.
 Volume (FEV1, FEV6, FVC): better than +-3% or +-0,05l related to the measuring range
 Max. airway resistance: <0.15 kPa/(l/s)
 T0 is determined according to ISO26782, 3.18
 The highest impedance is 0.15 kPa/(l/s) at 14 l/s according to ISO26782, chapter 5.6.1.d

Pressure

Measuring range: -500Pa to +500Pa
 Resolution: 0,1Pa
 Accuracy: 0.1Pa

Temperature

Operation +17 °C to +35 °C
 Storage/transport -20 °C to +50 °C

Air pressure

Operation 850 hPa to 1060 hPa
 Storage/transport 700 hPa to 1060 hPa

Humidity

Operation 30% to 75% non-condensing
 Storage/transport 30% to 75% non-condensing

Specification of charger:

Charger must meet protection class II
 Input voltage according to specification of charger
 Output voltage: 5V DC, at least 2A

Note: Exclusively use the charger and associated charging cable supplied by LOTHAR MEDTEC!

Specification of charging cable:

The charging cable must be approved for operation with a charger specified above.

Note: Exclusively use a charging cable supplied by LOTHAR MEDTEC!

28. Electromagnetic compatibility according to EN 60601-1-2:2015 / ISO 60601-1-2:2015

The CE symbol indicates that the ALDS complies with the provisions of the Medical Devices Regulation 2017/745 of the European Commission.

For Canada only: LOTHAR MEDTEC declares that the product described herein has been designed and manufactured in accordance with the following specifications and standards: Canadian Medical Device Regulation (SOR/98-282). This device also complies with the safety and effectiveness requirements.

The device is suitable for use in facilities of all kinds, e. g. in hospitals and medical practices. However, the system must not be operated in the vicinity of high-frequency surgical facilities or in high-frequency screen rooms used for magnetic resonance imaging, as high-intensity electromagnetic interference occurs there.

WARNING: Use of this equipment immediately adjacent to other equipment or with other equipment stored one above another should be avoided, as it may result in faulty operation. If use in the manner described above is nevertheless necessary, this equipment and the other equipment should be observed to make sure that they are operating properly.

The ALDS includes a charging cable with USB-A and mini-USB-B connectors. The charging cable is designed for a charging current of 2 A. Exclusively use the supplied USB charging cable for charging. If different cables compliant to the specification are used, their length must not exceed 1 meter.

WARNING: The use of different accessories, e. g. a charging cable other than that provided as an accessory of the ALDS, may result in increased electromagnetic interference or in reduced electromagnetic immunity of the device, and it may lead to faulty operation.

WARNING: Portable high-frequency communication-devices (radios) (including their accessories such as antenna cables and external antennas) should not be used within a range of less than 30 cm (or 12 inches) to the device itself and to the ALDS lines. Disregarding this instruction may result in a reduction of the performance characteristics of the device.

The system complies with the following levels of conformity in terms of emitted interference and immunity to interference.

Interference emission	Conformity level
HF emissions EN 55011/CISPR 11	Group 1 / Class B
Interference immunity	Conformity level
Immunity to static electricity discharge (ESD) IEC 61000-4-2	±8 kV contact / ±15 kV air
Immunity to high-frequency electromagnetic fields IEC 61000-4-3	80MHz-2.7 GHz: 10 V/m
Mains frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m
Electromagnetic compatibility for radio equipment and services ETSI EN 301489-1	80MHz-6GHz: 3V/m

The ALDS uses radio frequency communication according to the Bluetooth v4.2 BR/EDR and BLE specification for the internal communication between components and for data transmission.

Receiving frequencies	2402-2480 MHz
Transmitting frequencies	2402-2480 MHz
Maximum transmitting power	100 mW

Immunity to high-frequency wireless communications equipment:

Test frequency MHz	Frequency band ^a MHz	Radio service ^a	Modulation ^b	Maximum Power W	Distance m	Interference immunity-test level V/m
385	380 to 390	TETRA 400	Pulse modulation ^b 18Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	FM ^c ±5 kHz stroke 1 kHz sine	2	0,3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation ^b 217 Hz	0,2	0,3	9
745						
780						
810	800 till 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^b 18 Hz	2	0,3	28
870						
930						
1720	1700 till 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^b 217 Hz	2	0,3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n,	Pulse modulation ^b 217 Hz	2	0,3	28

		RFID 2450, LTE Band 7				
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ^b 217 Hz	0,2	0,3	9
5500						
5785						
Note: If necessary, the distance between the transmitting antenna and the device may be reduced to 1 m to achieve the immunity test levels. The test distance of 1 meter is permitted according to IEC 61000-4-3.						
For some radio services, only the frequencies for the radio link from the mobile communication device to the base station have been included in the table.						
^b The carrier must be modulated with a square wave signal of 50% duty cycle.						
^c As an alternative to frequency modulation (FM), pulse modulation with 50 % duty cycle at 18 Hz can be used, since this would represent, if not the actual modulation, then at least the worst case.						

Contact

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