DOVIDEQ
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Installation and User Manual

LeakControl

Automated Leak Tester for Flexible Endoscopes
Stand-Alone and Connected Version

June 2025 | Version 1.0   C E

Table of Contents

1.   Preface

1.1   Description of the User

⚠ WARNING

These instructions are intended for the end user of the product. The product's end user is a person who has read and understood these user instructions, is an experienced user of similar equipment, is aware of all possible dangers, and is capable of acting accordingly.

The LeakControl system is designed for professionals involved in the quality control, maintenance, and manufacturing of flexible endoscopes.

The primary users include hospital staff, Central Sterile Services Departments (CSSD), Biomedical Engineering Departments, endoscope repair companies, and endoscope manufacturers.

All users should have a basic understanding of endoscope design and optical performance. This document is intended for all primary users, including LeakControl operators and managers.

1.2   Explanation of Safety Warnings

⚠ DANGER

Danger indicates a hazard with a high level of risk, which, if not avoided, will result in death or serious injury.

⚠ WARNING

Warning indicates a hazard with a medium level of risk, which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution indicates a hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates information considered important but not hazard-related.

1.3 How to Use These Instructions

Ensure that each person using the product has read and understood this manual and its safety instructions before using it. Failure to do so can result in serious injury or death.

When this manual refers to the *product*, *appliance*, or *device*, it refers to LeakControl, possibly connected to the EndoscopeManager platform.

Take note of all warnings, safety precautions, and instructions to avoid potential fires, explosions, electric shocks, or other hazards that could damage property or cause severe or fatal injuries. Keep all safety information and instructions for future reference and pass them on to subsequent product users.

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the safety instructions. In such cases, the warranty will be voided.

This manual is periodically updated to match new software releases. The release date is printed on the front page of this document, ensuring that you always have the latest copy. Updates can be found at https://www.dovideqmedical.com/manual.

Unauthorized copying of this publication may not only infringe copyright laws but may also reduce DOVIDEQ Medical Systems B.V.'s ability to provide accurate and current information to users. The latest version of the documentation is available at www.dovideqmedical.com.

DOVIDEQ Medical Systems B.V. reserves the right to change the LeakControl system and this user manual. Product specifications are subject to change without notice. Nothing contained within this user manual is intended as an offer, warranty, promise, or contractual condition and must not be taken as such.

For information, contact:

DOVIDEQ Medical Systems B.V.

Hassinkweg 10   **Telephone:** +31 (0)570 760 800
7556 BV Hengelo   **Email** : info@dovideqmedical.com
The Netherlands

1.4 Declaration of Conformity

This device complies with all relevant European Directives. The Declaration of Conformity is available upon request.

1.5   Warranty

The manufacturer provides a full 12-month warranty on this product. Excluded from warranty are the use outside the scope of this manual, intentional damage, damage caused by external factors, and modifications without the written, pre-approved consent of the manufacturer.

1.6   Service

For maintenance and service requests, contact Dovideq Medical Services by emailing service@dovideqmedical.com.

Contact our sales department at info@dovideqmedical.com or +31 (0)570 760 800 for commercial inquiries.

If you have a service contract, please contact Dovideq before sending your LeakControl to the address below. We will then send you another LeakControl in exchange. If you do not have an exchange service contract, Dovideq will charge for the time and materials needed for the repair.

Always make sure the device is properly and securely packaged.

DOVIDEQ Medical Systems B.V.
Attn. Service Department
Hassinkweg 10
7556 BV Hengelo
The Netherlands

1.7   Disclaimer

This product is manufactured and assembled to the highest quality standards. The manufacturer reserves the right to change manuals. Future developments could lead to changes in data and description.

Copyrights must be respected for this manual. This manual contains specific information from the manufacturer. Distribution of partial or complete copies of this manual without prior written permission from the manufacturer is prohibited.

The manufacturer cannot be held liable for damage caused by misuse or use of the device that is not in accordance with the manual. If maintenance is done by unauthorized personnel, all warranty, repair, service, liability, and safety claims will be voided. The device's measurement results are purely for screening purposes.

No binding legal conclusions can be drawn from the results of LeakControl.

1.8 Software

1.8.1 Software Copyright

Software copyright ©2024 DOVIDEQ Medical Systems B.V. All rights are reserved. All other product names are the property of their respective owners. Reproduction in whole or in part in any form or by any means is prohibited without the written consent of the copyright holder.

1.8.2 Software Updates

Periodically, software updates will be released to improve or add functionality to LeakControl. Check out the latest changes at https://www.endoscopemanager.com.

Neither this software nor the device holds or transmits privileged patient data. This device, nor any software provided as an accessory to its use, should in no way be used to hold privileged patent data requiring adherence to confidentiality rules and regulations.

2.   About LeakControl

2.1   Intended Use

Dovideq LeakControl is an electronic leakage testing system for flexible endoscopes. It allows for reliable and consistent endoscope leakage testing, regardless of brand or type of scope. It is easy to operate and keeps the endoscope pressurized during the cleaning process to prevent liquids from entering the endoscope in case of a leakage. LeakControl is available in a stand-alone and connected version that can be connected to the EndoscopeManager platform.

2.2   Reasonably Foreseeable Misuse

NOTICE

Use the product, accessories, tools, software, etc. in accordance with these instructions, taking into account the working conditions and the work to be done. Using the product for operations different from those intended could result in a hazardous situation and void the warranty.

The LeakControl system shall not be used as follows:

- ▶ **Application beyond the design specifications.** Using the system with endoscopes outside specified parameters could cause damage or yield inaccurate results.
- ▶ **Operation by untrained individuals.** Use by untrained individuals could lead to erroneous data analysis, compromising endoscope safety and effectiveness.
- ▶ **Usage in unsuitable environments.** Use only in suitable environments to prevent damage to the system and maintain accuracy.
- ▶ **Adaptation for non-intended devices.** Use only flexible endoscopes to avoid incorrect assessments and damage to the system.
- ▶ **Neglecting system care.** Maintenance and calibration are essential to prevent a decrease in accuracy over time.
- ▶ **Circumventing safety protocols.** Modifying or disabling safety mechanisms could pose risks to the user and compromise data quality.

LeakControl shall be used with the following software, original accessories, and components only:

- ▶ DoviScan data matrix code scanner
- ▶ DoviRead RFID scanner
- ▶ EndoscopeManager cloud platform
- ▶ Flexible endoscopes

▶ Other compatible 3rd-party equipment that is supported by Dovideq. Go to www.dovideqmedical.com for more information.

The product shall only be used in accordance with the instructions described in this manual. Any use other than those described in this manual is considered non-intended use. This will also invalidate the warranty.

2.3 System Description

With the optional DoviScan data matrix code scanner attached to LeakControl, you can scan an endoscope's UDI. LeakControl pressurizes the endoscope and checks for a decrease in pressure over time. The test duration is automatically set for 60 or 120 seconds, depending on whether you're testing a small or large endoscope. This can also be set manually but is set to auto-detect by default. If a leak is found, LeakControl will alert the operator and keep the endoscope pressurized until the operator removes it from the water bath and stops the test. If LeakControl is connected to the EndoscopeManager platform, the test data is stored there. This ensures regulatory compliance and gives you crucial insights into your inventory, allowing you to track performance over time.

2.4 Product Specifications

Parameter	Unit
Device	
Device name	LeakControl
Model / Type	DMLE - (Year XX | XXX Piece count)
Protection ration	IP20
Protection class	Class 1
Dimension (LxWxH)	300 x 200 x 100 mm
Weight	2.6 kg
Input	5 VDC
Adapter input	100-240 VAC; 50/60 HZ; 1.4–0.7 A
Adapter output	5 V; 6.0 A
Max. power	30 W
Main power supply	C13 Power cable
Sound level	~60 dB
LeakControl Scope Connector	CPC-connector (female)
Nominal scope pressure	220 mbar (165 mmHg)
Maximal scope pressure	Safety valve set at +/- 275 mbar (205 mmHg)
Measuring time	60s / 120s / 180s / 240s / 300s / Auto detect (60s/120s)
Operation temperature	15° to 35 °C (59° to 95 °F)
Storage temperature	5° to 50 °C (41° to 122 °F)
Relative humidity	0–85% / Non-condensing (IEC 721)
Technical life span	5 years

Parameter	Unit
Connections and communication	
Operating system	Yocto-based Linux
USB connection	USB 2.0 (2x) / USB 3.0 (2x)
Ethernet connection	RJ-45 Ethernet port
Protocol	HTTPS
Ports	443 TCP 123 UDP (for NTP time synchronization) 53 UDP (for DNS name resolving)
Encryption	TLS
IP	DHCP/Static
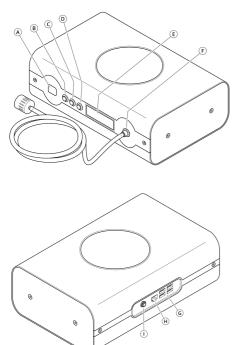
Pressure reference table

mbar	mmHg	kPa	psi
0	0	0	0
50	37.5	5	0.725
100	75	10	1.45
200	150	20	2.90
250	185.5	25	3.63
300	225	30	4.35
400	300	40	5.80

2.5   Product Elements
2.5.1 LeakControl

A	LED status indicator	F	CPC-connector (female)
B	Reset button	G	USB 2.0 / 3.0 sockets
C	Start button	H	Ethernet socket
D	Stop button	I	Power inlet
E	Display		
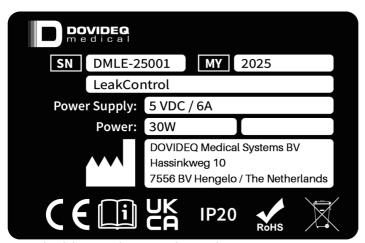
2.5.2 Visual and Audio Signals

The **LED status indicator** Ⓐ indicates whether LeakControl is turned on, the status of a test procedure, and whether an endoscope is pressurized.

	Green	**Yellow**	**Red**
Continuous	Ready	Busy	N/A
Blinking slow	Passed Test	Measuring	Failed Test
Blinking fast	N/A	Attention	Error

2.6 Type Plate

The type plate is attached to the side of the LeakControl appliance.

Example of the type plate on LeakControl

2.7 Endoscope Compatibility

To ensure optimal performance and safety, all endoscopes must meet the following specifications:

▶ **Type**
Suitable for all flexible endoscopes with a leak test connection. The type of connector could vary from endoscope to endoscope, but with the correct connector, it can be attached to the hose. Dovideq can supply Storz, Fujinon, Olympus, and Pentax connectors.

2.8   Navigating the LeakControl setup menu

To navigate through the setup menu of the LeakControl, the stop ■ , start ▶ , and reset button ⇄ are used:

▶   To cycle through available options, press the **stop** button.
▶   To select a menu item, press the **start** button.
▶   To go back or out of a (sub)menu, press the **reset** button.

3.   Safety

⚠ WARNING

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in serious injury, damage to the instrument, erroneous results, and data loss.

3.1   Explanation of Graphical Symbols

Symbol	Meaning
📖ℹ	Read and understand the manual and its safety instructions before using this product.
CE	The CE marking on the product is the manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety, and environmental protection legislation.
⏚	This marks that the equipment must be connected to an earthed mains socket outlet as required by some jurisdictions. In jurisdictions such as Finland, Norway, and Sweden, if the safety of class I pluggable electrical equipment type A intended for connection to other equipment or a network relies on connection to protective earth, or if surge suppressors are connected between the network terminals and accessible parts, the equipment must have a marking stating the requirement.
🗑	This symbol on the product, the accessories, or the packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately.

3.2 Safety Information Related to the Intended Use

▶ The product shall only be used for applications as described by the manufacturer. The manufacturer cannot be liable for damage resulting from errors, unintended use, or unprofessional product use.

▶ Use the product, accessories, tools, software, etc. in accordance with these instructions, taking into account the working conditions and the work to be done. Using the product for operations different from those intended could result in a hazardous situation.

▶ The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the user documentation. In such cases, the warranty will be voided.

▶ Do not operate electrical equipment in explosive atmospheric conditions, such as in the presence of flammable liquids, gasses, or dust. The equipment can create sparks, which could ignite the dust or fumes.

▶ The device is intended for use indoors. Never use outdoors.

▶ Only persons able to receive training and who demonstrate the capability to use the product in a way which adheres to the instructions and requirements written in this manual should be allowed to use the device without direct supervision or instruction.

▶ The product has been tested and complies with electromechanical device safety standards. The product is safe if handled properly and according to the instructions. Contact your physician if you have a pacemaker or other implanted device before use.

▶ Never leave children unattended with the packaging material. The packaging material represents a danger of suffocation.

3.3 Safety Information Related to Transport and Storage

▶ Lift, handle, and transport the product carefully. Ensure the product cannot move or slide during transport.

▶ Make sure any endoscope is disconnected before transporting the product.

▶ Always be careful when handling, transporting, and storing the product. Always put the product in the original packaging during transport and storage. The product contains delicate and fragile parts. If the product is not used for an extended period, unplug, clean, and store it in a cool, dry place away from direct sunlight.

▶ Store the product out of the reach of unauthorized persons, and do not allow persons unfamiliar with the product or these instructions to use it.

▶ Do not drop or hit the device.

3.4 Installation Safety Information

▶ Check the product for damage before installation. If there is any visible damage, do not install the product and contact the manufacturer.

▶ Do not place or store the product where it can fall or be pulled into water or other liquids.

▶ Two people are always required for the installation process.

▶ Only use the product when correctly and completely installed. Be aware that the manufacturer cannot be held responsible for tool damage or personal injuries resulting from the incorrect installation of the product.

▶ Use only the original power plug supplied with the product. Other power plugs could damage the product. Do not use the supplied product power plug with other devices.

▶ Extension cables and multi-plug adapters are prohibited between the earthed AC wall socket and the appliance plug.

▶ Do not place the device on uneven or unstable surfaces.

▶ Do not expose the device to dirty or dusty environments.

▶ Do not install the device close to magnetic/electric fields or electrical devices.

3.5 Safety Information Regarding Use

▶ Always be vigilant and careful about your actions. Do not use the product if you are lacking in concentration or awareness or are under the influence of drugs, alcohol, or medication. Even a moment of inattentiveness can lead to severe accidents and injuries when using the product.

▶ The risk of injury can be reduced by placing the product at the correct working height and taking proper ergonomic measures into consideration.

▶ Risk of damage. The device is a highly sensitive measurement device. Handle with care to avoid damage to the device and endoscopes.

▶ Risk of damage. The device is a highly sensitive measurement device. Only use the device in a controlled electromagnetic environment.

▶ To avoid overheating, do not cover the device. Do not use near heat sources or in direct sunlight and only at ambient temperatures of between 15° and 35 °C (59° to 95 °F).

▶ Do not expose the device to direct sunlight; do not place it on heat-sensitive surfaces or near heaters, air conditioners, or flammable substances.

3.6   Maintenance Safety Information

▶ Only qualified, certified personnel shall repair, disassemble, or discard the appliance.
▶ Alterations to the product and technical modifications are not permitted without written permission of the manufacturer.
▶ Disconnect the appliance from the power supply when you repair, disassemble, or discard the appliance.
▶ Maintenance and inspection should be done frequently. Infrequent maintenance shortens the life span of the machinery and voids the warranty.
▶ Use only original spare parts. Using other parts will void the warranty and the CE identification and could lead to injuries.
▶ All maintenance tasks shall only be done by qualified and skilled personnel. Qualified personnel shall perform regular maintenance per the manufacturer's instructions to ensure the product's operational safety.
▶ Clean the appliance with a dry, lint-free cloth. Do not use detergents or other solvents to clean the appliance.
▶ Performing maintenance tasks on the appliance can result in injuries due to sharp edges and pointed objects.
▶ Disconnect the power supply before cleaning the product.

3.7   Service and Repair Safety Information

▶ Only qualified, certified personnel shall repair, disassemble, or discard the appliance.
▶ Do not try to repair the product yourself. Call the manufacturer (+31 (0)570 760 800) if the product is not functioning properly.
▶ Disconnect the plug from the power source before installation, maintenance, repair tasks, making any adjustments, or changing accessories. Such preventive safety measures reduce the risk of starting the product accidentally.

4.   Preparation

4.1   Installing the LeakControl

NOTICE

▶ Keep the work area clean and well-lit. Cluttered or dark areas invite accidents.
▶ Do not expose the device to direct sunlight; do not place it on heat-sensitive surfaces or near heaters, air conditioners, or flammable substances.
▶ Install the device on a stable, level, and vibration-free surface that can easily support the weight of the device.
▶ The device does not have adjustable feet, so do not try to loosen or tighten its feet.

4.1.1 Unpacking the LeakControl

To unpack the LeakControl:
1. Remove the transport and packaging restraints.
2. Unpack the product.
3. Check if the packaging contains the following:
    ▶ LeakControl
    ▶ External tubing with/without an endoscope connector
    ▶ RJ-45 Ethernet cable
    ▶ Power cable and adapter
    ▶ Installation and User Manual
4. Remove the cardboard protection from the box.
5. Unpack all ordered Leakcontrol accessories, for example:
    ▶ DoviScan, or compatible scanner
    ▶ Compatible printer
6. Place the LeakControl appliance on a clean, flat surface. **NOTICE** If you install the LeakControl near a water bath, attach it securely to prevent it from falling in.
7. Inspect the product to make sure it is not damaged.
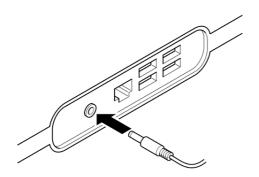
4.1.2 Installing the LeakControl

⚠ DANGER

▶ Do not plug the power plug into an outlet with a voltage other than the one specified on the device.
▶ Check the product for damage before installation. If there is any visible damage, do not install the product and contact the manufacturer.

▶ **Tripping hazard! Place the product's power cable in such a way that people, including children, cannot trip over it.**
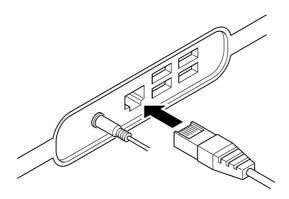
To install the LeakControl:

1. Connect the **power supply** to the **power inlet** (5 VDC) on the rear panel.
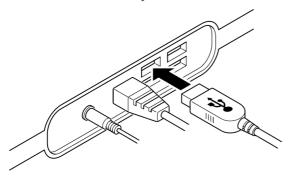
2. Optional: Connect the Ethernet cable to the **Ethernet socket**. This allows measurement data to be uploaded to EndoscopeManager, if subscribed.

   ⚠ **NOTICE! Make sure the Ethernet cable is connected to your local network and has an active Internet connection. See 4.2.1** *IT Network Preparation***.**

3. Optional: Connect a scanner to the **LeakControl** using the provided USB cable. This allows the operator to scan (data matrix) codes to improve traceability.
4. Optional: Connect a printer to the **LeakControl** using the provided USB cable. This allows Leakcontrol to print out test results.

5. Optional: Connect a USB data drive to the Leakcontrol. This allows the **LeakControl** to store test results locally.

4.2 Setting up EndoscopeManager

EndoscopeManager is a cloud-based inventory management system that stores your endoscopy equipment test data, tracks its performance, and ensures regulatory compliance.

4.2.1 IT Network Preparation

NOTICE

LeakControl uses an HTTPS connection to back up the database data and download new updates. For this purpose, an external connection must be made to the network to which LeakControl is connected.

To prepare your IT network for connection to EndoscopeManager:
1. Ensure your IT department assigns a dedicated person to assist in preparing your IT network. Share this person's email address with service@dovideqmedical.com. Dovideq will contact this person directly. Under normal circumstances, the preparations should take at most one hour.
2. Provide your IT department contact person with the Ethernet socket's address for LeakControl.
3. Ensure your IT department contact person has filled out, checked, and sent the LeakControl IT preparation checklist to Dovideq Support. The checklist can be found at www.dovideqmedical.com/prepare. You can add one Administrator and four regular users.
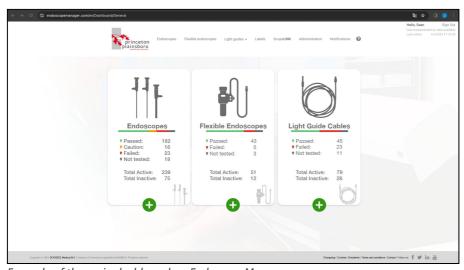
⚠ **NOTICE! LeakControl communicates to https://dovidash.nl through HTTPS / port 443. Your system's MAC address can be found in EndoscopeManager.**

4.2.2 Logging into EndoscopeManager

▶ To log in to EndoscopeManager, go to www.endoscopemanager.com and log in with your credentials. Contact our support team for assistance if you do not have an account.

▶ After logging in, you will go to the main dashboard.

Example of the main dashboard on EndoscopeManager

▶ From the main dashboard, you can:
  ▶ see your test results
  ▶ see an overview of your labels
  ▶ generate customized reports
  ▶ set notifications
  ▶ manage your account

▶ For more information and a more detailed overview of all functions in your dashboard, go to: https://www.dovideqmedical.com/dovideq-academy-endoscopemanager.

4.2.3 Adding an Endoscope to the Database

Before beginning the process, ensure you have the following:

▶ Access to your EndoscopeManager account.

▶ A DoviScan device or a 3rd party scanner.

▶ An endoscope equipped with a Unique Device Identification (UDI) code.

To add an endoscope to the database:

NOTICE Follow the steps below to add an endoscope to the database. Alternatively, run a test with the endoscope to add it automatically. Then, make modifications to the details, including the correct serial number, as desired.

1. Navigate to www.EndoscopeManager.com and log in to your account. Contact our support team for assistance if you do not have an account.
2. Upon successful login, locate and click the plus (+) icon in the `Flexible Endoscopes` section on the main dashboard.
3. Click on the textbox labeled `Scan Data Matrix Code` and use DoviScan to scan the UDI code found on your endoscope. After scanning, click `Next`.
4. Select the appropriate condition of your endoscope from the options: New, Used, or Refurbished. Then click `Next` to proceed.
5. Enter your endoscope type. This is usually found on the endoscope. For example, for an Olympus TJF100, enter `TJF100`. The system could suggest a type as you are typing.
   NOTICE If your endoscope type is not recognized, you can propose a new type for assessment by Dovideq. You will be contacted with further information.
6. Select the correct type if it appears, then click `Next`.
7. Enter the serial number of your endoscope. Click `Next` to continue.
   NOTICE If the UDI was accurately scanned in Step 3, it should autofill. If not, rescan the UDI using DoviScan. If your endoscope lacks a serial number, assign a unique identifier to this device.
8. Review all entered details for accuracy. You can assign the endoscope to a specific department or add comments for clarification. Once verified, click `Next` to finalize the addition.

Your endoscope has been successfully added to the EndoscopeManager database.

4.2.4 Locating Test Results

EndoscopeManager stores test results under the corresponding endoscope serial number. To locate LeakControl test results in EndoscopeManager:
1. Navigate to www.EndoscopeManager.com and log in to your account. Contact our support team for assistance if you do not have an account.
2. Click on the Flexible Endoscopes symbol on the main dashboard or select `Flexible Endoscopes` in the top menu.

You will see an overview of all the endoscopes registered to your account. Every endoscope has a timeline. A green dot indicates a passed test and a red dot indicates a failed test.

3. Your endoscopes are sorted by default by the most recent test. To find a specific endoscope, enter the serial number in the search box at the top right and press enter.
4. Click on the endoscope for which you want to see the test results.
   You'll see a summary of the endoscope usage on the bottom and a timeline showing every parameter score it got within the set date range on the top.
5. Navigate to the bottom right section and click `Test Report`. This section lists all tests conducted with the selected endoscope.
6. To generate a report, select the tests you wish to include and click `Create Report` on the right.
   A test report will be automatically generated based on your selection.

A comprehensive test report will be generated, consolidating all the results to provide an overview of the endoscope's performance and condition.

4.3 Commissioning

4.3.1 Calibrating the LeakControl

NOTICE

▶ When commissioning the LeakControl, the endoscope connection tube shall be calibrated by qualified or authorized personnel or by Dovideq. Recalibration is necessary when the endoscope connection tube is replaced or shortened in length.

▶ Full Calibration and Sensor Calibration shall only be done by qualified service personnel. Be careful when accessing these menu options. If entered accidentally, exit by pressing the reset button. Pressing the start button ▶ could cause calibration values to be overwritten. This requires service by qualified personnel to resolve.

▶ If an issue arises during the calibration steps, press the reset button and repeat the procedure.

▶ The calibration menu options `Calibrate full?` and `Calibrate sens?` are password protected and should only be used by qualified or authorized personnel or by Dovideq.In case these are accidentally entered, press the start button to continue with starting the device or press the reset button to restart the device.

The calibration menu of the LeakControl has the following options:

▶ `Calibrate full?`
   To do the full calibration (sens and vol), password protected

▶ `Calibrate sens?`
To calibrate the pressure sensor and test the pressure relief threshold, password protected.
▶ `Calibrate vol?`
To adjust the volume for the endoscope connection tube and set the threshold for small endoscope volume.

The `calibrate vol?` option is used:
▶ During commissioning
▶ To recalibrate the LeakControl when the endoscope connection tube is replaced or shortened in length.
▶ To calibrate the threshold for the auto test time option that determines whether the test time for a small or large endoscope is applied.

LeakControl devices connected to a scanner can directly go to a specific menu item by scanning one of the quickscan codes provided in *Appendix A. Quickscan menu codes*.

To do the volume calibration:
1. Press the **reset** button and immediately press and hold the **start** and **stop** buttons at the same time.
   The setup menu opens, and the **display** shows:
   ```
   Setup menu
   Cal=STA set=STO
   ```
2. Press the **start** button to open the **calibration** menu.
   The **display** shows `Calibrate full?`
   NOTICE DO NOT press the start button at this moment.
3. Press the **stop** button one or more times to select `Calibrate vol?`
4. Press the **start** button to open the volume calibration menu.
   The **display** shows `Tube length calibration`.
5. Press the **start** button.
   Wait for two seconds, when ready the display shows `Clamp on end press START`
6. Connect the **endoscope connection tube** to the **LeakControl** and clamp the end to make it air-tight.
7. Press the **start** button.
   The compressor starts, and the volume of the endoscope connection tube is measured.
   When ready, the compressor automatically stops.
8. The **display** shows `...counts`.
   NOTICE The number of counts is technical information and does not require any action.
9. Wait until the **display** shows `Press START`.

10. Press the **start** button.
    The **display** shows:
    ```
    Conn. small scp.
    Press START.
    ```
11. Connect a small volume endoscope to the **LeakControl** and press the **start** button.
    The compressor starts, and the **display** shows:
    ```
    Compressor ON.
    ```
12. When the **LeakControl** measures the volume of the small endoscope, the **display** shows `Determ scope vol.`
13. When ready, the **display** shows `time: XXXX ms press start.`
14. Press the **start** button.
    LeakControl now automatically applies a measuring time of 60 seconds to small endoscopes and 120 seconds to large endoscopes.
15. To confirm the measurement time setting, press the **reset** button.
    The **LeakControl** restarts.
    NOTICE During the start-up, the **display** shows `Auto`, or the selected measuring time that depends on the set measuring time.

4.3.2 Adjusting the LeakControl Settings

NOTICE

▶ **Changing the measuring time settings shall only be done by trained, qualified, or authorized personnel.**

The settings of each connected LeakControl can be viewed in EndoscopeManager under `Administration / LeakControl`.

Adjusting the settings of the LeakControl is done locally on the device itself.

LeakControl devices connected to a scanner can directly go to a specific menu item by scanning one of the quickscan codes provided in *Appendix A. Quickscan menu codes*.

To open the LeakControl settings menu:
1. Press the **reset** button and immediately press and hold the **start** and **stop** buttons at the same time.
   The `setup menu` opens, and the **display** shows:
   ```
   Setup menu
   Cal=STA set=STO
   ```
2. Press the **stop** button to open the **settings** menu.

The following settings are available:

Setting	Function	Explanation
`Set meastime`	To set the measurement time	Set to `Auto` or `Set time` ***NOTICE*** The LeakControl default setting for the measuring time is `Auto`. Changing the measuring time settings shall only be done by trained, qualified, or authorized personnel. **Auto:** Automatically changes between 60 and 120 seconds depending on the calibrated small endoscope volume threshold. **Set time:** to set a custom time between 60 and 300 seconds, with 60-second increments. ***NOTICE*** 60 seconds is preferred for smaller endoscopes or endoscopes without channels. 120 s is preferred as the minimal time for large endoscopes.
`Set w.bath det.?`	To enhance the measurement accuracy when using a water bath.	Set to ON or OFF. ***NOTICE*** With this setting ON, the overall testing time could increase. ***NOTICE*** When the endoscope is submerged in a hot water bath, and the pressure compensation is applied, do not remove the endoscope from the water bath for the remaining test time. Removing the endoscope and allowing it to cool outside the hot water bath can cause a pressure drop that may falsely trigger a leak indication.

Setting	Function	Explanation
Set leakper?	To specify the allowable threshold for a pressure drop during testing.	Set the leak percentage for: ▶ Large Endoscopes ▶ Small Endoscopes The leak percentage threshold can be set between 1% and 9%. It determines the allowable decrease in internal air pressure before a leak is detected. **NOTICE** The recommended default setting is 4. When set too low, false positives can be detected, resulting in unnecessary delays. When set too high, false negatives could occur, which can cause further damage to the endoscope.
Set scanner?	To define the requirements for scanning datamatrix quick scan codes before testing an endoscope.	The requirements can be set for Endoscope Scanning and Employee ID Scanning. Possible settings: Off: Scanning is not possible. Voluntary: Scanning is possible but not mandatory. Required: Scanning is mandatory. **NOTICE** To be able to use the quick scan menu codes to access menu items, do not set both Endoscope scanning and Employee ID Scanning to Off/
Set language?	To set the language of the interface.	Select your preferred language from the available options.
Set unit?	To set the unit of measurement	Select the preferred unit of measurement: Mbar, kPa, psi or mmHg.

Setting	Function	Explanation
End calibration?	To set the preferred behavior after selecting End calibration? In the calibration menu.	Set to Continue boot: to restart the device. Cycle back: to go back to the first menu option.

5. Operation

⚠️	**Always follow the intended use and operational guidelines. This ensures that the LeakControl system operates effectively and provides accurate and reliable measurements.**

5.1 Connecting and Operating

1. Make sure the **LeakControl** and, optionally, a supported data matrix scanner, such as a **DoviScan**, are installed. See *4.1.2 Installing the LeakControl*.
   - ▶ During startup, the LeakControl shows the current test settings:
     - ▶ The set test duration
     - ▶ The status of the water bath
     - ▶ The allowable error margin for testing
     - ▶ The software version.

     NOTICE The startup could take a minute or longer if the power was fully disconnected.
   - ▶ The **status indicator** flashes quickly in yellow if an endoscope is connected and it causes a positive pressure. In this case, you will be asked to press the **stop button**.
   - ▶ The **status indicator** is green if no errors occur.

     The system is prepared for operation.
2. Connect the **tube connector** to the scope.
3. Use the scanner to scan a data matrix code. *NOTICE* This step is only needed if `Scan endoscope data matrix` is set to `Voluntary` or `Required`. See *4.3.2 Adjusting the LeakControl Settings*.
4. Press the **start button**.
   - ▶ The **status indicator** is yellow.
   - ▶ The **display** shows `Pressurizing:`. The built-in compressor pressurizes the endoscope and stops at approximately 220 mbar, as indicated by the progress bar.
   - ▶ The **display** shows `Stabilizing` after a normal pressurization cycle. The LeakControl checks if a pressure drop occurs.

⚠️ **NOTICE! Check the error message(s) before putting the endoscope in the water bath.**

29.

⚠ **IMPORTANT! Always pressurize the endoscope before entering into the water bath.**

Possible error messages:

Message	Meaning
Pump-up timeout	This error will appear if the inflation of the endoscope takes too long. Check all connections and confirm that the endoscope has been connected correctly.
Pump time short	This error message appears if there is a blockage in the endoscope air connector. Check the endoscope air connector. In case of an older Olympus endoscope, check the filter in the air connector. If it gets wet it also blocks airflow.

Pressure drop compensation
A pressure drop could be caused by an internal endoscope air resistance. The LeakControl will compensate for this pressure drop during the test. The pressure drop compensation has the following steps:

1. During pressure drop compensation,
   ▶ The **display** shows Compensate X to indicate the current compensation attempt. *NOTICE* It can take a maximum of 4 attempts.
   ▶ The **display** shows the progress bar to indicate the internal pressure of the endoscope.
2. After the pressure drop compensation attempts are done, the LeakControl stabilizes the internal pressure of the endoscope.
   The **display** shows `Stabilizing`.
   The **display** shows `Press XXX mb` to indicate the actual endoscope inflation pressure.
3. After the stabilizing, the display shows the final pressure for measuring the pressure drop because of the leakage.
   ▶ The **display** shows `Stable at:`
   ▶ The **display** shows `Press: XXX mb`
4. The LeakControl starts to continuously measure the internal pressure for the time chosen in the settings.
   ▶ The **display** shows `**Measuring**` with a progress bar and the remaining time in seconds.
   ▶ The **status indicator** slowly flashes yellow during the measurement.

5. Depending on the protocol, the endoscope can now be placed in the disinfection bath. **NOTICE** In the event of a leakage, LeakControl tries to keep the endoscope under pressure.
6. Depending on the condition of the endoscope, one of two results is possible: No leakage detected (see 5.2) or Leakage detected (see 5.3).

5.2   No Leakage Detected

If no leakage is detected:
▶ The **status indicator** slowly flashes green.
▶ The **display** shows `Measuring done.`
▶ The **display** shows `Scope PASS.`
▶ The **display** shows `NO leakage.`
▶ The **display** shows `Press STOP.`

Note that during this period, the endoscope remains pressurized. If no leakage is detected:

1. Lift the endoscope from the disinfection bath (if the endoscope is submerged).
2. Press the **stop button**.
   ▶ The endoscope will now deflate. Depending on the endoscope size and resistance, this takes a couple of seconds.
   ▶ The **display** shows `Busy with deflating!!`
   ▶ The **display** shows `Press XXX mbar.`
   ▶ The **status indicator** turns yellow during deflation.
3. Disconnect the **endoscope connector** from the endoscope.

The **status indicator** turns green, and the LeakControl has completed the test cycle. It is ready to test the next endoscope.

5.3   Leakage Detected

⚠️	*NOTICE* **When the endoscope is submerged into a hot water bath, and the pressure drop compensation is applied, do not remove the endoscope from the water bath for the remaining test time. Removing the endoscope and allowing it to cool outside the hot water bath can cause a pressure drop that may falsely trigger a leak indication.**

If a leakage is detected:
- ▶ The **status indicator** slowly flashes red.
- ▶ The **display** shows `Leakage.`
- ▶ The **display** shows `Check scope!!`

1. Immediately lift the endoscope from the disinfection bath if it is submerged.
   - ▶ In case of a leakage, LeakControl tries to keep the endoscope pressurized to avoid moisture and liquid from entering the scope. If pressure falls below a threshold of 50 mbar, it will repressurize. Canceling the repressurization when the endoscope is submerged allows moisture and liquid to enter the scope, causing damage.
   - ▶ During this stage, the compressor repeatedly switches on and off. This is normal behavior.
2. Press the **stop button**.
   - ▶ The endoscope will now deflate. Depending on the endoscope's size and resistance, this takes a couple of seconds.
   - ▶ The **display** shows `Busy with deflating!!`
   - ▶ The **display** shows `Press XXX mbar.`
   - ▶ The **status indicator** turns yellow during deflation.
3. Check the endoscope connections.
   - ▶ If there are no errors relating to the endoscope connections, the endoscope has a leakage.

The **status indicator** turns green, and the LeakControl has completed the test cycle. It is ready to test the next scope.

⚠️ **IMPORTANT! Do not place the endoscope in a disinfection machine. Send it in for repairs. Respect contamination procedures!**

6. Maintenance and Cleaning

⚠ WARNING

▶ **Read and understand the safety instructions in the chapter SAFETY.**

▶ **Unplug all connections before cleaning the product. Do not use wipes or chemicals, as these could damage the surface. Wipe the housing with a damp cloth. Electrical/electronic parts shall not be cleaned.**

▶ **Maintenance and cleaning should be done frequently. If there is any visible damage, a strong odor, or an excessive overheating of components, stop using the product.**

▶ **LeakControl is assembled with great care. Periodic maintenance and proper device use will extend its accuracy and lifespan.**

▶ **Calibration and or repairs shall only be made by qualified personnel.**

▶ **The end user can do all maintenance and inspection work described in these user instructions unless clearly indicated otherwise.**

▶ **Use only original accessories and spare parts.**

6.1 Annual Checkup

The LeakControl must be serviced, at a minimum, one time per year by the manufacturer, distributor, or an authorized representative. For contact information, see *1.6 Service*.

The annual checkup consists of:

▶ An inspection for any visual damage to the power adapter, the power supply cable, and the **power inlet** of the device.

▶ A verification of the pressure sensor reading.

▶ An internal leak test.

▶ A check of the safety features such as:

    ▶ The overpressure valve functionality (safety relief valve)

    ▶ The minimum water bath pressure to prevent water ingress.

6.2 Cleaning

⚠ WARNING

▶ **Do not use any organic solvents, detergent agents, cleaning alcohol, or aerosols. These can damage LeakControl.**

▶ **Avoid the use of liquids. There is no moisture seal between the metal exterior and the electrical components of LeakControl.**

The recommended frequency of cleaning LeakControl is one time per month or when necessary.

To clean the white and gray cover parts of LeakControl, use a clean, dry cloth to wipe the outer casing. Use disinfectant on a clean cloth when necessary.

6.3 Recalibrating the LeakControl

NOTICE

▶ **Recalibration is necessary when the endoscope connection tube is replaced or shortened in length.**

▶ **Full Calibration and Sensor Calibration shall only be done by qualified service personnel. Be careful when accessing these menu options. If entered accidentally, exit by pressing the reset button. Pressing the start button could cause calibration values to be overwritten. This requires service by qualified personnel to resolve.**

▶ **If an issue arises during the calibration steps, press the reset button and repeat the procedure.**

To recalibrate the LeakControl in case the endoscope connection tube is replaced or shortened in length:

▶ **Follow the instructions in** *4.3.1 Calibrating the LeakControl*.

7. Troubleshooting

7.1 How to Identify and Solve Problems

⚠ WARNING

▶ Read and understand the safety instructions in the chapter *Safety*.
▶ Only qualified, certified personnel shall repair, disassemble, or discard the appliance.
▶ Alterations to the product and technical modifications are not permitted without written permission of the manufacturer.
▶ Do not try to repair the product yourself. Contact the manufacturer if the product is not functioning correctly.

Issue	Cause	Solution
Calibration fault	Wrong or incomplete sensor calibration procedure.	Repeat the sensor calibration steps.
Zero pressure offset	Wrong or incomplete sensor calibration procedure.	Contact manufacturer.
	Defective pressure sensor.	If the error persists, send in for repair.
LeakControl does not turn on.	No power.	Check if the power cord and a 115-240VDC power outlet are plugged into the machine.
LeakControl does not reset after a test cycle.		Turn LeakControl off, wait a few seconds, then turn it back on. If the problem persists, contact the manufacturer.
DoviScan does not read the scope's UDI.		Let Dovideq check if the DoviScan is set to the correct language.

Issue	Cause	Solution
No internet connection found.	LeakControl is unable to connect to the EndoscopeManager database.	Check if the Ethernet cable is plugged in correctly.
		Check if the Ethernet cable is damaged or broken.
		Check if the IT network is correctly set.

For more information and support, see https://expertise.dovideqmedical.com.

If none of the suggested solutions solve your issue, or if a persistent error is found that is not on the troubleshooting list, please email Dovideq Medical Systems at service@dovideqmedical.com.

8. Disposal

⚠ WARNING

▶ **Read and understand the safety instructions in the chapter *Safety*.**
▶ **Disconnect the appliance from the power supply when you repair, disassemble, or discard the appliance.**

8.1 Disposal of Electronic Components

The symbol on the product, the accessories, or the packaging indicates that this device must not be treated as unsorted municipal waste but must be collected separately. Dispose of the device via a collection point for recycling electrical and electronic equipment waste if you live within the EU and in other European countries that operate separate collection systems for electrical and electronic waste. By properly disposing of the device, you help avoid possible environmental and public health hazards that could otherwise be caused by improper treatment of waste equipment. The recycling of materials contributes to the conservation of natural resources.

8.2 Disposal of Packaging Waste

The packaging is made of environmentally friendly materials, which may be disposed of through your local recycling facilities. Disposing of the packaging and packaging waste properly helps avoid environmental and public health hazards. The symbol on the packaging indicates that the packaging is made of PAP.

9.　Accessories

NOTICE

▶ **Use only original accessories and spare parts.**
▶ **Use the product, accessories, tools, software, etc., in accordance with these instructions, taking into account the working conditions and the work to be done. Using the product for operations different from those intended could result in a hazardous situation.**

9.1　Compatible Scanners

To improve operational efficiency and maintain effective traceability, the following scanners are officially supported for use with the Dovideq LeakControl: DoviSCAN, DoviSCAN 2024, DoviREAD, Newland TYPE, and Honeywell.

9.2　Compatible Printers

The print test results, the following printers are officially supported for use with the Dovideq LeakControl: Aimo D520, Dymo 450 Turbo, and Dymo 550.

9.3　Spare Parts

Order spare parts by sending an email to service@dovideqmedical.com.

Part name	Part number
Anti Slip Rubber Feet Set	PROD0220
Front panel CPC O-ring (5 pcs)	PROD0042
Micro USB Cable (1 meter)	PROD0028
Cat 5e Network Cable (3 meter)	PROD0038
Power Adapter	PROD0025
Power Adapter C13 to Regional EU Plug	PROD0039
Power Adapter C13 to Regional UK Plug	PROD0040

| Power Adapter C13 to Regional USA/Japanese Plug | PROD0041 |

10. Appendix

A   Quick scan menu codes

NOTICE

Overview of the data matrix quick scan codes to enter setup menu items directly.
For these quick scan codes to work, make sure that endoscope and employee scan requirements are not both set to off. Otherwise, these quick scan codes are not accepted as input by the LeakControl.

Quick scan code	Menu item	Task
	Setup menu	To enter the setup menu of the LeakControl.
Calibration menu quick scan codes		
	Calibrate vol?	To enter the volume calibration menu.
Settings menu quick scan codes		
	Set meastime	To set the measuring time
	set w.bath det.?	To increase the measurement accuracy.
	Set leakper?	To set the allowable pressure drop threshold during testing.

Quick scan code	Menu item	Task
	Set scanner?	To define the requirements for scanning before doing a test.
	Set language	To set the interface language
	Set unit?	To select the desired units.