Gina

Neonatal Active Lung Model

Operating instructions
Foreword

These operating instructions are intended to inform the operator on how to use the Gina. They do not contain any information on how to carry out repair work or service the machine. As a general rule, only the manufacturer or authorised representatives are permitted to carry out this type of work.

The manufacturer can only guarantee the functionality and safety of the device as long as it is operated in accordance with the operating instructions.

These operating instructions are considered part of the device and must always be accessible to the operator, either in paper form or as a file on the target computer.

Each operator must read the safety instructions before use without exception.

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1 Intended use

The Neonatal Active Lung Model (NALM), also called Gina, serves the purpose of simulating the behavior of a homogenous infant’s lung in conjunction with a ventilator.

Taking a flight simulator as an analogy, i.e. the pilot uses a physical model of the plane to learn how to fly in a way that is safe, the doctor can use a lung simulator, which simulates the breathing mechanism of an infant as a physical model, to learn how to ventilate infants.

Gina was designed with the following target groups in mind:

- Medical staff who are to be trained in ventilation
- The ventilator manufacturing industry
- Researchers in clinical ventilation

Gina consists of two components: the electromagnetic lung model itself, hereinafter referred to as the “lung model,” and a software package which is to be installed on a laptop or PC.

The volume flows, volumes and pressures which are produced are measured and depicted on the graphic user interface (GUI) on the PC/laptop.

The lung model is connected pneumatically to the ventilator via the breathing tubes and Y piece. Gina enables the simulation of different breathing mechanism parameters such as different ventilation tubes and different airway resistances, and features an internal compliance which is adjustable using software. Additionally, an external compliance with a defined P-V characteristic curve may be attached. Gina also enables the simulation of the patient’s spontaneous breathing.

**NOTE** Gina is not considered a medical device in terms of the German medical products law.
2 Safety Instructions

2.1 Meaning
The following safety instructions must be observed at all times and must be read through before initial operation of the device.
The first table describes what the pictograms mean.

<table>
<thead>
<tr>
<th>Safety Instruction</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Danger</strong></td>
<td>This symbol identifies a state in which the device could pose a danger to life and limb of the operator or another person.</td>
</tr>
<tr>
<td><strong>Warning</strong></td>
<td>This symbol identifies a state which could lead to an operational error or the destruction of the device.</td>
</tr>
<tr>
<td><strong>Caution</strong></td>
<td>This symbol identifies a state which could lead to device malfunction.</td>
</tr>
<tr>
<td><strong>Note</strong></td>
<td>This symbol identifies additional information which is intended to make operating the device easier and help to avoid problems while operating it.</td>
</tr>
</tbody>
</table>

2.2 Safety instructions:

- **DANGER**: Gina is a lung simulator and is not a ventilator. It should not be connected to a patient’s respiratory system with tubes under any circumstances.

- **DANGER**: The ventilator which is to be connected to Gina must be disinfected and sterilised before each use, without exception, so that the patient’s germs cannot be transferred through the opening of the device.

- **WARNING**: Observe the instructions in the event that the temperature of the voice coil motor (VCM) exceeds its limit. The instructions must be observed when it is activated. Otherwise, the device may no longer be operated, as the driving coil could become overheated.

- **WARNING**: The device must always be operated under close supervision, particularly when the switch With Cex VcmON has been switched on. In this case, the plugs situated on the reverse side of the device must be pulled out immediately!

- **WARNING**: Gina is not a medical product and may not be operated in a patient’s surroundings.

- **WARNING**: The breathing gas may not be allowed to condense at ambient temperature. Any respiratory gas humidifiers within the breathing circuit must be switched off without exception.
CAUTION: The responsible operator (i.e. the senior physician) must become well-acquainted with the content of the operating instructions to the extent that they are able to instruct less-qualified operators in operating the device.

CAUTION: The device must be operated in a dust-free environment and may only be used with medical respiratory gas or dust-free ambient air. If necessary, a bacteria filter should be provided on the patient outlet.

CAUTION: The device must never be switched on directly after it has been brought from a cold to a warm room. The condensation which forms as a result of this could destroy the device. Allow the device to reach room temperature after it has been switched off.

CAUTION: Before storing the lung model in the device case, the compliance switch must be switched to the Cex position.

CAUTION: Before initial operation on the designated PC/laptop, after switching on the device and starting the GUI, the serial no. stated on the reverse side of the device must be entered under “options when using the software for the first time.

CAUTION: The TeamViewer program must be installed on the PC/laptop by the operator for servicing purposes and so that the manufacturer may access the PC/laptop using this program. In this case the PC/laptop will require internet access. Access to the computer using TeamViewer must not be inhibited by a Firewall!

This is a prerequisite for the manufacturer’s guarantee.

CAUTION: The screen should have a vertical resolution of 768 dpi. Otherwise, geometrical distortions may arise on the operating elements arranged on the graphic user interface.

CAUTION: Be careful with the device. It may be damaged by impacts, shocks or falls from a low height.

CAUTION: Ensure that the sealing plugs on the top, reverse side and bottom of the device are always reinserted after removing them for functional purposes.

NOTE: The PC or laptop is not included in the scope of delivery. This must be provided by the operator.

NOTE: We recommend that you always insert the USB cable into the same USB port of the PC/laptop so that the same ComPort is always requested.

NOTE: If you hover the mouse over an operating element, a note on its function will appear for most operating elements.

NOTE: The unit for pressure “hPa” has been chosen for this instruction manual. This unit is the appropriate SI unit. It is identical in value to the unit “mbar.”
3 General information

3.1 Requirements for use
Setting up and operating the device may only be undertaken by an individual who possesses the appropriate level of knowledge to do so.

An in-depth understanding of these operating instructions is required, as operating errors can lead to device failure.

These operating instructions should always be available either in paper form or as a file on the target computer.

Warranty claims which arise due to improper use of the device will not be recognised by the manufacturer.

The manufacturer can only guarantee the safety and reliability of the device if it is operated in accordance with these operating instructions.

3.2 Device combinations
Gina may be combined with all ventilators which are authorised for use on babies and infants. In doing so, it must be noted that Gina may exert negative pressures of up to 40 hPa on the ventilator during spontaneous breathing. The operator must ensure that the ventilator is not damaged in any way.

The maximum pressure exerted by the ventilator may not exceed a value of 60 hPa.

**NOTE**

Gina may only be operated using non-condensing respiratory gas. For this purpose, the ventilator’s respiratory gas humidifiers must either be removed or switched off.

The ventilator which is operated in conjunction with Gina must always be sterilised or disinfected before use in order to avoid the contamination of GINA.

3.3 Electrical safety and EMC

3.3.1 Electrical safety
Gina was developed in accordance with the low-voltage directive 2014/35/EU.

3.3.2 Electromagnetic Compatibility (EMC)
In terms of its EMC characteristics, Gina is categorized as a piece of electrical equipment for measurement, control and laboratory use.

Therefore, the EMC directives and DIN EN 61326-1 standard apply.

The relevant tests have been undertaken.
3.4 Materials used

<table>
<thead>
<tr>
<th>Assembly</th>
<th>Component</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device case</td>
<td>Polyethylene</td>
<td></td>
</tr>
<tr>
<td>Housing</td>
<td>AlMgSi0.5</td>
<td></td>
</tr>
<tr>
<td>Piston-cylinder system</td>
<td>Cylinder</td>
<td>Glass, graphite</td>
</tr>
<tr>
<td></td>
<td>VCM cover</td>
<td>St37</td>
</tr>
<tr>
<td></td>
<td>VCM magnet</td>
<td>Neodymium</td>
</tr>
<tr>
<td></td>
<td>VCM coil</td>
<td>Copper</td>
</tr>
<tr>
<td>Pneumatic switch</td>
<td>Housing</td>
<td>AlMgSi0.5</td>
</tr>
<tr>
<td></td>
<td>Piston</td>
<td>PEEK CA30</td>
</tr>
<tr>
<td></td>
<td>O-ring, X-ring</td>
<td>EPDM</td>
</tr>
<tr>
<td>Valve bank</td>
<td>Chock</td>
<td>AlMgSi0.5</td>
</tr>
<tr>
<td>Tubes</td>
<td>Silicone rubber, transparent</td>
<td></td>
</tr>
<tr>
<td>Endotracheal tubes</td>
<td>AlMgSi0.5</td>
<td></td>
</tr>
<tr>
<td>Airway resistances</td>
<td>Cannula tube</td>
<td>Rust-free stainless steel 1.4301</td>
</tr>
<tr>
<td>Pneumotachograph</td>
<td>Housing</td>
<td>POM</td>
</tr>
<tr>
<td></td>
<td>Tube bracket</td>
<td>PEEK</td>
</tr>
<tr>
<td></td>
<td>Tubes</td>
<td>Stainless steel 1.4301</td>
</tr>
<tr>
<td>Printed circuit boards</td>
<td>RoHS</td>
<td></td>
</tr>
</tbody>
</table>

3.5 Scope of delivery, packaging and transportation

3.5.1 Scope of delivery

Device case, containing

1. “Neonatal Active Lung Model Gina” device
2. Flask lung model 1000 ml
3. Flask lung model 500 ml
4. Silicone model lung
5. USB stick with device and driver software, as well as operating instructions
6. Power cable
7. 2 connectors
8. Silicon tube 10 cm
9. USB cable

The PC or laptop is not included in the scope of delivery. It must be provided by the operator.
3.5.2 Packaging

The device is stored in the device case with all accessories listed under Point 3.5.1.

Items 4 to 8 are arranged in an infill as depicted in the diagram.
3.5.3 Transportation
Always ensure that Gina is transported in its protective case and, when in a vehicle, is safely secured to avoid potential impact damage due to sudden braking.

The same applies to transportation on an airplane if it is to be carried as hand luggage.

If it is to be packed in the luggage, the device case must be secured sufficiently against vibrations using the appropriate padding material and by packing it in an extra layer of packaging.

**NOTE**
Ensure that the compliance switch is switched to the **Cex position**.

3.6 Support, maintenance and repair work
If any problems relating to the device or its operation arise, the manufacturer must be notified.

If the problem cannot be resolved over the telephone, troubleshooting is undertaken by the manufacturer using the program **TeamViewer x**.

For this purpose, the operator is to connect to the internet and download TeamViewer for free on the computer connected to the lung model. ([www.teamviewer.com/de/download/](http://www.teamviewer.com/de/download/)).

Afterwards, troubleshooting is carried out by the manufacturer through TeamViewer.

If the error is not resolved, the user must return the device to the manufacturer packaged appropriately, using sufficient and suitable protective material around the device case to protect it from impacts and vibration. The provision of appropriate packaging is the responsibility of the sender.

If the error occurs during the warranty period, the transportation costs are borne by the manufacturer.

Maintenance and repair work will be undertaken by the manufacturer after the warranty period expires, however, this will be subject to a charge.

**NOTE**
Ensure that the compliance switch is in the Cex position.

3.7 Disposal

**Disposal of delivery packaging**
Outer packaging and film materials are made from a recyclable material which may be disposed of easily and in a conventional manner.

**Disposal of the device**
The device does not contain any batteries or accumulators.

The company Dr. Schaller Medizintechnik guarantees that they will accept and dispose of the device for free, whereby the transportation costs to send the device to the manufacturer must be borne by the customer.

The device may also be disposed of professionally by a certified electronic waste recycling center.

3.8 Warranty
Dr. Schaller Medizintechnik guarantees a 12 month warranty which is valid from the delivery date onwards.

Any defects which arise within this period of time will be repaired by the manufacturer at their own cost. Transportation costs are also included in this.

The prerequisite for this is

- that the device is operated correctly in accordance with the operating instructions,
- and that the manufacturer can access the operator’s PC/laptop with the Gina program on it using the TeamViewer program.

The warranty claim is invalidated if the device is tampered with by the user.
### 3.9 Abbreviations and specialist terminology

All abbreviations used while operating the Gina will be subsequently explained.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Specialist term</th>
<th>Meaning</th>
<th>Explanation</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>#breath</td>
<td>number of breaths</td>
<td>Number of breaths, after which a sigh is initiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AlvVent</td>
<td>Alveolar ventilation</td>
<td>Alveolar ventilation</td>
<td>l/min</td>
<td></td>
</tr>
<tr>
<td>Apnea</td>
<td>Function group for all parameters required for apnea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breathing</td>
<td>Function group for all parameters required for breathing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Compliance</td>
<td>Lung elasticity</td>
<td>ml/hPa</td>
<td></td>
</tr>
<tr>
<td>Ccv</td>
<td>Compressible volume</td>
<td>Compliance of the device due to compressible volume</td>
<td>ml/hPa</td>
<td></td>
</tr>
<tr>
<td>Cex</td>
<td>External compliance</td>
<td>External compliance may be attached to the lung model, consists of a flask filled with steel wool</td>
<td>ml/hPa</td>
<td></td>
</tr>
<tr>
<td>Cex+s. B.</td>
<td>Ext. Compl+ Spontan-Breathing</td>
<td>External compliance is attached, but it is ventilated by the piston-cylinder system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chann.</td>
<td>Channels</td>
<td>Settings tab for all parameters required for the data channels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ChX</td>
<td>Channel X</td>
<td>8. 8th channel for the graphic display. Different signals may be assigned to this using a selection switch.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cint</td>
<td>Internal compliance</td>
<td>Compliance generated within the device by the piston-cylinder system</td>
<td>ml/hPa</td>
<td></td>
</tr>
<tr>
<td>clock/ms</td>
<td>Timing cycle</td>
<td>Timing cycle for the PC program</td>
<td>ms</td>
<td></td>
</tr>
<tr>
<td>Copy</td>
<td>Copy</td>
<td>Copy button which initiates copying the graphic display to the clipboard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dtaApn%</td>
<td>max. modification of all apnea parameters set in RANDOM mode</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dtaFrequ%</td>
<td>max. modification of the frequency in RANDOM mode</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dtaPrm%</td>
<td>max. modification of Prm in RANDOM mode</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dtaTins%</td>
<td>max. modification of Tins in RANDOM mode</td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eff</td>
<td>Effective value</td>
<td>Effective value of a signal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exit</td>
<td>Exit</td>
<td>Exit button which initiates closing the program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F. Thr.</td>
<td>Flow threshold</td>
<td>Flow threshold for differentiating inspiration and expiration</td>
<td>l/min</td>
<td></td>
</tr>
<tr>
<td>Fbw</td>
<td>Bandwidth</td>
<td>Bandwidth for the band-pass filter and band-stop filter</td>
<td>Hz</td>
<td></td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
<td>Details</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td>--------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fc</td>
<td>Cutoff frequency</td>
<td>Threshold frequency for the high-pass and low-pass filter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiO2</td>
<td>Oxygen fraction</td>
<td>Oxygen concentration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow</td>
<td>Flow</td>
<td>Volume flow at the device inlet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fmb</td>
<td>Mid-band frequency</td>
<td>Mid-band frequency in band-pass and band-stop filters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRC</td>
<td>Functional residual capacity</td>
<td>Functional residual capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freeze x</td>
<td>Freeze</td>
<td>Freeze the graphic display in the x-y graph</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequ</td>
<td>Frequency</td>
<td>Spontaneous breathing frequency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hPa</td>
<td>hectoPascal</td>
<td>Pressure unit 100 Pa or 1 hPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kex</td>
<td>Transmission factor for external channels</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KPrm</td>
<td></td>
<td>Factor used to multiply Prm during a sigh, relative to its setting value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ktins</td>
<td></td>
<td>Factor used to multiply Tins during a sigh, relative to its setting value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCS</td>
<td>Piston-cylinder system</td>
<td>Piston-cylinder system is the basis for compliance and respiratory musculature simulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Log</td>
<td>Data logging</td>
<td>Setting tab for setting all parameters required for data logging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MinVent</td>
<td>Minute ventilation</td>
<td>Minute ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OFF</td>
<td></td>
<td>Switch-off mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opt.</td>
<td></td>
<td>Tab for setting all optional parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2P</td>
<td>Peak to Peak</td>
<td>Peak to peak value of a signal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palv</td>
<td>Pressure in the alveolus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patm</td>
<td>Atmospheric pressure</td>
<td>Atmospheric air pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pCO2ex</td>
<td>End expiratory CO2</td>
<td>End expiratory CO2 partial pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pCO2ins</td>
<td>End inspiratory CO2</td>
<td>End inspiratory CO2 partial pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Petr</td>
<td>Endotracheal pressure</td>
<td>Pressure between the end of the ventilation tube and start of the airway resistance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PNT</td>
<td>Pneumotach</td>
<td>Volume flow sensor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pref</td>
<td>Reference Pressure</td>
<td>Reference pressure for determining respiration work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prm</td>
<td>Pressure of respiratory muscles</td>
<td>Pressure supplied by respiratory musculature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Py</td>
<td>Pressure at the Y piece</td>
<td>The pressure sensor for Py has two inputs (+ and -). Using these, the differential pressure, for example, may also be measured with an applicator.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14 Instruction manual Gina V3.0
<table>
<thead>
<tr>
<th>Random</th>
<th>Function group for all parameters required to vary breathing parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reff</td>
<td>Average resistance which is calculated using the effective values</td>
</tr>
<tr>
<td></td>
<td>hPa*s/l</td>
</tr>
<tr>
<td>resp. M.</td>
<td>Tab for setting breathing mechanism parameters</td>
</tr>
<tr>
<td>rH</td>
<td>Relative humidity</td>
</tr>
<tr>
<td>RQ</td>
<td>Respiratory quotient</td>
</tr>
<tr>
<td>Scale</td>
<td>Scale the graphic display</td>
</tr>
<tr>
<td>Sigh</td>
<td>Function group for all parameters required for the sigh</td>
</tr>
<tr>
<td>SN#</td>
<td>Serial number which is stated on the reverse side of the device</td>
</tr>
<tr>
<td>Spec.</td>
<td>Tab for setting all parameters required for special functions</td>
</tr>
<tr>
<td>Start</td>
<td>Start button which initiates the program</td>
</tr>
<tr>
<td>Tapn</td>
<td>Time for apnea during the apnea phase</td>
</tr>
<tr>
<td>tau_e</td>
<td>Exsp. Time constants for all patterns</td>
</tr>
<tr>
<td>tau_i</td>
<td>Insp. Time constants for rectangular pattern</td>
</tr>
<tr>
<td>Tbr</td>
<td>Time for breathing during the apnea phase</td>
</tr>
<tr>
<td>TewEff</td>
<td>Evaluation window for determining an effective value</td>
</tr>
<tr>
<td>TewP2P</td>
<td>Evaluation window for determining a peak to peak value</td>
</tr>
<tr>
<td>Tins</td>
<td>Inspiration time</td>
</tr>
<tr>
<td>Tta2b</td>
<td>Transition time from apnea to breathing</td>
</tr>
<tr>
<td>Ttb2a</td>
<td>Transition time from breathing to apnea</td>
</tr>
<tr>
<td>Uex0</td>
<td>Offset-value for external channels</td>
</tr>
<tr>
<td>V'</td>
<td>Volume flow</td>
</tr>
<tr>
<td>V'd</td>
<td>Volume flow at which the non-linear resistance of the pressure drop is</td>
</tr>
<tr>
<td></td>
<td>twice as high as that of a low flow</td>
</tr>
<tr>
<td>V</td>
<td>Volume</td>
</tr>
<tr>
<td>VCM</td>
<td>Piston drive in the piston-cylinder system</td>
</tr>
<tr>
<td>V'CO2</td>
<td>Body's CO2 production</td>
</tr>
<tr>
<td>Vdead</td>
<td>Anatomical dead space</td>
</tr>
<tr>
<td>Vol</td>
<td>Piston-cylinder system volume</td>
</tr>
<tr>
<td>Vtid</td>
<td>Volume calculated from the flow through integration</td>
</tr>
<tr>
<td></td>
<td>ml</td>
</tr>
</tbody>
</table>

Instruction manual Gina V3.0
4 Gina’s operating principle

Gina was developed to provide the doctor or developer with a tool with highly variable settings to safely test ventilators for infant use.

Gina is designed to effectively simulate the breathing mechanism of an infant and thus has breathing tubes, airway resistances, a lung compliance and a respiratory drive.

All these elements and functions are realized as physical elements, and therefore act in the same way as real pneumatic resistances, a real lung compliance and a real respiratory drive.

The volume flows, volumes and pressures which arise intrapulmonary and extrapulmonary are measured and represented numerically as well as graphically.

Gina consists of two components:

- a physical lung model, hereinafter referred to as the “lung model” and
- a graphic operator interface, hereinafter referred to as the “GUI” (Graphical User Interface).

The lung model contains all mechanical, pneumatic and electronic components which are required to physically simulate an infant’s lungs.

In addition, it contains the following: sensors for measuring the volume flow, which are used to determine the volume through integration; position sensors which enable the immediate determination of the piston-cylinder volume, and pressure sensors.

The GUI originates from a program which is installed on a PC or laptop which has been written in the language LabVIEW. This program undertakes all necessary calculations, displays, graphic representations, data storage as well as communication with the lung model through a USB interface.

The following diagram demonstrates this principle.

Any ventilator may be connected to Gina’s pneumatic input via its breathing tubes. The Gina may be connected to the PC which contains the GUI software with a USB cable.
5 Lung model

5.1 Operating principle
The following diagram displays the lung model’s operating principle.

![Diagram of lung model](image)

Figure 5-1: Schematic representation of the lung model

The air flows from the input connector through the volume flow sensor to the switchable tube resistances $R_t$ for pneumatic switch S1 (in the block diagram this tube resistance modification option is identified by an arrow). There is a branch to the leakage valve and to the airway resistances at its outlet. The outlet of the leakage valve leads to a Luer-Lock connection at which a leakage resistance may be connected.

The sizes of the airway resistances $R_a$ are also selectable using pneumatic switch S2. The air flows from the outlet of the airway resistances through the pneumatic switch S3 either to the variable internal compliance $C_{int}$ or the fixed external compliance $C_{ex}$.

All three pneumatic switches, S1, S2 and S3, are operated by hand.

Operation shall be described in more detail as follows.

The tube resistance $R_t$ is realised by the endotracheal tubes in different diameters (2.0mm, 2.5 mm, 3.0 mm and 5.0 mm). Each tube may be selected using the switch S1. The 5.0 mm tube may be used immediately to simulate non-invasive ventilation.

The airway resistance $R_a$ is generated by multiple stainless steel tubes arranged in parallel. The resistance becomes more linear compared to the tube resistance and less dependent on the flow through the parallel connection. Four different airway resistances may be selected using the switch S2.

Compliance is created by either an internal compliance $C_{int}$ in the form of a moving piston within a cylinder or an external compliance $C_{ex}$ with a defined volume.

The drive of the Cint piston is effected through the voice coil motor (VCM).

The internal compliance $C_{int}$ is generated by the VCM developing a proportional counterforce to the cylinder volume which is settable and controlled through a microcontroller.
The **external compliance Cex**, which is supplied as a wide-neck flask filled with steel wool with the greatest possible isothermal behavior, has a 15 mm male tapered connector. It is inserted into a 15 mm female tapered connector situated on the top of the device. There are two flasks with volumes of 500 ml and 1000 ml respectively.

In addition, there is a silicone bellows lung with a compliance of approx. 1ml/hPa which may also be attached to the female tapered connector to act as an external compliance.

The shift between the external compliance on the one hand and the Cint on the other occurs using the switch S3.

The switch S3 for the compliance has three switching positions. In switching position 1 the internal compliance is activated and in the switching positions 2 and 3 the external compliance Cex is activated. In switching position 2 additional air may be supplied through flow resistance R1 from the internal compliance to the external compliance. As a result, a spontaneously breathing patient with a defined Cex compliance is simulated.

The **pressure source Prm (respiratory muscles)** simulates the spontaneous breathing activity of the patient. The piston within the cylinder is moved and generates a volume-specific shift in doing so.

A **magnetic valve (MV)** is located at the transition point between Rt and Ra which leads to the outside through a Luer-Lock connection. A Luer-Lock reverse tap attached to this enables setting the leakage resistance Rl.

The magnet valve (MV) is switched on and off using the software.

The following **physical quantities** are measured:

- **Py**   Pressure at the Y piece
- **Petr** endotracheal pressure at the end of the “trachea,” i.e. between Rt and Ra
- **Palv** Pressure in the “alveolus,” i.e. the pressure immediately before the respective active compliance
- **Flow** Volume flow into the lung model
- **Vlung** Cylinder volume

The **ventilator connection**, usually the Y piece, or the pneumotachograph belonging to it, are attached to the 15 mm tapered connector of the lung model, whereby the lung model and ventilator are connected to one another pneumatically.

Additionally, the **pressure measuring outlet on the Y piece and the pressure measuring inlet Py** on the lung model must be connected to each other with a short tube.

The **volume flow is measured** through a pneumatic resistance element (pneumotachograph) which generates a differential pressure which is proportional to the volume flow to the greatest possible extent.

The respective sensors measure this differential pressure and other pressures. A micro-controller undertakes signal processing.

Valves (V1 to V4) are located between the measurement points for the respective pressures and the corresponding sensors, which switch the sensor inlet to the atmosphere when switched on. It is in this way that zero-point calibration for the sensors is achieved.

**Controlling the lung model** as well as communication with the graphic user interface (GUI) on the PC/laptop occurs via a USB interface.
5.2 Resistance
The pressure drop through the endotracheal tube or respiratory system is non-linear. The same applies to its flow resistance. This is described by the following equation

\[ R = R_{lam} \left( 1 + \frac{V'}{V_d'} \right) \]  

with the double-resistance flow \( V'd \). The double-resistance flow \( V'd \) is the flow at which the resistance is twice as high as the laminar resistance dominating at low flow.

See Appendix 10.1

5.2.1 Tube resistance \( Rt \)
We get the following total flow characteristic curve for the breathing tubes

![Pressure flow characteristic curves](image)

Figure 5-2 Pressure flow characteristic curves of the tube resistance \( Rt1 \) (black) to \( Rt4 \) (red).

The resistance characteristic curve as a secant to the pressure flow curve passes through the zero point.
The resistance curves correspond relatively well to the theory. The resistance parameters for the individual tubes are

\[ R_{\text{lam}} = [6.8 \quad 10.4 \quad 30.5 \quad 80.1] \text{ in hPa/l/s} \]

\[ V'd = [2.6 \quad 2.9 \quad 3.0 \quad 2.6] \text{ in l/min} \]
5.2.2 Airway resistance $Ra$

The characteristic curves for the airway resistance are as follows:

![Pressure flow characteristic curve](image1)

**Figure 5-4:** Pressure flow characteristic curve of the airway resistance $Ra_1$ (black) to $Ra_4$ (red) within the lung model

![Resistance characteristic curve](image2)

**Figure 5-5:** Resistance characteristic curve of the airway resistance $Ra_1$ (black) to $Ra_4$ (red) within the lung model
The linear dependency of the total resistance on the volume flow is clearly visible. The decreasing curve proportion arises as a result of limiting the pressure sensor at 20 hPa.

We get the following parameters for the Raw:

\[
\begin{align*}
R_{\text{lam}} &= [26, 45, 84, 179] \\
V'd &= [13.5, 14, 13.7, 16]
\end{align*}
\]

You can see from the double-resistance flow \(V'd\), which is almost 5 times higher, that the airway resistance is significantly more linear than the tube resistance.

5.3 Compliance

5.3.1 Variable internal compliance

This is the compliance which is modifiable or variable using the program. It may be set between 0.3 ml/hPa and 3 ml/hPa.

5.3.2 External fixed volume compliance

The external compliances are plastic containers with an empty volume of 500 ml and 1114 ml respectively which are filled with steel wool and therefore display a practical isothermal behavior.

The isothermal compliance is calculated using

\[
C_{\text{iso}} \, \text{ml} / \text{mbar} = \frac{V}{P_{at}} = \frac{1087}{P_{at} / \text{mbar}}
\]

For high accuracy requirements, the exact compliance value must be calculated while factoring in the actual air pressure \(P_{at}\).

**For an air pressure of 1000 hPa** and for a 10,000 ml flask, we get

\[
C_{\text{iso}} = 1.1 \, \text{ml} / \text{mbar}
\]

However, the actual compliance is dependent on the frequency.

5.3.3 External bellows - compliance

A bellows compliance may also be attached to the upper connection for the external compliance.

This has a compliance of about 1ml/hPa.

5.3.4 Compressible volume

In addition to the previously mentioned compliance, the lung model features an unpreventable compressible volume which corresponds to an additional internal compliance of approx. 0.12 ml/hPa.
5.4 Operating elements of the lung model
The following diagram shows the front view of the lung model.
The front panel is divided into four parts.

Figure 5-6: Front view of the lung model
Section 1 consists of the ventilator connections. The Y piece or the PNT is attached to the 15 mm tapered connector on the ventilator.

Two hose connectors are located to the left of this which lead to the differential pressure sensor for the Y piece’s pressure. The connector projecting from the front panel is connected to the positive pressure measurement inlet and the connector situated behind the hole is connected to the negative pressure measurement inlet of the sensor. The latter is usually not connected. However, it may be used for differential pressure measurements within the range of the Y piece.

A Luer-Lock connection as an outlet for the leakage volume flow is situated to the right of the 15 mm tapered connector. A Luer-Lock reverse tap can be attached to this which may be used to set the leakage resistance.

Section 2 comprises of the compliance switch S3 with three switch settings:

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cint</td>
<td>The variable internal compliance is switched on</td>
</tr>
<tr>
<td>2</td>
<td>Cex+s. B.</td>
<td>The constant external compliance or bellow lung is switched on. Spontaneous breathing is possible.</td>
</tr>
<tr>
<td>3</td>
<td>Cex</td>
<td>The constant external compliance or bellow lung is switched on. Spontaneous breathing is not possible.</td>
</tr>
</tbody>
</table>

**WARNING** In the switch position 1, the sealing plugs must be inserted without fail and in the switch positions 2 and 3 the external compliance must be inserted into the 15 mm tapered connector.

Section 3 comprises of the resistance switches S1 and S2. The respective endotracheal tube (tube) may be selected using S1 and the respective airway resistance (Airways) may be selected using S2.

The airway resistance value is stated in the technical data. In the case of both switches, the resistance increases with a clockwise rotation.
Section 4 comprises of connections and indicators for communicating with the PC.

- The upper LEDs display the device’s on-position.
- Input for three analogous external signals.
- Reset button for the controller within the lung model.
- USB connection and indicator LED for connecting to the PC’s USB port
  (If the LED is red, the connection has been interrupted)
5.5 Connection for the external compliance
Gina has three different external compliances which may be inserted into the 15 mm tapered connector situated on the top of the device:

- Bellow compliance
- Flask compliance 500 ml
- Flask compliance 1000 ml

This tapered connector is normally sealed with a plug.

Figure 5-7: Lung model with three different external compliances

Figure 5-8: Front view with attached external compliance

**NOTE** Ensure that the plugs are always inserted while the internal compliance is in use.
5.6 Software
The lung model contains a controller which regulates internal processes and guarantees an informal connection to the laptop.

5.7 Operation
Operating the device on the lung model itself is carried out by setting the switches S1, S2 and S3 to select the size of the tube $R_t$, the airway resistance $R_a$ and type of compliance, as well as by using the graphic user interface on the computer.
6 Graphic user interface

6.1 General

The software for the graphic user interface (GUI) is generated by a program written in the programming language Labview which is installed on a PC or preferably a laptop.

The operator operates the device using the GUI.

The main screen of the GUI is depicted in Figure 4.1.

Figure 6-1: Graphic user interface of the lung model

The GUI is divided into two horizontal sections.

A tab menu is located in the section on the left where the lung model’s setting elements are divided into several tabs in which the setting elements for the lung model applied using the software are located.

The graphic display of measuring signals in the form of bar graphs, Y-T diagrams, X-Y graphs and a magnified, partial view of the Y-T diagram are located in the section on the right.

The start/stop, scaling, sensor offset, copy, freeze and exit menu buttons are located below the tab menu.

Four fields for notes and warnings are arranged in a row above the graphic display.

NOTE If you hover over an operating element with the mouse, a note on its function appears for most of the operating elements.
6.2 Tab menu

6.2.1 “Respiratory Mechanics” tab

The individual parameters for spontaneous breathing are set in the “respiratory mechanics” tab. It comprises of 8 function groups:

- Breathing
- Apnea
- Random
- Sigh
- Compliance/Resistance
- Leakage

![Image of the GUI](figure.png)

Figure 6-2: “Respiratory Mechanics” tab
“Breathing” function group
In this function group, all parameters which relate to the patient’s regular spontaneous breathing may be set.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prm shape</td>
<td>Selection switch for inspiratory breathing pattern</td>
<td></td>
</tr>
<tr>
<td>Square</td>
<td>Rectangular pattern</td>
<td></td>
</tr>
<tr>
<td>Cosine</td>
<td>Cosine pattern (0-90°)</td>
<td></td>
</tr>
<tr>
<td>Sine</td>
<td>Sine pattern (0-90°)</td>
<td></td>
</tr>
<tr>
<td>Linear</td>
<td>Linearly increasing pattern</td>
<td></td>
</tr>
<tr>
<td>Linear2</td>
<td>Linearly increasing and sloping pattern</td>
<td></td>
</tr>
<tr>
<td>Cosine2</td>
<td>Cosine-shaped increasing and sloping pattern</td>
<td></td>
</tr>
<tr>
<td>Freq</td>
<td>Spontaneous breathing frequency</td>
<td>1/min</td>
</tr>
<tr>
<td>Tins</td>
<td>Inspiration time</td>
<td>s</td>
</tr>
<tr>
<td>tau_i</td>
<td>Time constant for inspiration with rectangular pattern</td>
<td>ms</td>
</tr>
<tr>
<td>tau_e</td>
<td>Time constant for expiration</td>
<td>ms</td>
</tr>
<tr>
<td>Prm</td>
<td>Respiratory pressure amplitude (respiratory muscles)</td>
<td>hPa (hPa)</td>
</tr>
</tbody>
</table>

The patterns **Linear2** and **Cosine2** are intended for testing purposes.

**Apnea function group**

In this function group, all settings which relate to apneic periods within spontaneous breathing are applied.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>FF</td>
<td>On/off switch for switching on the apnea pattern</td>
<td></td>
</tr>
<tr>
<td>Tbr</td>
<td>Time for breathing</td>
<td>s</td>
</tr>
<tr>
<td>Tapn</td>
<td>Time for apnea</td>
<td>s</td>
</tr>
<tr>
<td>Tta2b</td>
<td>Transition time from breathing to apnea</td>
<td>s</td>
</tr>
<tr>
<td>Ttb2a</td>
<td>Transition time from apnea to breathing</td>
<td>s</td>
</tr>
</tbody>
</table>
Random function group

Using this function group, irregular spontaneous breathing may be simulated by varying all parameters arbitrarily, from breath to breath, within a maximum proportional deviation, positively and negatively.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFF</td>
<td>On/off switch for switching on the random function</td>
<td></td>
</tr>
<tr>
<td>ΔPrm%</td>
<td>Maximum Prm modification relative to the set value</td>
<td>%</td>
</tr>
<tr>
<td>ΔTins%</td>
<td>Maximum Tins modification relative to the set value</td>
<td>%</td>
</tr>
<tr>
<td>ΔFreq%</td>
<td>Maximum frequency modification relative to the set value</td>
<td>%</td>
</tr>
<tr>
<td>ΔApn%</td>
<td>Maximum modification of all apnea function parameters relative to the set value. In this case, each individual apnea parameter deviates individually</td>
<td>%</td>
</tr>
</tbody>
</table>

Sigh function group

This function group enables simulation of the patient’s sigh

A setting of #breath=6 and KPrm=1.6 and KTins=1.2 would mean that after every sixth spontaneous breath, a sigh with 160% of the set breath depth and 120% of the set inspiration period is carried out.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFF</td>
<td>On/off switch for switching on the sigh function</td>
<td></td>
</tr>
<tr>
<td>#breath</td>
<td>Number of breaths after which a sigh is initiated</td>
<td></td>
</tr>
<tr>
<td>KPrm</td>
<td>Factor at which the amplitude of the sigh is multiplied relative to the Prm setting</td>
<td></td>
</tr>
<tr>
<td>KTins</td>
<td>Factor used to multiply the sigh inspiration period relative to the Tins setting</td>
<td></td>
</tr>
</tbody>
</table>
Leakage function group

The effect of a leakage between the tube and the trachea is simulated using this function group. For this purpose, a valve is provided which is adjusted at the end of the tube and is opened or closed depending on the settings and the pressure.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFF</td>
<td>On/off switch for switching on the leakage function</td>
<td></td>
</tr>
<tr>
<td>Pleak</td>
<td>Endotracheal pressure at which the valve and therefore the leakage are opened</td>
<td>hPa</td>
</tr>
<tr>
<td></td>
<td>Differential pressure relative to the Pleak at which the valve and therefore the leakage are opened</td>
<td>hPa</td>
</tr>
</tbody>
</table>

If Pleak=13hPa and dPleak=3 this means, for example, that the magnetic valve opens the leakage if 13 hPa is exceeded and closes it again if Petr = (13-3)=10hPa is exceeded. However, please observe that if the pressure Petr is increased too steeply, the valve will not be able to switch ON or OFF precisely at the set values due to its response time.

Internal compliance Cint function group

The internal compliance or external compliance with spontaneous breathing may be selected for the lung model using the S3 switch.

All operating elements are deactivated by selecting Cex.

 NOTE

This function group consists of settings for the internal compliance Cint in ml/hPa, the lower lung volume L.Lung Volume in ml, the display for the S1 and S2 switch positions for the endotracheal tubes and the airway resistances Raw.

In the upper left section of this function group, the switch position of the compliance switch (S3) on the device is displayed in a field with text and its own color. The color green means that switch position Cint has been activated, the color red means that switch position Cex has been activated. The color yellow means that the switch position Cex+s.N. has been activated, which means that the external compliance is in effect but is "breathing" spontaneously.

Depending on the position of the compliance switch, the slide controls for Prm and Cint are activated or deactivated.

Using the slide control Cint, the internal compliance value is set within a range from approx. 0.3 ml/hPa to approx. 3.0 ml/hPa.

The horizontally running slide control “L. Lung Volume” (Lower Lung Volume) allows the piston to be set at a lower position within the internal compliance cylinder, depending on the ventilator’s PEEP setting and the Cint value. The digit specifications are to be viewed merely as relative values. They do not correspond to the actual Cint volume and also do not relate to the functional residual capacity (FRC). This slide control must be set in such a way that the indicators situated to the right of the slide control must not flash red in the Cint and Cex+s.B. switch positions for the compliance switch S3 within the entire movement area of the piston. In doing so, the upper LED is for the upper volume limit of the piston and the lower LED is for the lower volume limit.
6.2.2 “Channels” tab

The data channels which are to be displayed on the screen on the right are set using the channels tab. These values are measured or calculated.

Time Axis in s determines the time range in s, which is taken from the graph in the Y-T representation for the x-axis. This value must be set before requesting the program, but before clicking on the start button. It is deactivated after this and can no longer be changed.
Channel X is in the 8th data channel that can be displayed on the graph. Using the selection switch, different signal combinations may be selected and either represented as a graph or used for further calculations.

The signal names and their meanings are featured in the following table.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOB</td>
<td>Work of breathing</td>
<td>mJ</td>
</tr>
<tr>
<td>Reff/10</td>
<td>Calculated effective resistance, divided by a factor of 10</td>
<td>hPa*s/l</td>
</tr>
<tr>
<td>Py-Prm</td>
<td>Differential pressure between Py and Prm</td>
<td>hPa</td>
</tr>
<tr>
<td>Py-Palv</td>
<td>Differential pressure between Py and Palv</td>
<td>hPa</td>
</tr>
<tr>
<td>Py-Ptr</td>
<td>Differential pressure between Py and Ptr</td>
<td>hPa</td>
</tr>
<tr>
<td>Ptr-Palv</td>
<td>Differential pressure between Ptr and Palv</td>
<td>hPa</td>
</tr>
<tr>
<td>Palv-Prm</td>
<td>Differential pressure between Palv and Prm</td>
<td>hPa</td>
</tr>
<tr>
<td>Prmc</td>
<td>Calculated pressure for Prm</td>
<td>hPa</td>
</tr>
<tr>
<td>dtaP</td>
<td>Differential pressure through across the pneumotachograph</td>
<td>hPa</td>
</tr>
<tr>
<td>Inspiration</td>
<td>Value is 1 for spontaneous inspiration and 0 for expiration</td>
<td></td>
</tr>
<tr>
<td>dtaT</td>
<td>Labview program cycle time</td>
<td>ms</td>
</tr>
<tr>
<td>Compl</td>
<td>Actual compliance value in ml/hPa</td>
<td>ml/hPa</td>
</tr>
<tr>
<td>Current</td>
<td>Current through the voice coil motor (VCM) in A</td>
<td>A</td>
</tr>
<tr>
<td>Kt</td>
<td>PWM duty cycle for the VCM (0-1)</td>
<td></td>
</tr>
<tr>
<td>v</td>
<td>VCM speed</td>
<td>mm/s</td>
</tr>
<tr>
<td>Ext0</td>
<td>External signal channel 0 weighted with offset Uoff0 and Kex0 factor</td>
<td></td>
</tr>
<tr>
<td>Ext0</td>
<td>External signal channel 1 weighted with offset Uoff1 and Kex1 factor</td>
<td></td>
</tr>
<tr>
<td>Ext0</td>
<td>External signal channel 2 weighted with offset Uoff2 and Kex2 factor</td>
<td></td>
</tr>
<tr>
<td>TempVcm</td>
<td>Coil temperature of the VCM</td>
<td>°C</td>
</tr>
<tr>
<td>SpecFilt #1</td>
<td>Special filter channel 1 output</td>
<td></td>
</tr>
<tr>
<td>SpecFilt #2</td>
<td>Special filter channel 2 output</td>
<td></td>
</tr>
<tr>
<td>SpecFilt #2/#1</td>
<td>SpecFilt#2 divided by SpecFilt#1</td>
<td></td>
</tr>
<tr>
<td>SpecFilt #2-#1</td>
<td>SpecFilt#2 minus SpecFilt#1</td>
<td></td>
</tr>
<tr>
<td>SpecFilt #2+#1</td>
<td>SpecFilt#2 plus SpecFilt#1</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**

When calculating the respiration work or the effective resistance in the specials tab, either WOB or Reff/10 must be selected.
In the **Plot Filters (8#)** function group, settings are applied which are required for filtering all 8 channels represented in the graphics screen.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ON</td>
<td>On/off switch for the filter function</td>
<td></td>
</tr>
<tr>
<td>Low-pass</td>
<td>Selection switch for the filter function</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low-pass</td>
<td>Low-pass filter</td>
</tr>
<tr>
<td></td>
<td>High-pass</td>
<td>High-pass filter</td>
</tr>
<tr>
<td></td>
<td>Band-pass</td>
<td>Band-pass filter</td>
</tr>
<tr>
<td></td>
<td>Band-stop</td>
<td>Band-stop filter</td>
</tr>
<tr>
<td>Butterworth</td>
<td>Selection switch for the filter type</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Butterworth</td>
<td>Butterworth filter type</td>
</tr>
<tr>
<td></td>
<td>Bessel</td>
<td>Bessel filter type</td>
</tr>
<tr>
<td></td>
<td>Chebyshev Bessel</td>
<td>Chebyshev Bessel filter type</td>
</tr>
<tr>
<td>n</td>
<td>Order of the selected filter</td>
<td></td>
</tr>
<tr>
<td>Fc</td>
<td>Cut-off frequency of the selected filter, This setting is only visible for the low-pass and high-pass filters</td>
<td>Hz</td>
</tr>
<tr>
<td>Fmb</td>
<td>Mid-band frequency This setting is only visible for the band-pass and band-stop filters</td>
<td>Hz</td>
</tr>
<tr>
<td>Bandwidth</td>
<td>Bandwidth This setting is only visible for the band-pass and band-stop filters</td>
<td>Hz</td>
</tr>
</tbody>
</table>

The **trigger/flow/volume** function group enables the parameters required in conjunction with all signals to be set. In particular, this relates to the way in which the integrator which calculates the volume \( V_{tid} \) from the flow is periodically deleted.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearing Mode</td>
<td>Integrator clearing mode</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OFF</td>
<td>Clearing mode is off</td>
</tr>
<tr>
<td></td>
<td>Spont. Insp.</td>
<td>Clear at beginning of spontaneous inspiration</td>
</tr>
<tr>
<td></td>
<td>Flow Threshold</td>
<td>Clear if the flow threshold is exceeded</td>
</tr>
<tr>
<td>Flow Threshold</td>
<td>Flow Threshold</td>
<td>l/min</td>
</tr>
<tr>
<td>Flow Disp. Gain</td>
<td>Factor used to multiply the flow representation in the graph</td>
<td></td>
</tr>
<tr>
<td>Zero Vt</td>
<td>Button to manually clear the integrator</td>
<td></td>
</tr>
</tbody>
</table>
The function group **Freeze x-y** comprises of four buttons through which graph plots which have been frozen in the **X-Y representation** may be switched on and off and the colors of the buttons correspond to the colors of the graph plot. By pressing the button **Clear**, all saved plots are deleted.

**NOTE**

The freeze function is only active for x-y representations.

The function group **Special Filters (2#)** comprises of filters for two channels which produce a displayed numerical output value under **Result**.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OFF</strong></td>
<td>Selection switch for the filter function</td>
<td></td>
</tr>
<tr>
<td>LP filter</td>
<td>Low-pass filter</td>
<td></td>
</tr>
<tr>
<td>Eff. Unfiltered</td>
<td>Calculation of the effective value from the unfiltered signal over the time ( T_{\text{ewEff}} )</td>
<td></td>
</tr>
<tr>
<td>P2P Unfiltered</td>
<td>Calculation of the peak to peak value from the unfiltered signal over the time ( T_{\text{ewp2p}} )</td>
<td></td>
</tr>
<tr>
<td>Eff. Filtered</td>
<td>Calculation of the effective value from the unfiltered signal over the time ( T_{\text{ewEff}} )</td>
<td></td>
</tr>
<tr>
<td>P2P Filtered</td>
<td>Calculation of the peak to peak value from the filtered signal over the time ( T_{\text{ewp2p}} )</td>
<td></td>
</tr>
<tr>
<td>Channel</td>
<td>Selection switch for the channel to be filtered</td>
<td></td>
</tr>
<tr>
<td>Fc/Hz</td>
<td>Cut-off frequency of the low-pass filter.</td>
<td>Hz</td>
</tr>
<tr>
<td></td>
<td>This entry is only possible for low-pass filtering</td>
<td></td>
</tr>
<tr>
<td>TewEff</td>
<td>Time period over which the effective value is calculated</td>
<td>s</td>
</tr>
<tr>
<td></td>
<td>This entry is only possible for effective value measurement</td>
<td></td>
</tr>
<tr>
<td>TewP2P</td>
<td>Time period over which the peak to peak value is calculated.</td>
<td>s</td>
</tr>
<tr>
<td>Result</td>
<td>Display of calculated results from top to bottom</td>
<td></td>
</tr>
<tr>
<td>#1 result, channel 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2 result, channel 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2 / #1 quotient of #2 and #1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2-#1 difference between #2 and #1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2+#1 sum of #2 and #1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The function group **external channels** relates to external analogous channels which may be supplied through the input socket on the front panel of the device.

The voltage range of these three channels lies between -10 V and +10 V. Compensation of the offset may be carried out through Uex0. Kex determines the transmission factor by multiplying the voltage measured by it in order to get a result in the desired measurement unit. The result is displayed in the display situated on the right.

The calculation formula for the channel is

$$ U_{out}(i) = K_{ex}(i) \times (U_{ex}(i) - U_{ex0}(i)) $$

Measurement for all channels may be switched on and off using the OFF button.

### 6.2.3 “Options” tab

![Options tab](image)

**Figure 6-4: Options tab**
The **Options** tab contains potential settings and displays for optional parameters. Its activity state is differentiated, if necessary, depending on whether the START button has already been pressed or not.

The **serial number** is entered before starting the device for the first time and **before pressing the START button** during initial operation. It must match the serial number stated on the reverse side of the device. It is saved and does not have to be reentered after restarting the device.

**NOTE**

During ongoing operation the serial no. can no longer be changed.

In **ComPort#** the current COM-Port of the PC/laptop which is responsible for communication between the device and the PC through the USB interface is selected. The device can only be started if there is a valid COM-Port#. This may be recognized by the START button flashing. The word “USB serial” must appear under **COM Port Name**. If this is not the case, a corresponding entry must be entered into the PC’s control panel. If necessary, the button **update** may also be selected after pressing the arrow button in COMPort# after which the valid COMPort# is displayed.

**NOTE**

During ongoing operation, the ComPort cannot be changed.

Either the manufacturer or the authorized operator enters a password which is required for certain service programs into this input field.

The **desired cycle time** is entered into this input field in ms. This must be carried out before clicking the START button. When the program is running, this button is deactivated. The standard value is 5 ms.

**NOTE**

This value should not be changed where possible, or only changed after consulting the manufacturer.

The display field for the software shoes the **current version of the LabVIEW program** as well as the **micro-controller program**.

The display field **operation hours** shows the operational duration of the device in hours.

The parameters for the current breathing gas may be entered under **gas parameters**. Depending on whether you are working with air or with helium as a carrier gas, the carrier gas is selected.
The oxygen concentration, gas temperature, relative humidity and current air pressure are selected in addition to this.

An entry is only required if particular accuracy requirements for the volume flow measurement are set. These parameters are required for the exact calculation of the volume flow. These parameters are saved when the device is switched off and are loaded as the start values when it is turned on again.

In **Compliance Mode** it can be determined whether the compliance curve in the shape of a P-V loop should appear as a linear or an S-shaped gradient.

- See Appendix 10.2 also

In the case of **linear compliance**, the set compliance value over the total volume range applies, i.e. it produces a linear P-V loop.

In the case of **Sigmoid Compliance (Kcv)** the P-V loop is sigmoid-shaped. After selecting the operating mode in the options menu, four other fields open which must also be set.
The factors \( Kc1 \) and \( Kc2 \) determine the compliance within the limits after multiplication by the set compliance value (\( Kc1 \) lower limit, \( Kc2 \) upper limit). This means that the P-V loop within the limits merges to a straight line with a minimum increase (compliance).

The compliance limit \( Clim \) within the limits is calculated at

\[
Clim1, 2 = Kc1, 2 \times C
\]

where \( Clim1, 2 <0.2 ml / hPa \).

**NOTE**

If the setting values for \( Kc1,2 \) are low or the compliance \( C \) exceeds this limit the setting elements for \( Kc1,2 \) flash red. They cannot be reduced any further if this is the case.

The factor \( Kcv \) is multiplied by the set compliance value. It states the volume range excluding what has been reached within the limit compliance values. Using the value \( P0 \) in hPa, the P-V loop may be shifted along the x-axis (pressure).

In **Sigmoid Mode** (V) the volume range as stated above can be set independently to the compliance.

**Control Mode** determines the control algorithm which is used to regulate the compliance. It is possible to regulate the power balance as well as the stated compliance value.

**NOTE**

The control should preferably be set to power balance. In this case, the hysteresis loop of the lung compliance will be easy to recognize.

**CAUTION**

For this purpose, however, the stops situated on the reverse side of the device must be removed without exception. Otherwise, the voice coil motor may overheat.

**NOTE**

Switching on must be deliberately carried out before pressing the start button. Afterwards, the switch will be deactivated and may no longer be operated.
6.2.4 “Specials” tab

This tab consists of special device functions which may be carried out by an experienced operator.

This function group enables the respiration work (work of breathing) and the effective resistance to be calculated. The measurement unit for respiration work is mJ and the measurement unit for effective resistance is hPa*s/l.

The prerequisite for this, however, is that either the respiration work (WOB) or the effective resistance Reff/10 is selected under channel X in the Channels for ChX tab.

This function only works for a spontaneously breathing patient who is not being ventilated. A ventilated patient version is in development. The type of WOB may be selected using the selection switch Mode of WOB:
The specialist terms for this tab are as follows

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total WOB</td>
<td>Total respiration work, consists of resistive and elastic respiration work</td>
<td>mJ</td>
</tr>
<tr>
<td>Elastic WOB</td>
<td>Elastic respiration work in mJ</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (Total1)</td>
<td>Total resistive respiration work calculated from Py-Palv</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (Total2)</td>
<td>Total resistive respiration work, calculated from Pref-Palv</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (Raw)</td>
<td>Resistive respiration work due to airway resistance (Raw)</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (ETT)</td>
<td>Resistive respiration work due to endotracheal tube (ETT)</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (App)</td>
<td>Resistive respiration work due to applicator</td>
<td>mJ</td>
</tr>
<tr>
<td>Res. WOB (ChX)</td>
<td>Resistive respiration work due to differential pressure selected using ChX</td>
<td>mJ</td>
</tr>
</tbody>
</table>

Using an algorithm, it may determined whether the algorithm used in calculating the work of breathing is integrated with the cylinder volume dV or the flow.

\[ W = \int p \cdot dV \quad \text{oder} \quad W = \int p \cdot V \cdot dt \]  

Furthermore, using the specific WOB, (i.e. W/V) it may be determined whether the specific work of breathing i.e. the work of breathing related to the volume or the absolute work of breathing is to be calculated.

In the display field situated on the right, the work of breathing in mJ, the volume in ml, the specific work of breathing in mJ/ml and effective resistance in hPa*s/l are displayed from top to bottom.

Further information is explained in detail in Appendix 10.3.

NALM also allows alveolar ventilation to be determined.

The FRC in ml, dead space in ml, CO2 production in ml/min and trigger flow (Flow threshold) in l/min, which determines the beginning of inspiration and expiration, must be predetermined by the operator.

The minutes of ventilation in ml/min, the alveolar ventilation in ml/min, end-expiratory CO2 value and end-inspiratory CO2 value are displayed as results. Both are displayed in mm Hg respectively.

Further information is explained in detail in Appendix 10.4.
6.2.5 “Data logging” tab

Data logging may take place parallel to working with the NALM. This type of data logging is based on data storage in the TDMS format provided by the company National Instruments.

![Data logging tab](image)

**Figure 6-7: Data logging tab**

The respective directory is selected by the operator and the filename is entered.

If the filename already exists within the directory, this filename will be highlighted in red and will flash continuously. If this is the case, the saving process cannot be started. Either the filename must be changed or the already existing filename is deleted from the directory.

**NOTE**

The title of the test and a short description of it are added. **Fixed parameters** are those which do not change during the test.
Variable parameters, in contrast, are those which may change during the test. The fixed parameters are written to a file at the start of data logging; the variable parameters as well as remarks, which are provided with a time stamp, are written over the course of the saving process.

The sampling rate is determined by the NALM program's cycle time (the standard is 5 ms which may be set under Options). If not very many samples are required, the sampling rate may be reduced using the decimation factor.

Using the setting external channels it may be determined how many external channels may be saved in addition. If the value is set at zero, no other external channels are saved; if the value amounts to three, three additional external channels are saved.

The variable and fixed parameters within the test series do not always have to be reentered as these are saved after ending the program and reload when the program is requested again. Press the delete button to delete all parameter entries. Of course, these parameters may also be overwritten individually.

The operating elements are located in the bottom row. Their functions are described below:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>Meaning</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mode</td>
<td>Storage mode</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Delay time</td>
<td>Selectable delay time in ms relative to the triggering event for individual measurements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start</td>
<td>Start of saving process for each individual mode.</td>
<td>Becomes active when this mode is selected. Afterwards, it changes to “interruption.”</td>
</tr>
<tr>
<td></td>
<td>Pause</td>
<td>Interruption of the saving process for each individual mode</td>
<td>Afterwards, it changes to “start.”</td>
</tr>
<tr>
<td></td>
<td>Save remarks</td>
<td>Save remarks with a time stamp</td>
<td>It is activated while saving is in process</td>
</tr>
<tr>
<td></td>
<td>Save Var. Parameters</td>
<td>Save variable parameters with a time stamp.</td>
<td>It is activated while saving is in process</td>
</tr>
<tr>
<td></td>
<td>Interrupt</td>
<td>Interrupt saving process and delete file.</td>
<td>Reusing the same file name is possible</td>
</tr>
<tr>
<td></td>
<td>Stop</td>
<td>Stop save</td>
<td>After this, the file name will flash red. The file name must be changed for resaving</td>
</tr>
<tr>
<td></td>
<td>Store Set.</td>
<td>Save all NALM settings under directory/filename.txt</td>
<td></td>
</tr>
</tbody>
</table>
There are many different **saving modes** which run either as continuous saving or individual saving processes.

The continuous saving process runs continuously after pressing **START**. The individual saving process requires a trigger signal. Additionally, using **delay**, a delay in x milliseconds in the saving time relative to the trigger time is possible.

In each case, the saving process begins when the **START** button is pressed.

<table>
<thead>
<tr>
<th>Name</th>
<th>Meaning</th>
<th>Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode OFF</td>
<td>Data logging is switched off. No save</td>
<td>Inactive</td>
</tr>
<tr>
<td>Single Mode</td>
<td>Individual saving process after pressing the <strong>STORE</strong> button</td>
<td>Inactive</td>
</tr>
<tr>
<td>Cont. Mode</td>
<td>Continuous saving process after pressing <strong>START</strong> and until <strong>STOP</strong>, <strong>PAUSE</strong> or <strong>CLEAR</strong> is pressed</td>
<td>Inactive</td>
</tr>
<tr>
<td>Ex&gt;In</td>
<td>Individual saving process upon switching from spontaneous inspiration to expiration after pressing the <strong>STORE</strong> button</td>
<td>Active</td>
</tr>
<tr>
<td>In&gt;Ex</td>
<td>Individual saving process upon switching from spontaneous expiration to inspiration after pressing the <strong>STORE</strong> button</td>
<td>Active</td>
</tr>
<tr>
<td>Ex&gt;In&gt;Ex</td>
<td>Individual saving process upon switching from spontaneous inspiration to expiration and from spontaneous inspiration to expiration</td>
<td>Active</td>
</tr>
<tr>
<td>Fex&gt;Fin</td>
<td>Individual saving process upon switching from inspiration to expiration if the flow exceeds the default trigger flow (<a href="#">Options/Trigger/Threshold Flow</a>).</td>
<td>Active</td>
</tr>
<tr>
<td>Fin&gt;Fex</td>
<td>Individual saving process upon switching from expiration to inspiration if the flow exceeds the preset <strong>negative</strong> trigger flow (<a href="#">Options/Trigger/Threshold Flow</a>).</td>
<td>Active</td>
</tr>
<tr>
<td>Fex&gt;Fin&gt;Fex</td>
<td>Combination of both previous modes</td>
<td>Active</td>
</tr>
</tbody>
</table>

**NOTE**

The flow threshold value which decides whether the start of inspiration or expiration is recognized is set under **Options/Trigger/Threshold Flow**.

The data saved in the TDMS format (provided by the company National Instruments) should be evaluated preferably using the program **DIADEM** ([provided by the company National Instruments](#)). This enables a very convenient evaluation of all data including the parameters and remarks provided with a time stamp.

If the data volume is low, it may also be possible to evaluate it in Excel.
6.2.6 “Evaluation” tab

The evaluation tab is usually deactivated. Your content may be activated if YT-Zoom in the graphic display (see diagram) is selected.

Two signal progression charts (SVD) will appear over each other, a small SVD1 which contains the content of the main signal progression chart SVD0 and a large SVD2 in which the magnified data content contained between the two SVD1 cursors is displayed.

It is important to click on at least one of the SVD1 cursors with the mouse in order to properly transfer the actual content from SVD1 to SVD2. The same applies to the SVD2 cursors.

Depending on the selected sub-tab “Zoom y-t” or “Zoom x-y” the selected signals are either displayed as a function of the time \( Y = f(t) \) in a Y-T representation or an X-Y diagram.

In the case of Zoom y-t the desired curve points may be selected using both of the cursors situated within SVD2. The cursor values for the individual signals are displayed numerically in the table depicted in the left section.

![Figure 6-8: GUI in the case of zoom mode with Zoom Y-T](image)

**NOTE**

Ensure that the red cursor is always situated to the left of the yellow cursor. If merely one cursor is visible, it means that the yellow cursor is over the red cursor and is hiding it. In this case, the yellow cursor must be shifted to the right.
The same is possible for Zoom x-y. Here, the two desired signals which are to be displayed together in the x-y representation are firstly selected for the respective axes (x-axis and y-axis).

If it needs to be scaled, the button Scale, which is responsible for all scaling within the graph, must be pressed. Afterwards, the desired curve points may also be selected using both cursors and their value and the increase developing between the cursor crosses are displayed.

Ensure that only the temporal data range may be shown on the x-y diagram, which has previously been selected in SVD1 (situated on the top) using the sensors.

**Data Export**

The export method for files from the zoomed screen may be chosen using three selection switches.

The selection switch on the left determines the destination, which is either the clipboard or a file. The selection switch in the center allows you to choose between export as a graph or as a file.

The selection switch on the right determines the file format in the case of data export.

By pressing the button “Export” the export is sent to the desired destination.

Depending on the position of the selection switch, the entry fields for the path and file names are activated or deactivated.
6.2.7 "Service" tab
This tab and its functions are subject to alterations by the manufacturer. However, the operator may calibrate the pressure sensors. See Chapter 8.2 on this.

6.3 Graphic display of measurement data
The measurement data may be displayed graphically in the right half of the GUI either as a bar graph, a YT graph, an XY graph or as a magnified display.

This is selected in the row of tabs visible underneath the graph.

Figure 6-10: Row of tabs for selecting the graphic representation of measurement data

6.3.1 Bar Graph
The bar graph provides a clear representation of the intrapulmonary pressures in conjunction with the volume flow, volume as well as tube and respiratory system resistances. The time information is lost.

Figure 6-11: Bar graph representation
6.3.2 YT Graph

The measurement data is represented as a signal path diagram over the time in two separate plot levels.

![YT Graph Image]

In the upper plot level, the pressures Prm, Py, Petr and Palv are displayed and in the lower plot level the Flow, Vlung, Vtid and Channel X signals are displayed.

A selection field is located at the top left beside the graph which displays the signal name. Switches are allocated to these signal names which may be used to switch the graphic representation of the respective signal ON and OFF. Scaling is carried out separately for each plot level by pressing the button SCALE.

The colors for the signals of each respective switch match the colors of the plots.
6.3.3 XY Graph
Signals may be allocated to the x-axis and the y-axis on the x-y graph which may be selected using a corresponding selection switch. This usually results in a loop sequence.

This selection switch is located at the upper left beside the graph. Using the selection fields, the desired signals may be allocated to the x-axis and y-axis.

A storage time (memory time) may be determined, during which the data is saved. The graph may also be deleted by using the Clear button.

Scaling the XY graph occurs in the same way as the other graphs by using the Scale button. There are no cursors for measuring the loop in this display.

If you wish to measure this, the YT Zoom display must be selected.
6.3.4 YT Zoom
If this tab is selected, the data display is interrupted and the following screen opens.

Figure 6-14: YT Zoom display

The details on this function have already been described in the chapter “Evaluate Tab.” Refer to this chapter if necessary.

If the curve graph is to be restarted, only the desired display types YT GRAPH or XY GRAPH have to be reselected.

The YT ZOOM tab cannot be selected from the XY GRAPH tab!

NOTE

Ensure that the red cursor is always situated to the left of the yellow cursor. If they are on top of each other, only one cursor may be seen. If this is the case, the yellow cursor must be moved to the right to make the red cursor visible.
6.4 Main control keys
The main control keys are located underneath the tab in the left section of the GUI.
When you request the program, you should see the following.

![Main control keys before pressing START](image1)

**Figure 6-15: Main control keys before pressing START**

After pressing the **Start** button, this button changes its inscription to **Stop**.

![Main control keys after pressing START](image2)

**Figure 6-16: Main control keys after pressing START**

By pressing the **Stop** button, the curve graph is paused and the curves may be observed in detail. The button which previously said STOP now has the inscription CONTINUE. After pressing **Continue**, the button changes its inscription back to **STOP**.

By pressing the button **Scale**, all graphic representations are scaled.

By pressing the button **Zero all**, all pressure sensors as well as the differential pressure sensor for determining the volume flow regarding its offset are corrected.

Pressing the button **Copy** means that the content of the respective graphic representation is copied to the clipboard where it can be transferred to other documents.

**NOTE**

The copy function does not work for the bar graph.

The **Freeze** button is only activated for the XY representation. Pressing this button freezes the current graph. Four curves in total, each with their own different colour, may be frozen. See the section **Freeze x-y** in section 6.2.2 for more information.

Clicking on the **Exit** button ends the program.
6.5 Display field for warnings and notes

Four display fields for notes and warnings are situated above the graphic display.

The color of the first display field on the left shows whether the volume flow in the graphic display has been magnified or not. The color is yellow for a magnified display. Otherwise, the color is green.

The second display field from the left displays whether a data logging process is currently being carried out. It will be red in color if this is the case.

The third display field from the left displays, through different colors, whether

- a note or low-priority warning (green)
- a medium-priority warning (yellow)
- or a high-priority warning (red)

is displayed in the text field situated to the right. This display appears for as long as the warning state exists.

The fourth display field displays the text for the warnings and notes.

These warnings have been summarized in the following table

As an individual cannot be grievously injured by the Gina, the warnings are divided into high-priority, medium-priority and low-priority notes.

High-priority warnings are displayed in red and medium-priority warnings are displayed in yellow.

<table>
<thead>
<tr>
<th>AlNo.</th>
<th>Priority</th>
<th>Color</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>USB Connection failed! Check the USB cable, switch off the device and switch it on again. Go to Exit and Start again.</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>USB connection failed! Check whether the device is switched off. Switch off the device and switch it on again. Go to Exit and Start again.</td>
</tr>
<tr>
<td>3</td>
<td>High-priority</td>
<td></td>
<td>USB connection failed. Switch on the device!</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td>Wrong Serial Port! Select another Serial Port</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td>I2C connection failed! Switch off the device and switch it on again. Go to Exit and Start again.</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td>Temperature of the VCM is too high! Switch the lung model off immediately!</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Medium-priority</td>
<td></td>
<td>Either wrong serial number or LM_SensKalFile.dat is missing. You can continue, however, with reduced measurement accuracy.</td>
</tr>
</tbody>
</table>

[Enter here] Instruction manual Gina V3.0 53
7 Initial operation of the device

These initial operation instructions are applicable when using Gina for the first time.

This process occurs in four stages:

1. Unpacking the device
2. Installing the program on the PC
3. Configuring the serial interfaces
4. Initial operation

7.1 Unpacking the device

1. Open the outer packaging and store in the case of a potential claim
2. Remove from the device case and open carefully by unclipping the fasteners.
3. Carefully pull out the infill with the accessories
4. Remove the external compliance flasks
5. Remove the lung model from the device case
6. Ensure that all parts are complete according to the delivery note
7. Ensure that all parts are intact by inspecting them. Contact the manufacturer or the distributor if you detect any damages.

7.2 Installing the program on the PC

7.2.1 USB stick content

1. The USB stick containing the program is inserted into the PC’s USB port.
2. The following files are contained on the USB stick
   - Driver software for the USB interface (Comport) CDM....
   - Installer
   - The directory CDMxxx contains driver files for the USB interface
     - armd54
     - i386
     - Static
     - ftd2xx.h
     - ftdibus.cat
     - ftdibus.inf
     - ftdiport.cat
     - ftdiport.inf
     - LegoVerificationReport.pdf
   - The installer has a volume submenu which contains

Temperature of the VCM is high. Reduce the pressure and come slowly to an end

At least one switch for resistances or compliance is in an intermediate position. Choose the right position!
7.2.2 Installing the NALM program

Installing the program occurs in the following steps:

1. Insert the supplied USB stick into the computer’s USB port
2. Open the directory `Computer\STORE NGO\Installer\Volume` or something similar
3. Double-click on setup.exe

The program NALM-Vx under the program (x86) will then automatically be installed on the target computer.

Additionally, a “Lung Model” directory under `C:\user\Dokumente` is set up with the subdirectories data and manual. These in turn contain data files and the updated instruction manual.

4. After installation, restart the computer.
5. On the desktop, the icon for the Labview program i.e. NALM _Vx appears under program.
6. Double-click on this icon to start the program.
7. Create a link for the file NALM _Vx-n.exe on the desktop.

The USB stick remains in the device as it contains the driver for the USB interface.

7.3 Setting up the serial interface on the PC

So that the PC can communicate with the lung model over the USB port, a so-called ComPort must be set up on the PC. This must always be carried out during the initial installation.

If the lung model and the PC are once more connected to one another using the USB cable afterwards, the required data has already been saved. Ensure that the USB cable is always inserted into the same PC USB port later on.

For the purpose of setting up the serial interface for the first time, proceed as follows:

1. The lung model is switched off, the PC is switched on.
2. Connect the PC to the lung model using the USB cable supplied (the PC will sound a brief acoustic signal)
3. Switch on the lung model.
4. Go to control panel on the PC and select device manager from system manager/device manager.
5. The key word `connections COM &LPT` is located in the upper section and must be clicked on.
6. A submenu opens with the name USB Serial Port (Com n) whereby n displays the port number.
7. Click on the entry once with a right mouse click and select update driver software
8. Select the USB stick driver location:
9. Install the driver.

Installation is usually completed in this way.
Initial operation of the complete device

1. Switch off the power switch on the reverse side of the device.
2. Insert the mains plug into the power socket on the reverse side of the device and connect to the power supply.
3. Switch on the computer and wait until it is ready to use.
4. Insert the USB cable into the lung model’s USB port and connect it to the computer. The computer confirms insertion of the USB cable with a short acoustic signal.
5. If the external compliance is to also be used, remove the plugs on the top of the device and attach the external compliance.
6. Attach the T piece with the pressure measuring port to the lung model inlet (15 mm external tapered connector)
7. Attach the Y piece of the ventilator to the T piece.
8. Connect the Py inlet of the device using a short tube to the T piece’s pressure measuring port
9. Switch on the lung model’s power switch.
10. Start the NALM_Vx program on the computer.
11. Wait until the following inscription or a similar inscription appears in the field underneath the ComPort setting: ASRL…..USB Serial Port. If this text does not appear, select another port #.
12. Check whether the set serial no. SN# matches the serial no. of the device stated on the type plate. If not, this must be corrected. The set serial no. only has to be entered the first time. After this, it will be saved on the target computer.
13. Press the START button.

Installing a program update

If a new program version is available, the installer loads on the PC in the same way as previously described.

The driver for the serial interface does not have to be reinstalled.

However, a driver update may also be searched for in the control panel/device manager.

For this purpose however, the PC must be connected to the internet.

Downloading a software update

An updated version of GUI software is available on the Dr. Schaller Medizintechnik server.

Provided that the hardware in the lung model is compatible with this software, the operator can download this software. The login data for the server is as follows:

- Server address: ftp://schaller-mt.de
- Login: f006fa4c
- Password: NALMLr7ko5

A window will open which will display the files authorized for download. These are saved in a packaged format and must be unzipped after downloading.
8 Operation

8.1 Operating Gina

After successfully operating Gina for the first time, i.e. after installing the software and entering the serial number, operating the device is very straightforward.

**CAUTION**

It must be ensured that the sealing plugs on the top, the bottom and the reverse side of the device are inserted properly without exception.

Furthermore, ensure that the USB cable is always inserted into the same USB port of the computer.

Operation occurs in the following steps:

1. Switch on the computer and wait until it is ready to use.
2. Insert the USB cable into the lung model’s USB port and connect it to the computer. The computer confirms insertion of the USB cable with a short acoustic signal.
3. If the external compliance needs to be used, the sealing plugs on the top of the device must be removed and the external compliance must be attached.
4. Attach the T piece with the pressure measuring port to the lung model inlet (15 mm external tapered connector)
5. Attach the Y piece of the ventilator to the T piece.
6. Connect the Py inlet of the device using a short tube to the T piece’s pressure measuring port
7. Switch on the lung model’s power switch.
8. Start the NALM_Vx program on the computer.
9. Check that the correct serial number has been set.
10. Select the “Resp. Mechanics” tab
11. Set all parameters according to the operator’s wishes.
12. Select the graphic display according to the operator’s wishes.

8.2 Calibration options for the user

8.2.1 Calibrating the pressure sensors

The operator may calibrate the pressure sensors inside of the device if they have their own calibrated precision pressure sensors.

**CAUTION**

Calibration may only be performed by a person authorized to do so by the operator responsible. This is the full responsibility of the operator. If the device no longer works properly due to incorrect calibration, the costs will be borne by the operator and this will not be covered by the guarantee.

The procedure is as follows:

1. Attach the T piece with the pressure measurement outlet to the lung model inlet
2. Connect the pressure measuring outlet to the pressure measuring inlet Py+ using a short tube
3. Switch the compliance switch to the Cex position
4. Attach the Cex1000
5. Check in the “Resp. Mechanics” tab that the leakage is switched off.
6. Select the “options” tab
7. Connect the T piece inlet to the calibration pressure source and set the desired pressure value within the range of 30 hPa to 50 hPa.

**NOTE**

The set pressure does not have to correspond exactly to a determined pressure. It merely has to be read accurately and the read value must be entered precisely.

8. Press the “zero all” button
9. Enter the password 0123 into the “options” tab
A new window will appear.

- Kcalold are the calibration factors for the pressure sensors Py, Petr and Palv in the first three rows.
- Cal. Pressure is the entry field for calibration pressure.
- “Wait for Start” is the notification which indicates that the calibration process is in progress.
- KcalNew contains new calibration factors received after the calibration process.

10. Enter the pressure displayed by the calibration pressure source into the entry field “Cal. Pressure” and press the START button.
11. The calibration state notification changes to “Measure” and then to “CalcStore” which means that the newly calculated calibration factors are being saved.
12. The new calibration factors for the three pressure sensors are displayed under “KcalNew” in the first three rows. They may deviate only slightly from 1.00.
13. If the result seems plausible, these new factors can be saved by pressing the button “STORE” in the sensor Kalfile.
14. If the calibration seems incorrect or dubious, the calibrated process may be repeated by pressing the “REPEAT” button.
15. After pressing the “Exit” button, the calibration panel disappears and the familiar Gina GUI appears again.
16. Switch off Gina using “EXIT” and restart. It is only in this way that the new factors will be activated.

**NOTE**

Switch off Gina immediately after the calibration process through Exit and restart again.

**NOTE**

It may happen that the calibration panel on the GUI suddenly disappears if another operating element is pressed. If this is the case, it will be located behind the GUI and may be made visible once more by pressing the button combination Alt+Tab.
8.2.2 Checking the flow sensor
Gina’s volume flow sensor is calibrated precisely by the manufacturer using a precise piston calibration device. The result of this calibration is a non-linear calibrated characteristic curve which may not be modified by the operator.

If the operator happens to have a precision measuring station for the flow then they can check the displayed volume flow.

For this purpose it is necessary to enter the **exact gas parameters** of the testing gas under “Options.”

The device must be placed on its side and the sealing plugs located on the bottom of the device must be removed. In this way, the active volume flow can leak directly through the lung model inlet once more without passing the tube resistance.

Afterwards, the test volume flow is set and compared with the volume flow displayed on the Gina.

A whole series of measurements may also be carried out while using the data logging function.

If you have any questions or great deviations arise, the manufacturer must be consulted.

**NOTE**
Calibration of the volume flow sensor is carried out by the manufacturer using a precise piston device. In the case of deviations relating to the calibration device used by the operator, it is uncertain who is responsible for the error.

**NOTE**
After ending the test procedure, the sealing plugs on the bottom of the device must be reinserted without exception.

8.3 Operating the Gina as a HFO generator
You have the option of also operating Gina as a HFO generator at frequencies of up to 10 Hz.

**NOTE**
However, this option should only be carried out by an experienced operator as improper use could lead to instability within the control circuit.

The following procedure is to be carried out on the switched-off lung model:
1. Remove the plugs on the reverse side of the device.
2. Switch on the lung model.
3. Request the program, but do not press START yet.
4. Switch on the switch “with Cex, VCM ON” in the “options/compliance mode” tab
5. Switch the compliance switch to the Cex position
6. Program START
7. Set the breathing parameters in the same way as in the diagram opposite.

**NOTE**
After ending the test, the sealing plugs located on the reverse side of the device must be reinserted without exception.
9 Technical data

9.1 Electrical data

- Protection class: SK1
- Supply voltage: 100-240 V~
- Frequency: 40-60 Hz
- Power: 100VA
- Mains fuse: 2*1.6AT

9.2 Mechanical data

- Dimensions (L*W*H): 275 * 160*185 mm
- Mass (lung model): 4.5 kg
- Mass device case: 1.6 kg
- Mass Cex500: 0.3 kg
- Mass Cex1000: 0.4 kg
- Total mass with accessories and device case: 7.8 kg

9.3 Environmental conditions

- Ambient operational temperature during operation: 15°C - 35°C
- Storage temperature: 0°C - 45 °C
- Atmospheric humidity (non-condensing): 0 - 95%

9.4 Resistance values (hPa/l/s)

The flow is to be set in l/min for calculating the resistance.

<table>
<thead>
<tr>
<th>Name</th>
<th>Resistance hPa*s/l</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endotracheal tube</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ET tube 5.0 mm</td>
<td>R=6.8*(1+V'/2.6)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>ET tube 3.0 mm</td>
<td>R=10.4*(1+V'/2.9)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>ET tube 2.5 mm</td>
<td>R=30.5*(1+V'/3)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>ET tube 2.0 mm</td>
<td>R=80*(1+V'/2.6)</td>
<td>+/-20%</td>
</tr>
<tr>
<td><strong>Airway resistance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R1</td>
<td>R1 = 26*(1+V'/13.5)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>R2</td>
<td>R2=45*(1+V'/14)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>R3</td>
<td>R3=84*(1+V'/13.7)</td>
<td>+/-20%</td>
</tr>
<tr>
<td>R4</td>
<td>R4=179*(1+V'/16)</td>
<td>+/-20%</td>
</tr>
<tr>
<td><strong>Pneumotachograph</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total resistance</td>
<td>Rg=9*(1+V'/20)</td>
<td>+/-15%</td>
</tr>
<tr>
<td><strong>Leakage resistance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance switch on Cint</td>
<td>&gt; 30000</td>
<td></td>
</tr>
<tr>
<td>Compliance range on Cex</td>
<td>&gt; 70000</td>
<td></td>
</tr>
</tbody>
</table>

(Flow in l/min)
9.5 Compliance values

<table>
<thead>
<tr>
<th>Name</th>
<th>Value / ml/hPa</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal compliance</td>
<td>Adjustable within the range of 0.3 - 3</td>
<td>10%</td>
</tr>
<tr>
<td>Cint</td>
<td></td>
<td></td>
</tr>
<tr>
<td>External compliance</td>
<td>Cex500 V=500 ml</td>
<td>$Cex = \frac{V}{Patm}$</td>
</tr>
<tr>
<td>Cex1000 V=1090 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bellows lung</td>
<td>Approx. 1ml/hPa</td>
<td></td>
</tr>
<tr>
<td>Compressible volume</td>
<td>Ccv</td>
<td>0.12</td>
</tr>
</tbody>
</table>

9.6 Sensors

<table>
<thead>
<tr>
<th>Sensor type</th>
<th>Measuring range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure sensor</td>
<td>Depending on serial nr.</td>
<td>-103 - +103 hPa</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-75 hPa - +75 hPa</td>
</tr>
<tr>
<td>Volume flow sensor</td>
<td>Pneumotachograph</td>
<td>-20 - +20 l/min</td>
</tr>
<tr>
<td>Differential pressure sensor</td>
<td></td>
<td>-5 - +5 hPa</td>
</tr>
</tbody>
</table>

The flow measurement is based on the differential pressure principle, by which the volume flow triggers a differential pressure using the pneumotachograph which is measured by a differential pressure sensor and recalculated as a volume flow signal. Linearization of the differential pressure volume flow characteristic curve occurs in the program.

9.7 Ventilation pressure

The input tapered connector pressure on the lung model must always be set within the range of -70 and 70 hPa. This value is dependent on the internal compliance setting value. If a warning relating to the engine flow appears in the warning text field it must be observed. If this is the case, the lung model may not be used at this ventilation pressure.

9.8 PC requirements

- Operating system: at least Windows XP (last SP)
- Processor: Frequency at least 1.4 GHz
- Memory: at least 1 GB
- Internet access with LAN or WLAN
- Vertical resolution of the screen is 768 pixels
- The suitability of the PC is to be examined through testing.

NOTE

The PC is not included in the scope of delivery. It must be provided by the operator.
10 Appendix

10.1 Non-linear resistance

The resistance characteristic curves of the tube and airway resistance are determined by measuring the total pressure as a volume flow function. The inlet flow and outlet flow are included in this. "Formula section 10"

A second degree polynomial is produced almost every time for this characteristic curve.

\[ P = k_1 * V' + k_2 * V'^2 \]  

(10.1)

The factor \( k_1 \) corresponds to the percentage pressure resulting from the laminar flow and the factor \( k_2 \) corresponds to the percentage pressure resulting from the turbulent flow.

The representation, known in medicine as Rohrer’s equation, is, however, less clear.

For example, we get the following relationship for a 2.5 mm endotracheal tube

\[ P = 30.5 * V' + 610 * V'^2 \]

mit \( k_1 = 30.5 \frac{\text{mbar}}{\text{l/s}} \)

sowie \( k_2 = 610 \frac{\text{mbar}}{(\text{l/s})^2} \)

(10.2)

with the flow in l/s and the pressure in hPa.

We use another representation to convert the ratio to 1.1

\[ P = k_1 * V' + k_2 * V'^2 \]

\[ P = k_1 * V' \left(1 + \frac{k_2}{k_1} \frac{V'}{V'}\right) \]

\[ P = k_1 * V' \left(1 + \frac{V'}{V'}\right) \]

(10.3)

using the double-resistance flow

\[ V_d = \frac{k_1}{k_2} \]

The double-resistance flow \( V_d \) is the flow at which the pressure is twice as high as the pressure resulting from a purely laminar flow.

The double-resistance flow amounts to 3 l/min or 0.05 l/s for the 2.5 mm tube. The equation for the pressure is as follows:

\[ P = 30.5 * V' \left(1 + \frac{V'}{0.05 \text{l/s}}\right) \]

(10.4)

The resistance for the given volume flow is calculated using

\[ R = \frac{P}{V'} = k_1 \left(1 + \frac{V'}{V_d}\right) \]

(10.5)

The factor \( k_1 \) corresponds to the constant resistance \( R_{lam} \) resulting from the laminar flow.

\[ R = R_{lam} \left(1 + \frac{V'}{V_d}\right) \]

(10.6)

and at \( V_d = 3 \text{ l/min} \) for the 2.5 tube we get
\[ R = 30,5 \left( 1 + \frac{V'}{3l / \text{min}} \right) \]  

(10.7)

This equation is very convincing. It proves that the resistance increases proportionally to the volume flow. At a flow of 3l/min the tube’s resistance is twice as high as with the laminar resistance. At 6l/min it is thrice as high, etc.

Figure 10-1: Resistance characteristic curve for airway resistances
10.2 Non-linear compliance
The non-linear compliance is realised as a sigmoid function in accordance with the equation

\[ V = 0.5 \cdot \text{d}t \text{a}V \left( \text{sign}(p - pm) \cdot \left( \frac{1 - \exp\left(\frac{4 \cdot C \cdot \text{max} \cdot \text{abs}(p - pm)}{\text{d}t \text{a}V}\right)}{1 + \exp\left(\frac{-4 \cdot C \cdot \text{max} \cdot \text{abs}(p - pm)}{\text{d}t \text{a}V}\right)} \right) + 1 \right) \]  

(10.8)

However, its realization creates very small compliance value problems in terms of control technology. For this reason, the curve is segmented at the top and at the bottom and continued on both sides by tangents. It therefore has the following shape.

Figure 10-2: Sigmoid-shaped compliance curve with tangential continuations at the ends
10.3 Determining the respiration work using Gina

10.3.1 Target position
The Neonatal Active Lung Model (NALM) is also designed to enable inspiratory respiration work. This is achievable, as we are already able to determine all pressures \( P_y, P_{tr}, P_{alv} \) and \( P_{rm} \), the flow and the volume.

10.3.2 Theoretical basis
We can safely assume that the respiration work of the child is itself triggered by the inspiratory respiratory musculature. We accept that expiration is passive and that it takes place due to energy saved in the elastic lung.

In NALM, real pressures are measured and this results (i.e. in the case of CPAP systems) in an interaction between NALM and the ventilator, which also has an effect on the respiration work.

Therefore, external pressures such as \( P_y \) must also be factored in.

In this case, the following equivalent circuit diagram applies:

![Figure 10-3: Basic pattern for the breathing mechanism](image)

This system is described by

\[
P_y = F^* (R_t + R_{aw}) + P_c + P_r m
\]

\[
F = C^* \frac{dP_c}{dt}
\]

Which results in

\[
P_y = C^* (R_t + R_{aw}) \frac{dP_c}{dt} + P_c + P_r m
\]

Or due to

\[
V = C^* P_c
\]

\[
P_y = (R_t + R_{aw}) \frac{dV}{dt} + \frac{V}{C} + P_r m
\]

\[
P_y = R \frac{dV}{dt} + \frac{V}{C} + P_r m
\]

\[
P_y - P_r m = R \frac{dV}{dt} + \frac{V}{C}
\]

With \( R = R_t + R_{aw} \).
10.3.3 Total respiration work WOBtot

The respiration work Wtot which is to be supplied by the patient ventilator system is calculated as follows.

\[
W_{tot} = \int \left( P_y - P_{rm}\right)^* dV
\]  

(10.13)

The minus sign for \( P_{rm} \) stems from the fact that \( P_{rm} \) is negative as a prerequisite.

Applying equation 2.4 to 2.5 for \( P_y=0 \) results in

\[
W_{tot} = \int \left( \frac{R}{C} \frac{dV}{dt} + \frac{V}{C} \right)^* dV = R \int \frac{dV}{dt}^* dV + \frac{1}{C} \int V^* dV
\]

(10.14)

The first term relates to the resistive respiration work and the second relates to the elastic respiration work.

Conversion leads to

\[
W_{tot} = R \int \frac{dV}{dt}^* \frac{dV}{dt} dt + \frac{1}{C} \int V^* dV
\]

\[
W_{tot} = R \int V^2 dt + \frac{1}{C} \int V^* dV
\]

(10.15)

At the end of inspiration, respiration work amounts to

\[
W_{tot} = R \int_{\text{insp}} V^2 dt + \frac{V_{e}^2}{2C}
\]

(10.16)

While only the end volume \( V_e \) is relevant to elastic respiration work, the flow progress over the time is relevant to resistive respiration work.

How high is the respiration work \( W_{tp} \) supplied by the patient with a breathing aid and how high is the respiration work \( W_{tv} \) supplied by the ventilator? As the system is linear, the superposition theorem applies and we can observe the individual components of the equation 2.5.

As we do not know the resistance nor the compliance, we must refer to the output equation 2.5

\[
W_{tp} = - \int \left( P_{rm}\right)^* dV
\]

(10.17)

The specific respiration work i.e. the respiration work \( W/V \) related to the respiratory volume must therefore be taken. The specific respiration work of the patient then reduces under ventilation for the same related volume.

Under the influence of the ventilator, when it comes to the NALM nothing about the pressure \( P_{rm} \) is changed through \( P_y \), although the volume will change. It depends on whether \( P_y \)’s modification is caused by an internal resistance or is reduced or increased by ventilatory support on the part of the ventilator.

Only \( P_{rm} \) must be taken into account for the total respiration work \( W_{tot} \) \( P_y \)’s influences have an effect on the volume and the effect on the patient is recognisable from the specific respiration work.

10.3.4 Resistive respiration work

The differential pressure for the resistive respiration work over the airway resistance is given by

\[
W_{res} = \int \left( P_y - P_a\right)^* dV
\]

(10.18)

The following results from using the flow
\[ W_{res} = \int_{in}^{sp} (P_y - P_a)^* \frac{dV}{dt} * dt \]
\[ W_{res} = \int_{in}^{sp} (P_y - P_a)^* V' * dt \]

10.19

How high is the resistive respiration work that the patient has to supply?

Prm and Py are phase-synchronous and therefore the percentage of respiration work that must be supplied by the patient is calculated using

\[ W_{rp} = \frac{-Prm}{P_y - Prm} \int_{in}^{sp} (P_y - P_a)^* dV \]
\[ W_{rp} = \int_{in}^{sp} \frac{-Prm}{P_y - Prm} (P_y - P_a)^* dV \]

10.20

Py must relate to a reference pressure Pref. This could be from the PEEP and in the case of an inadvertent PEEP from this iaPEEP.

\[ W_{rp} = \int_{in}^{sp} \frac{-Prm}{(P_y - Pr ef) - Prm} ((P_y - Pr ef) - P_a)^* dV \]

10.21

10.3.5 Elastic respiration work

The total elastic respiration work is calculated using

\[ W_{el} = \int_{insp} (P_a - Prm)^* dV \]

10.22

To calculate the elastic respiration work that the patient has to supply we also apply the ratio from Prm to Py

\[ W_{elp} = \int_{insp} \frac{-Prm}{(P_y - Pr ef) - Prm} (P_a - Prm)^* dV \]

10.23

The sum of both respiration works WRp and Welp must be equal to the patient’s total respiration work Wtotp.

Disregarding the reference pressure Pref, we get:

\[ W_{totp} = W_{rp} + W_{elp} \]
\[ W_{totp} = \int_{in}^{sp} \left( \frac{-Prm}{P_y - Prm} (P_y - P_a) + \frac{-Prm}{P_y - Prm} (P_a - Prm) \right) dV \]
\[ W_{totp} = \int_{in}^{sp} \frac{-Prm}{P_y - Prm} (P_y - P_a + P_a - Prm) dV \]
\[ W_{totp} = \int_{in}^{sp} \frac{-Prm}{P_y - Prm} (P_y - Prm) dV \]
\[ W_{totp} = \int_{in}^{sp} -Prm * dV \]

10.24

Excellent. This is OK. The calculations up to this point have been OK.

10.3.6 Measurement units

Pressure in hPa, volume in ml leads to
\[ W = hPa \cdot ml = 10^2 \frac{N}{m^2} \cdot 10^{-6} m^3 = 0.1 mJ \] 

The calculated result for \( W \) must be multiplied by 0.1 to get the result in mJ.
The same applies to the specific respiration work which gives the units in ml/ml

### 10.3.7 Frequency dependence

It must be determined to what extent the respiratory work is dependent on frequency.

This happens in the best and simplest way within the frequency range. With an angular frequency of \( \omega = 2 \pi f \) we get the following for the pressure \( prm \) and the flow \( F \)

\[
prm = \left( R + \frac{1}{j \omega C} \right)^* F = \left( \frac{1 + j \omega CR}{j \omega C} \right)^* F
\]

\[
F = \frac{j \omega CR}{1 + j \omega CR} \overline{prm}
\]

\[
| F | = \frac{\omega C}{\sqrt{1 + (\omega CR)^2}} \overline{prm}
\]

### 10.3.8 Resistive power

The resistive power is calculated using \( F^2 R \) and we get

\[
Pre_{es} = F^2 R = \frac{w^2 C^2 R}{1 + (w CR)^2} \overline{prm}^2
\]

For low frequencies, \( w CR << 1 \), applies

\[
Pre_{es} = w^2 C^2 R \overline{prm}^2
\]

And for high frequencies, \( w CR >> 1 \) applies

\[
Pre_{es} = \frac{\overline{prm}^2}{R}
\]

These equations prove that at low frequencies and for the given compliance, the resistive power for lung expansion increases proportionally to \( R \) and at high frequencies reduces by \( 1/R \).

This means that not every increase in resistance must necessarily lead to an increase in the resistive respiration work. At high frequencies, this means that there is a decrease or no dependency within the transition range due to \( F^2 \) dependency.

The resistive respiration work results in

\[
W_{res} = \int Pre_{es} dt = \frac{Pre_{es}}{j \omega}
\]

\[
W_{res} = \frac{w^2 C^2 R}{1 + (w CR)^2} \overline{prm}^2
\]

The same statements apply to the \( Pres \) regarding \( R \).
To calculate the **specific respiration work** (i.e. \(W/V\)) requires knowledge of the volume.

For the **volume** we get

\[
V = \int F dt = \frac{F}{jw}
\]

\[
V = \frac{1}{jw} \frac{jwC}{1 + jwCR} \frac{prm}{prm} = \frac{C}{1 + jwCR} \frac{prm}{prm}
\]

\[
|V| = \frac{C}{\sqrt{1 + (wCR)^2}} \frac{prm}{prm}
\]

Based on this, we calculate the specific respiration work using

\[
W_{\text{spec}} = \frac{W_{\text{res}}}{V} = \frac{wC^2R}{1 + (wCR)^2} \frac{prm^2}{prm^2} = \frac{wCR}{\sqrt{1 + (wCR)^2}} \frac{prm}{prm}
\]

(10.31)

**It is worth noting that the \(W_{\text{spec}}\) dimension is a type of pressure.**

\(W_{\text{spec}}\) increases with increasing \(wCR\) and asymptotically reaches a maximum, however, it does not reduce again.

### 10.3.9 Elastic respiration work

This is actually a reactive power, however, as it only has an inspiratory effect, it must be taken into account. In this respect, the observations within the frequency range are not totally accurate.

We then get the following for the work:

\[
W_{el} = \frac{V^2}{2C} = \frac{C^2}{2C} \frac{(1 + (wCR)^2)}{(wCR)^2} \frac{prm^2}{prm^2} = \frac{C}{2(1 + (wCR)^2)} \frac{prm^2}{prm^2}
\]

(10.33)

It also applies here that \(W_{el}\) for \(wCR<1\) is proportional to \(C\), however when \(wCR>1\), \(W_{el}\) reduces with an increasing \(C\).

The following applies to the specific \(W_{el}\)

\[
W_{\text{elspec}} = \frac{W_{el}}{V} = \frac{C}{2(1 + (wCR)^2)} \frac{prm^2}{prm^2}
\]

(10.34)

This also has the pressure dimension. It reduces with an increasing \(wCR\). Wow!

It may be anticipated that the elastic respiration work changes depending on the oscillation amplitude. This usually reduces.
### 10.4 Calculating the alveolar ventilation

As a result of the anatomical dead space, the alveolar ventilation is lower than the minute ventilation. The CO₂ partial pressure in the breathing air is dependent on the body’s CO₂ production, V’CO₂, the dead space VD, the breathing volume VT and the functional residual capacity FRC.

#### 10.4.1 Inspiration phase

During inspiration, the expired CO₂ located in the dead space is inhaled again. In addition, a constant CO₂ volume flow FC0₂ flows from the blood into the lung during inspiration.

The inspired CO₂ from the dead space amounts, in the case that VT>VD, to

$$
VCO2_{in1} = VD \cdot \frac{pCO2_{ex}}{patm - pH2O}
$$

(10.35)

The CO₂ volume flowing from the blood into the lung during inspiration amounts to:

$$
VCO2_{in2} = V'CO2 * Tin
$$

(10.36)

At the end of inspiration, the CO₂ volume amounts to

$$
VCO2_{in} = VD \cdot \frac{pCO2_{ex}}{patm - pH2O} + V'CO2 * Tin
$$

(10.37)

The oxygen flowing from the alveolar air into the blood may be disregarded. The end inspirational CO₂ partial pressure in the lung is then given by

$$
pCO2_{in} = \frac{VCO2_{in}}{VT + FRC} (patm - pH2O)
$$

(10.38)

#### 10.4.2 Expiration phase

The CO₂ is exhaled during the expiration phase. CO₂ flows from the blood into the lung at the same time.

At the beginning of expiration, the CO₂ volume VCO₂ is located in the lung with the partial pressure pCO₂in. During expiration, CO₂ also flows back at the volume flow V’CO₂.

Using the program’s cycle time Tz (5 ms) and the expiratory Flow V’ as well as the current volume V, the change in CO₂ during expiration from Cycle n-1 to Cycle n is calculated as follows

$$
VCO2(n) = VCO2(n-1) \cdot \left(1 - \frac{V' * Tz}{FRC + V}\right) + V'CO2 * Tz
$$

(10.39)

The CO₂ partial pressure is

$$
pCO2(n) = \frac{VCO2(n)}{FRC + V(n)} (Patm - PH2O)
$$

(10.40)
10.5 Specific driver installation
If driver installation does not take place automatically, it may be carried out as follows:

1. **Request Select** the control panel / device manager
2. **Properties/port settings** leads to the following screen

3. Click on the arrow in **Bits per second** and select the entry 115200

4. Then, click on the button **Expanded** and the following screen opens.
5. The appropriate COM No. n is depicted under **COM Connection Number**. This is not changed. All other fields are set by clicking on the arrow with the left mouse button as depicted in the above picture. Then, press the **OK button** and this will lead back to the previous screen (Point 7 above).

6. Here, select the **driver tab** by clicking on it and this will then open a similar screen.

7. The **driver provider, date and version** will be visible. The button **update driver** may be selected if no driver update has been carried out in a long time. The prerequisite for this, however, is that the PC must be connected to the internet. The driver version depicted in the following diagram is simply an example. This may differ from driver to driver.

8. The driver on the USB is to be used for the initial installation.

9. If all operations have been concluded correctly, all open fields may be confirmed with **OK** until no menus relating to the control panel are still open.
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