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Where a product meets IEC 60601-1 it is under the principle that:

- this is a more rigorous standard than other standards that could be chosen.
- it provides a high safety level for subjects and operators.

The choice to meet IEC 60601-1 is in no way to be interpreted to mean that a product:

- is a medical device,
- may be interpreted as a medical device, or
- is safe to be used as a medical device.

Safety and Quality Standards

When used with ADInstruments isolated front-ends, PowerLab systems are safe for connection to subjects. The FE231 Bio Amp, FE232 Dual Bio Amp and FE234/FE238 Quad/Octal Bio Amps front-ends conform to international safety requirements. Specifically these are IEC60601-1 and its addenda (Safety Standards, page 3) and various harmonized standards worldwide (CSA601.1 in Canada and AS/NZS 3200.1 in Australia and New Zealand).

In accordance with European standards they also comply with the electromagnetic compatibility requirements under IEC60610-1-2, which ensures compliance with the EMC directive.

ADInstruments manufactures products under a quality system certified as complying with ISO 9001:2008 by an accredited certification body.

Regulatory Symbols

Amplifiers and signal-conditioners manufactured by ADInstruments that are designed for direct connection to humans and animals are tested to IEC60601-1:2012 (including amendments 1 and 2), and carry one or more of the safety symbols below. These symbols appear next to those inputs and output connectors that can be directly connected to human subjects.

**BF (body protected) symbol.** This means that the input connectors are suitable for connection to humans and animals provided there is no direct electrical connection to the heart.

**Warning symbol.** The exclamation mark inside a triangle means that the supplied documentation must be consulted for operating, cautionary or safety information before using the device.

**CE Mark.** All front-end amplifiers and PowerLab systems carry the CE mark and meet the appropriate EU directives.

**UKCA mark.** All front-end amplifiers and PowerLab systems carry the UKCA mark and meet the appropriate UK directives.

**Refer to booklet symbol.** This symbol specifies that the user needs to refer to the Instruction manual or the booklet associated with the device.

**Date of Manufacture/ Manufacturer’s name symbol.** This symbol indicates the date of manufacture of the device and the name of the manufacturer.

**WEEE directive symbol.** Unwanted equipment bearing the Waste Electrical and Electronic Equipment (WEEE) Directive symbol requires separate waste collection. (See disposal section at the end of this chapter)

Further information is available on request.
Safety Standards

IEC Standard - International Standard - Medical Electrical Equipment

IEC 60601-1-1:2000  Safety requirements for medical electrical systems
IEC 60601-1:2012 + A1  General requirements for safety

General Safety Instructions

To achieve the optimal degree of subject and operator safety, consideration should be given to the following guidelines when setting up a PowerLab system either as stand-alone equipment or when using PowerLab equipment in conjunction with other equipment. Failure to do so may compromise the inherent safety measures designed into PowerLab equipment. ADInstruments front-ends are only suitable for operation with ADInstruments PowerLabs. Front-ends are suitable for use with any S/, SP/, /20, /25, /30 and /35 series and 15T PowerLabs (FE234 and FE238 only suitable for use with 35 series PowerLabs). Note that compliance with IEC60601-1 can only be achieved when front-ends are used with a /35 series Powerlab.

The following guidelines are based on principles outlined in the international safety standard IEC 60601-1: General requirements for safety – Collateral standard: Safety requirements for medical systems. Reference to this standard is required when setting up a system for human connection. The user is responsible for ensuring any particular configuration of equipment complies with IEC60601-1-1. Guidance on compliance with this standard is provided in the following sections.

PowerLab systems (and many other devices) require the connection of a personal computer for operation. This personal computer should be certified as complying with IEC 60950 and should be located outside a 1.8 m radius from the subject (so that the subject cannot touch it while connected to the system). Within this 1.8 m radius, only equipment complying with IEC 60601-1 should be present. Connecting a system in this way obviates the provision of additional safety measures and the measurement of leakage currents.

Accompanying documents for each piece of equipment in the system should be thoroughly examined prior to connection of the system.

While it is not possible to cover all arrangements of equipment in a system, some general guidelines for safe use of the equipment are presented below:

- Any electrical equipment which is located within the SUBJECT AREA should be approved to IEC 60601-1.
- Only connect those parts of equipment that are marked as an APPLIED PART to the subject. APPLIED PARTS may be recognized by the BF symbol which appears in the Safety Symbols section of these Safety Notes.
- Never connect parts which are marked as an APPLIED PART to those which are not marked as APPLIED PARTS.
• Do not touch the subject to which the PowerLab (or its peripherals) is connected at the same time as making contact with parts of the PowerLab (or its peripherals) that are not intended for contact to the subject.
• Cleaning and sterilization of equipment should be performed in accordance with manufacturer’s instructions. The isolation barrier may be compromised if manufacturer’s cleaning instructions are not followed.
• The ambient environment (such as the temperature and relative humidity) of the system should be kept within the manufacturer’s specified range or the isolation barrier may be compromised.
• The entry of liquids into equipment may also compromise the isolation barrier. If spillage occurs, the manufacturer of the affected equipment should be contacted before using the equipment.
• Many electrical systems (particularly those in metal enclosures) depend upon the presence of a protective earth for electrical safety. This is generally provided from the power outlet through a power cord, but may also be supplied as a dedicated safety earth conductor. Power cords should never be modified so as to remove the earth connection. The integrity of the protective earth connection between each piece of equipment and the protective earth should be verified regularly by qualified personnel.
• Avoid using multiple portable socket-outlets (such as power boards) where possible as they provide an inherently less safe environment with respect to electrical hazards. Individual connection of each piece of equipment to fixed mains socket-outlets is the preferred means of connection.

If multiple portable socket outlets are used, they are subject to the following constraints:
• They shall not be placed on the floor.
• Additional multiple portable socket outlets or extension cords shall not be connected to the system.
• They shall only be used for supplying power to equipment which is intended to form part of the system.

Earthing and Ground Loop Noise

The prime function of earthing is safety, that is, protection against fatal electrocution. Safety concerns should always override concerns about signal quality. Secondary functions of earthing are to provide a reference potential for the electrical equipment and to mitigate against interference.

The earthing (grounding) stud provided on the back panel of the PowerLab is a potential equalization post and is compatible with the DIN 42801 standard. It is directly connected to the earth pin of the power socket and the PowerLab chassis. The earthing stud can be used where other electronic equipment is connected to the PowerLab, and where conductive shields are used to reduce radiative electrical pick-up. Connection to the stud provides a common earth for all linked devices and shields, to reduce ground-loops.

The earthing stud can also be used where a suitable ground connection is not provided with the mains supply by connecting the stud to an earthed metal infrastructure, such as a metal stake driven into the ground, or metal water piping. This may also be
required in laboratories where safety standards require additional grounding protection when equipment is connected to human subjects. Always observe the relevant safety standards and instructions.

Note that electromagnetically-induced interference in the recorded signal can be reduced by minimizing the loop area of signal cables, for example by twisting them together, or by moving power supplies away from sensitive equipment to reduce the inductive pick-up of mains frequency fields. Please consult a good text for further discussion of noise reduction.

Cleaning and Sterilization

ADInstruments products may be wiped down with a lint free cloth moistened with industrial methylated spirit. Refer to the manufacturer's guidelines or the Data Card supplied with transducers and accessories for specific cleaning and sterilizing instructions.

Inspection and Maintenance

PowerLab systems and ADInstruments front-ends are all maintenance-free and do not require periodic calibration or adjustment to ensure safe operation. Internal diagnostic software performs system checks during power up and will report errors if a significant problem is found. There is no need to open the instrument for inspection or maintenance, and doing so within the warranty period will void the warranty.

Your PowerLab system can be periodically checked for basic safety by using an appropriate safety testing device. Tests such as earth leakage, earth bond, insulation resistance, subject leakage and auxiliary currents and power cable integrity can all be performed on the PowerLab system without having to remove the covers. Follow the instructions for the testing device if performing such tests. If the PowerLab system is found not to comply with such testing you should contact your PowerLab representative to arrange for the equipment to be checked and serviced.

Environment

Electronic components are susceptible to corrosive substances and atmospheres, and must be kept away from laboratory chemicals.

Disposal

- Forward to recycling center or return to manufacturer.
- Unwanted equipment bearing the Waste Electrical and Electronic Equipment (WEEE) Directive symbol requires separate waste collection. For a product labeled with this symbol, either forward to a recycling center or contact your nearest ADInstruments representative for methods of disposal at the end of its working life.
Chapter 2
Overview

The PowerLab system consists of a recording unit and application programs that run on the computer to which the unit is connected. It provides an integrated system of hardware and software designed to record, display, and analyze experimental data.

Front-ends are ancillary devices that connect to the PowerLab recording unit to extend the system’s capabilities. They provide additional signal conditioning, and other features, and extend the types of experiments that you can conduct and the data you can record.

All ADInstruments front-ends are designed to be operated under full software control. No knobs, dials, or switches are needed, although some may be provided for reasons of convenience or safety.
Introduction

The PowerLab controls front-ends through an expansion connector called the I²C (eyesquared-sea) bus. This makes it very easy to add front-ends to the system or to transfer them between PowerLabs. Many front-ends can be added to the system by connecting the I²C sockets in a simple daisy-chain structure. The PowerLab provides control and low-voltage power to front-ends through the I²C bus so, in general, no separate power supply is required.

In addition, each front-end requires a separate connection to one or more analog input channel(s) of the PowerLab. External signals are acquired through the PowerLab analog inputs and amplified before being digitized by the PowerLab. The digitized signal is transmitted to the computer using a fast USB connection. ADInstruments software applications LabChart, LabTutor, LabStation and Lt receive, display, and record the data and your analysis to the computer’s hard disk.

Front-ends are automatically recognized by the PowerLab system. Once connected, the features of the front-end are combined with the appropriate features of the PowerLab (for example, range and filtering options) and are presented as a single set of software controls.

Note: The Stimulator front-ends differ from other front-ends in two respects:

1. Since they need to produce a reasonably high voltage and current, the Stimulator front-ends require a power supply in addition to the power provided by the I²C bus.
2. As they produce voltage output for stimulation, they are connected to a positive analog output socket of the PowerLab as a source for timing and producing pulses.

A variety of accessory products are available with ADInstruments Front-ends, such as transducers, signal cables and recording electrodes. Some of these are listed in the Getting Started with Front-end Signal Conditioners booklet, supplied with your Front-end. For more details see: http://www.adinstruments.com/ or contact your local ADInstruments representative.

Checking the Front-end

Before connecting the front-end to anything, check it carefully for signs of physical damage.

1. Check that there are no obvious signs of damage to the outside of the front-end casing.
2. Check that there is no obvious sign of internal damage, such as rattling. Pick up the front-end, tilt it gently from side to side, and listen for anything that appears to be loose.

If you have found a problem, contact your authorized ADInstruments representative immediately and describe the problem. Arrangements can be made to replace or repair the front-end.
Connecting to the PowerLab

To connect a front-end to the PowerLab, first ensure that the PowerLab is turned off. Failure to do this may damage the PowerLab, the front-end, or both.

The BNC cable from the front-end signal output must connect to an analog input on the PowerLab. If you have an older PowerLab that has differential (rather than single-ended) inputs, the front-end must connect to a positive input.

Single Front-ends

Connect the I²C output of the PowerLab to the I²C input of the front-end using the I²C cable provided. Figure 2–1 shows how to connect up a single front-end to your recording unit.

Figure 2–1 Connecting a front-end to the PowerLab: a PowerLab has only one I²C output, and each front-end has one I²C output and one I²C input

Check that the connectors for the I²C bus are screwed in firmly. Check the BNC cable for firm connections as well. Loose connectors can cause erratic front-end behavior, or may cause the front-end to fail to work at all.

The Signal Output Socket

The BNC socket labelled Signal Output on the back panel of the front-end provides the signal output to connect to an analog input socket on the front of the PowerLab. A BNC-to-BNC cable is supplied for this connection. If necessary, use a BNC to DIN smart adapter [MLAC22] to connect the BNC cable to your PowerLab’s input.

Note: If you have an older PowerLab with differential (rather than single-ended) inputs, the BNC cable must connect to a positive analog input on the PowerLab.
Multiple Front-ends

Multiple separate front-ends can be connected up to a PowerLab. The initial front-end should be connected with the I2C cable as in Figure 2–1. The remainder are daisy-chained via I2C cables, connecting the I2C output of the last connected front-end to the I2C input of the front-end to be added (Figure 2–2).

The number of normal front-ends that can be connected to a PowerLab depends on the number of analog input channels on the PowerLab. Each BNC cable from a front-end should be connected to one analog input channel on the PowerLab, for example, Input 1 on a /30 or /35 series PowerLab.

**Note:** Only one Stimulator front-end such as a Stimulus Isolator can be connected to the positive output of the PowerLab.

**Special Cases**

Some front-ends have their own specific connection requirements. Please refer to the individual chapter for each front-end in this guide.

**Connecting Stimulator Front-Ends**

The PowerLab analog outputs provide a variable, computer-controlled voltage output that can be used with LabChart, LabTutor, LabStation or Lt to connect a Stimulator front-end, or to stimulate directly, or to control a peripheral device. A voltage output is generated by the PowerLab and delivered via the BNC output sockets, giving positive, negative, differential, or independent stimuli, depending on the PowerLab used and the software settings.

The /20, /25, and /26 series PowerLabs have analog outputs labeled + and –. In contrast, the SP, ST, /30 and /35 series PowerLabs have the outputs labeled Output 1 and Output 2.
For the /20, /25 and /26 series PowerLabs:

The negative (–) output is the complement of the positive (+) output, so the stimuli from the two outputs are mirror images. If one output gives a positive voltage, the other gives a negative one, and the two together give a differential voltage. One Stimulator front-end such as a Stimulus Isolator or Stimulator HC can be connected to the positive output of these PowerLabs.

Note: If you connect the Stimulator HC to a PowerLab that has an in-built Isolated Stimulator, such as a PowerLab 26T, only the external, connected stimulator is used.

For /SP, /ST, /30 and /35 series PowerLabs:

Output 1 and Output 2 can function independently. However, only one Stimulator front-end such as a Stimulus Isolator or Stimulator HC can be connected to the positive output (Output 1) of these PowerLabs. With a Stimulator front-end connected, the second output (Output 2) can function independently, and a second tab appears in the Stimulator dialog in LabChart 7 for Windows. Therefore, Output 2 remains available for other uses, such as creating analog waveforms and triggering other systems.

Maximum Number of Front-Ends

The I²C bus can control a maximum of sixteen front-ends. Therefore, if you are using a PowerLab 16/30, which has sixteen input channels, you can record from sixteen single channel front-ends.

Using ADInstruments Programs

Front-ends are designed for use with PowerLabs and ADInstruments programs such as LabChart, LabTutor, LabStation and Lt. The functions of the front-end are combined with those of the PowerLab, and are presented as a single set of software controls in the ADInstruments program. Depending on the front-end(s) connected, front-end-specific dialogs replace the Input Amplifier dialogs or the Stimulator dialog.

The LabChart Help detail the Input Amplifier and Stimulator dialogs, and explain relevant terms and concepts, but they do not cover front-end-specific features. These features are described in detail in the following chapters for each front-end.

Front-end Drivers

A device driver is a piece of software that allows the computer’s operating system and other software to interact with a hardware device. ADInstruments applications like LabChart communicate with a front-end via an appropriate front-end driver. These drivers are automatically set up on the computer when ADInstruments applications are installed, and their operation is usually invisible to the user.

However, under certain circumstances you may receive an error message during the startup of LabChart indicating that there is a problem with the front-end driver. Subsequently, the front-end will not function. This is invariably caused by the absence or incompatibility of a driver required for communication with the front-end due to an old version of the software being run. The problem can be remedied simply by reinstalling...
and rerunning a current version of the software, which will include the latest front-end drivers.

**The Front-end Self-test**

Once the front-end is properly connected to the PowerLab, and the proper software is installed on the computer, a quick check can be performed on the front-end. To perform the self-test:

- Turn on the PowerLab and check that it is working properly, as described in the owner’s guide that was supplied with it.
- Once the PowerLab is ready, start LabChart, LabTutor, LabStation or Lt.
- While the program is starting, watch the Status indicator on the front-end’s front panel. During initialization, you should see the indicator flash briefly and then remain lit.

If the indicator lights correctly, the front-end has been found by the PowerLab and is working properly. If the indicator doesn’t light, check your cable connections and repeat the start-up procedure.

**Software Behavior**

When a front-end is connected to a PowerLab and the ADInstruments software is successfully installed, the Input Amplifier… menu command from the Channel Function pop-up menu in LabChart should be replaced by the <Front-end>... menu command.

For example, with a Bio Amp front-end connected, Bio Amp… should appear in the Channel function pop-up menu.

![Figure 2–3](image)

Channel Function pop-up menu in LabChart with the Bio Amp front-end connected

If the application fails to find a front-end attached to a channel, the normal Input Amplifier… command or button remains. If you were expecting a connected front-end, you should close the program, turn everything off, check the connections, restart the PowerLab and then relaunch LabChart, LabTutor or the Kuraloud Desktop App.
Preventing Problems

Several problems can arise when using the PowerLab system for recording biological signals. It is important to understand the types of problems that can occur, how they manifest themselves, and what can be done to remove them or to minimize their effect. These are usually problems of technique, and should be addressed before you set up your equipment.

Aliasing

Recordings of periodic waveforms that have been undersampled may have misleading shapes and may also have artifacts introduced by aliasing. Aliasing occurs when a regular signal is digitized at too low a sampling rate, causing the false appearance of lower frequency signals. An analogy to aliasing can be seen in old films: spoked wagon wheels may appear to stop, rotate too slowly or even go backwards when their rate of rotation matches the film frame speed – this is obviously not an accurate record.

The Nyquist–Shannon sampling theorem states that the minimum sampling rate ($f_s$) to accurately describe an analog signal must be at least twice the highest frequency in the original signal. Therefore, the signal must not contain components greater or equal to $f_s/2$. The term $f_s/2$ is known as the Nyquist frequency ($f_n$) or the ‘folding frequency’ because frequencies greater than or equal to $f_n$ fold down to lower frequencies about the axis of $f_n$.

When aliasing of noise or signals is seen, or even suspected, the first action you should take is to increase the sampling rate. The highest available sampling rates are 100k /s or 200k /s, depending on your PowerLab. To view the frequencies present in your recorded signal open the Spectrum window in LabChart. For more information about Spectrum, see the LabChart Help Center.

If unwanted high-frequency components are present in the sampled signal, you will achieve better results by using a low-pass filter to remove them. The best kind of filter for this purpose is the Anti-alias filter option available in the front-end-specific Input Amplifier... dialog. This is a special low-pass filter that is configured to automatically remove all signals that could alias; i.e., those whose frequency is greater or equal to half the sampling rate.

For certain PowerLabs, the Anti-alias filter option is not available. Therefore you should select an appropriate low-pass filter to remove any unwanted signals (or noise) occurring at frequencies greater or equal to half the sampling rate.

Frequency Distortion

Frequency distortion will occur if the bandwidth of your recording is made smaller than the bandwidth of the incoming signal. For example, if an ECG was measured with a sampling rate of 100 samples per second (100 Hz) and the Bio Amp had a low-pass filter applied at 50 Hz, the fast-changing sections of the waveform (the QRS complex) may appear smaller and ‘blunted’, while the slower T-wave sections remain relatively unchanged. This overall effect is called frequency distortion.

It can be eliminated by increasing the frequency cut-off of the low-pass filter in the front-end-specific Input Amplifier... dialog to obtain an undistorted waveform.
Similarly, if the high-pass filter was set too high, the amplitude of the T-wave sections may be reduced. The **Input Amplifier...** dialog allows you to examine ECGs and similar slowly changing waveforms to fine-tune filter settings before recording.

**Saturation**

Saturation occurs when the range is set too low for the signal being measured (the amplification, or gain, is too high). As the signal amplitude exceeds the allocated range, the recorded waveform appears as if part of the waveform had been cut off, an effect referred to as clipping.

Clipping can also be caused by excessive baseline offset: the offset effectively moves the whole waveform positively or negatively to an extent that causes all or part of it to be clipped. This problem is overcome by selecting a higher range from the Range menu in the front-end-specific **Input Amplifier...** dialog. In the case of excessive baseline offset, you may wish to apply a high-pass filter with a higher frequency cut-off.

**Ground Loops**

Ground loops occur when multiple connected pieces of recording equipment are connected to mains power grounds. For safety reasons, all electrical equipment should have a proper connection to the mains power grounds, or to a primary earth connection in situations where a mains ground connection is not available. Connecting linked electrical equipment to a common earth connection (equipotential connection point) – such as the earthing (grounding) stud provided on the rear of all PowerLabs – can prevent ground loops.

The electric fields generated by power lines can introduce interference at the line frequency into the recorded signal. Electromagnetic fields from other sources can also cause interference: fluorescent tubes, apparatus with large transformers, computers, laptop batteries, network cables, x-ray machines, microwave ovens, electron microscopes, even cyclic air conditioning.

Reasonable care in the arrangement of equipment to minimize the ground loop area, together with proper shielding, can reduce electrical frequency interference. For example, use shielded cables, keep recording leads as short as possible, and try twisting recording leads together. For sensitive measurements, it may be necessary to place the subject (the biological source) in a Faraday cage.

Interference should first be minimized, and then you can turn on the Mains filter in the front-end-specific **Input Amplifier...** dialog.

**Mains filter**

The Mains filter (/20, /25, /30, /35 and 26T PowerLabs) allows you to filter out interference at the mains frequency (typically 50 or 60 Hz). The mains filter is an adaptive filter which tracks the input signal over approximately 1 second. A template of mains-frequency signal present in the input is computed from the signal. The width of the template is the mains power period (typically 16.6 or 20 ms) as determined from zero-crossings of
the mains power. The filtered signal is obtained by subtracting the template from the incoming signal.

In comparison with a conventional notch filter, this method produces little waveform distortion. It attenuates harmonics of the mains frequency as well as the 50 or 60 Hz fundamental and therefore effectively removes non-sinusoidal interference, such as that commonly caused by fluorescent lights.

The filter should not be used when:

- the interference changes rapidly. The filter takes about 1 second to adapt to the present level. If interference is present and then is suddenly removed, interference in the filtered signal will temporarily worsen.
- your signal contains exact factors or harmonics of frequencies close to the mains frequencies, for example, a 30 Hz signal with 60 Hz mains frequency.
- your signal is already free from interference. If the signal-to-noise ratio is greater than about 64 the mains filter introduces more noise than it removes.
- you are recording at close to maximum sampling rates. The mains filter uses some of the PowerLab’s processing power and therefore reduces the maximum rate at which you can sample.

**Electrode Contact**

Occasionally one of the lead wires connecting the subject to the front-end may become disconnected, or an electrode contact may become poor. If this should happen, relatively high voltages (potentials) can be induced in the open wire by electric fields generated by power lines or other sources close to the front-end or the subject. Such induced potentials will result in a constant amplitude disturbance in the recorded waveform at the power line frequency (50 or 60 Hz), and loss of the desired signal. If the problem is a recurring one, one of the leads may be faulty. Check connections and replace faulty leads, if necessary.

**Motion Artifacts**

A common source of artifacts when recording biological signals is due to motion of the subject or equipment. Often applying a high-pass filter can help to remove slowly changing components in a recorded signal.

- Muscular activity generates its own electrical signals, which may be recorded along with an ECG, say, depending on the location of the electrodes.
- If an electrode is not firmly attached, impedance (and hence the recorded signal) may vary as the contact area changes shape owing to movement.
- Movement of patient cables, particularly bending or rubbing together (triboelectric effects) may generate artifacts in a signal.
- Subject respiration can also generate a signal; breathing can result in a slowly changing baseline corresponding to inspiration and expiration.

If the subject is liable to move during recording, then special care needs to be taken when attaching the electrodes and securing the patient leads. Make sure the skin is cleaned and lightly abraded before attaching the electrodes.
Chapter 1

Spirometer

The FE141 Spirometer is a modular device, in a family called front-ends, designed to extend the capabilities of the PowerLab system. The Spirometer is a precision differential pressure transducer for measurement of respiratory variables.

The Spirometer is essentially an extension of the PowerLab’s analog input. The Spirometer provides:

- a precision differential pressure input used to determine flow rates using an attached flow head;
- the additional amplification necessary to deal with a variety of flow rates, from fractions of a liter per minute (mice and rats) to a thousand liters per minute (adult humans during exercise);
- additional programmable filtering to remove unwanted signal frequencies; and
- digitally controlled zeroing circuitry, for offset removal of unwanted constant flow rates, for instance, to measure volume accurately when using computed integration.
The Spirometer

The Spirometer [FE141] is a precision differential pressure transducer for measuring respiratory variables such as inspiration and expiration flows, hence allowing the calculation of tidal volumes. It measures differential pressure across fine gauze mounted in a flow head. With a flow head of a suitable size, the Spirometer can be used with a variety of creatures, from small animals such as mice and rats, to large animals and humans. Accessories such as flow heads (various sizes), tubing, and calibration syringes are available and can be purchased separately.

The rest of this chapter contains general information about the features, connections, and indicators of the Spirometer. It also looks at the flow head and its calibration for spirometry. More detailed information can be found in the technical section.

The Front Panel

![Figure 1–1]

The front panel of the Spirometer

The Status Indicator

When an ADInstruments program such as LabChart starts up, the Status indicator light should flash briefly and then remain green, indicating that the program has found the front-end, checked and selected it, and is ready to use it. If it does not turn on and stay on when the program is run, this indicates either that the front-end is not connected properly or that there is a software or hardware problem.

The Spirometer Input Fittings

Connections are made to the Spirometer using two female Luer fittings on the front panel. These are physical connections for airflow, not electrical ones. Two flexible plastic tubes (3 mm internal diameter, 5 mm external diameter) connect the female Luer fittings on the Spirometer to the connection pipes on the flow head. The female Luer fittings carry a warning symbol (see margin).
The Back Panel

I2C Input and Output Sockets

Two nine-pin sockets are used to communicate with the PowerLab (they are marked ‘I2C Bus’: a ‘bus’ is simply information-transmission circuitry such as cables and connectors). These sockets, in conjunction with the proper cables, allow multiple front-ends to be used independently with one PowerLab. Power and control signals to connected front-ends come from the PowerLab. ADInstruments front-ends are connected to each other in series, output to input (discussed in more detail in the next chapter).

The Analog Out Socket

The Signal Output provides the signal to an analog input socket on the front of the PowerLab. A BNC-to-BNC cable is supplied for this connection.

Connecting to the PowerLab

To connect a front-end to the PowerLab, first ensure that the PowerLab is turned off. Failure to do this may damage the PowerLab, the front-end, or both.

Connect the Signal Output on the rear panel of the Spirometer to an analog input on the front panel of the PowerLab using a BNC cable.

Single Front-ends

Connect the I2C output of the PowerLab to the I2C input of the front-end using the I2C cable provided.
Check that the plugs for the I²C bus are screwed in firmly. Check the BNC cable for firm connections as well. Loose connectors can cause erratic front-end behavior, or may cause the front-end to fail to work at all. The BNC cable can be tucked under the front-end to keep it out of the way if desired.

**Multiple Front-ends**

Multiple front-ends can be connected up to a PowerLab; up to sixteen, depending on the number of positive inputs sockets on the PowerLab. The first front-end is connected with the I²C cable as in Figure 11–3. The remainder are daisy-chained via I²C cables, connecting the I²C Output of the previous connected front-end to the I²C Input of the next front-end to be added (Figure 11–4). The BNC cable for each front-end is connected to one of the analog inputs of the PowerLab.
Using LabChart

Front-ends are used with PowerLabs and ADInstruments programs such as LabChart. The combined amplification and filtering of the Spirometer, the PowerLab and the program are presented as a single set of software controls.

When the Spirometer is connected to a channel and successfully installed, the **Input Amplifier**... menu command from the Channel Function pop-up menu in LabChart is replaced by the **Spirometer**... menu command. The LabChart Help Center has details on the Input Amplifier dialog, and explain some of the software terms used here.

If the application fails to find a front-end attached, the normal text remains. If you were expecting a connected front-end, close the program, turn the PowerLab off and check the connections. Then turn on the PowerLab and restart the program.

Choosing the **Spirometer**... menu command will open the Spirometer dialog. Only the Spirometer dialog for LabChart is described here, but the Spirometer dialog for Scope is similar.

**The Spirometer dialog**

The Spirometer dialog allows software control of the combined filters and other circuitry in the PowerLab and Spirometer. Change settings in the dialog, then click **OK** to apply them.

To set up many channels quickly, open the **Setup > Channel Settings**... dialog. Here you can view all the channels that are turned on, and you can turn off any unnecessary channels. Clicking on **Spirometer**... in the Input Settings column of the Channel Settings dialog will also open the Spirometer dialog.

---

**Figure 1–5**  
The Spirometer dialog  

![The Spirometer dialog](image)

- **Signal amplitude**
- **Pause/Scroll buttons**
- **Range options**
- **Filter options**
- **Amplitude axis**
- Click this to remove the offset for the spirometer
Signal Display
The signal at the channel input is displayed so you can see the effects of changing settings – data is not recorded while setting things up. The average signal value is displayed at the top of the display area: the offset is displayed when the Spirometer is not zeroed, and may indicate a problem if it is large.

You can shift and stretch the vertical Amplitude axis by clicking and dragging it in various ways, to make the best use of the available display area. It functions in the same as the Amplitude axis of the Chart Window – the controls are identical and any change is applied to the Chart Window.

Setting the Range
The Range pop-up menu lets you select the input range or sensitivity of the channel. Changing the range in the Spirometer dialog is equivalent to changing it in the Chart or Scope window. The available ranges are 500 mV, 200 mV, 100 mV, 50 mV and 20 mV. The default range is 200 mV.

Filtering
The Low Pass pop-up menu gives a choice of 1, 10 and 100 Hz low-pass filters. These filters are appropriate for the built-in pressure transducer in the Spirometer and help to eliminate high-frequency components, such as noise, from the input signal.

Inverting the Signal
Click the Invert checkbox to invert the signal displayed on screen. It provides a simple way to change the polarity of the recorded signal without having to swap the tubes on the Spirometer or flow head. For example, you might be recording an experiment where expiration gives a positive signal, but you want the expired air to give a negative signal on the screen. The Invert checkbox would change the display.

Zeroing
The Spirometer is effectively a pressure transducer and amplifier, transducing flow into voltage. Transducers almost always produce some amount of signal, usually small, when at equilibrium or rest. Prior to making a recording, offsets need to be removed, in a process called zeroing. This enables more accurate measurement of the changes in the signal under stimulus.

Before zeroing, the signal value above the display area shows this offset – if it is large, it may indicate a problem. To perform automatic zeroing, click Zero. The program works out a corrective DC voltage that cancels, as closely as possible, the transducer output voltage. Auto-zeroing takes a few seconds to work out the best zeroing value at all ranges.
Note: Variations in the transducer signal during the auto-zeroing operation will cause the software to fail to zero the offset properly. Make sure the Spirometer and flow head are kept still and that there is no airflow during the auto-zeroing.

Units

Click **Units...** to open the Units Conversion dialog, with which you can set the units for a channel and, using waveform measurements, calibrate the channel. The waveform in the data display area of the Spirometer dialog is transferred to the data display area of the Units Conversion dialog. (Use the Pause button to capture a specific signal.) This units conversion only applies to subsequently recorded signals, so it is more limited than choosing **Units Conversion...** from the Channel Function pop-up menu, as it does not allow the conversion of previously recorded data.

Using the Spirometer

The ADInstruments Spirometer and attached flow head together function as a pneumotachometer, with an output signal proportional to the airflow during breathing. Airflow is measured by means of a pressure differential across a fine wire mesh inside the flow head. This works on the principle that air flowing through an orifice of fixed cross-section produces a pressure difference across the mesh proportional to the air’s velocity – within certain limits. The greater the velocity of the air (that is, the higher the flow), the larger the pressure difference.

The flow head itself contains no electronic parts, and is simply a tube with a wire mesh placed across it. Two pipes, one on either side of the mesh, allow the pressure difference to be measured by a high-precision differential pressure transducer in the Spirometer itself, when connected with plastic tubing.
• MLT1L Respiratory Flow Head, 1 L/min, suitable for mice
• MLT10L Respiratory Flow Head, 10 L/min, suitable for rats
• MLT300L Respiratory Flow Head, 300 L/min, suitable for adult humans at rest
• MLT3813H Heated Pneumotach, 800 L/min, suitable for adult humans during exercise
• MLT1000L Respiratory Flow Head, 1000 L/min, suitable for adult humans during exercise.

Fitting the Flow Head

To connect the flow head to the Spirometer, simply push the ends of the two connection tubes firmly over the flow head pipes and over the female Luer fittings on the front panel of the Spirometer. In some cases you may find that the tubes are difficult to fit because they are too tight. If so, dip the ends of the tubes into some boiling water to soften the plastic to make it easier to push the tubes onto the pipes.

Any leakage from the connections will affect the precision of the flow readings, so ensure that the tubes are pushed in firmly. The flow head is washable and can be cold-sterilized, and should be dried gently before use. Care should be taken to ensure that condensation does not block the tubing connecting the flow head to the Spirometer. To avoid problems, the flow head should be turned so that the tubing connects at the top, not at the bottom.

More elaborate setups are possible. For human respiration, disposable mouthpieces and filters are widely used, to prevent contamination between subjects and to minimize drift due to moisture (the filter helps remove droplets). For humans during exercise, the flow head could be fixed in position, perhaps attached to a stand, and connected to a mouthpiece and filter by a length of wide-bore flexible tubing, to allow the subject to exercise freely. To obtain useful results with any method of spirometry, all the air breathed by the subject must be measured. A nose clip prevents inadvertent nasal breathing. With a little practice, the subject can prevent air leaks around the mouthpiece.

ADInstruments supplies suitable accessories separately:
• MLA140 Spirometer kit (containing each item below)
• MLA1026 Pack of 10 vinyl disposable mouthpieces
• MLA1008 Pack of 50 foam-tipped disposable nose clips
• MLA304 Pack of 50 disposable droplet filters
• MLA1011A Clean bore tubing, 250 mm long by 35 mm i.d.

Calibrating the Flow Head

Before using the flow head, you will probably want to calibrate the Spirometer to read in terms of flow (L/s rather than V). There are two ways of doing this: using an approximate conversion factor, or injecting a known volume and integrating. The Spirometry Extension for LabChart, which is available as a free download for both Windows and Macintosh, can be used to assist with either of these methods.

Extensions are available from LabChart’s Feature Manager, or from the ADInstruments website. To open Feature Manager, on Windows choose Help > Feature Manager… and on Macintosh choose LabChart > Feature Manager…. For more information, see the LabChart Help Center.

Using an approximate conversion factor

You can use an approximate conversion value for converting the voltage signal to L/s. For the MLT1000L Flow Head, the linear conversion is given approximately by 0 V = 0 L/s; 1 V = 40.1 L/s. You apply this conversion in the Units Conversion dialog, opened from the Channel Function pop-up menu.

Injecting a known volume and integrating

You can determine an accurate conversion value for your particular flow head by injecting a known volume of air through the breathing circuit and integrating the flow signal in LabChart. This section describes the procedure in detail.

ADInstruments has calibration syringes available for this purpose, such as the a 3-liter MLA5530 calibration syringe. Try to depress the plunger at a steady rate, neither too quickly or too slowly, and try not to bring the plunger to an abrupt stop at the end of the syringe.

Connect the Spirometer to an input on the PowerLab. Set up that input channel using the Channel Settings dialog:

1. Change the channel name to ‘Flow’.
2. Click Spirometer… in the Input Settings column to display the Spirometer dialog.
3. Set the range to a suitable value, such as 500 mV or 200 mV.
4. Click Zero to zero the flow head signal. You should always do this before you start a recording.
5. Set up a new channel called ‘Volume’ in the Channel Settings dialog. To display the integral of the flow signal in this channel, choose Integral… from the Channel Function pop-up menu. In the Integral dialog, select Flow as the source channel, and use a standard integral with no reset.

Injections can now be recorded and integrated using the spirometer (Flow) and Volume channels. Making a single injection should produce a trace similar to that shown in
Figure 11–8, in which a 3 L calibration syringe was used to simulate a single expiration. The absolute value of the integral at the cursor position is 76.79 mV.s. This corresponds to a flow head correction factor of 39.1 L/s/V, obtained by dividing the syringe volume by the integral value (converted to V.s).

\[
\frac{3 \text{ L}}{0.07679 \text{ V.s}} = 39.1 \text{ L/s/V}
\]

The correction factor is applied in the Units Conversion dialog: (0 V = 0 L/s; 1 V = 39.1 L/s). Click OK to apply the units conversion and close the dialog.

Using the Spirometry Extension

The Spirometry Extension for LabChart (for either the Windows or Macintosh platforms) is available as a free download using Feature Manager in LabChart, or from the ADInstruments website.

The Spirometry Extension can be used to perform the units conversion required for the Spirometer channel, by using either an appropriate conversion value for your flow head, or a value calculated by integrating the injection of a known volume. The extension adds an item called Spirometry Flow... to the Channel Function pop-up menu.
Full details on using the Spirometry Extension can be found in the *Spirometry Extension User’s Guide* (Macintosh), or in the *LabChart Help Center* (Windows), both of which are installed with the software.

**Reducing Drift**

The Spirometer is subject to drift for various reasons. There are a number of ways to reduce this. Zeroing the Spirometer immediately before use is an essential step in the setup procedure. Zeroing ensures that the recorded flow signal is zero when there is no airflow, and thereby prevents steady drift of the integrated volume trace.

- Internal drift in the Spirometer’s electronics is minimized if you leave the PowerLab unit and Spirometer turned on for 15 minutes or so, before zeroing and use. We recommend placing the Spirometer beside the PowerLab unit, or on a shelf above, to avoid its being affected by heat from the power supply.
- Expired volume is greater than inspired volume in most atmospheric conditions. The increase, due to warming and humidification, is typically 5–10%. For this reason there may be ‘breath-dependent drift’ of an integrated (volume) trace even when the Spirometer is correctly zeroed. Non-ideal distribution of air flow across the flow head’s mesh screen may also contribute to breath-dependent drift. This component of drift is minimized by use of disposable droplet filters.
- Finally, if you are using the Spirometry Extension, you can apply drift correction after recording, provided that your recording meets certain conditions.

For more details on drift correction, please refer to the *Spirometry Extension User’s Guide* (Macintosh) and the *LabChart Help Center* (Windows).
Technical Aspects

The Spirometer and other ADInstruments front-ends have been designed to integrate fully into the PowerLab system. Each requires connection to the PowerLab via a special communications connector called the I\textsuperscript{2}C (eye-squared-sea) bus, and a BNC connector.

The internal functions of the Spirometer are controlled from the PowerLab through the I\textsuperscript{2}C bus, which also supplies power to the Spirometer. The front-end is also connected to an analog input channel of the PowerLab via a BNC-to-BNC cable, through which the pressure signal from the flow head is sent. The overall operation of the Spirometer can be better understood by referring to Figure 11–10.

The Spirometer and an attached flow head together function as a pneumotachometer, with an output signal proportional to the airflow rate during breathing. Expired or inspired air has to pass through a very fine wire mesh in the attached flow head. This creates a pressure differential between the two sides of the mesh proportional to the flow rate or velocity of the air passing through the flow head. The input of the Spirometer is a differential pressure transducer that converts the differential pressure in the flow head into an analogous voltage. This output voltage is in turn fed into a programmable gain amplifier, which provides additional signal amplification. The output of the amplifier is passed through a set of software-selectable, fourth-order, low-pass filters. The signal is then sent to the PowerLab.

To remove any offsets caused by its pressure transducer or a signal baseline, the Spirometer uses a DC offset circuit consisting of a 12-bit DAC (digital-to-analog converter) that is internally connected to the input stage when in the DC coupling mode.

Zeroing of offsets is achieved by applying a corrective DC voltage to the input stage via the DAC, under software control. Since the DAC is only capable of producing corrective voltages in ‘steps’, a facility to set the offset range is provided to decrease the size of these steps and make the zeroing circuit more sensitive, especially at the higher range settings.
Troubleshooting

If the solutions here do not work, earlier chapters, the LabChart Help Center, and the guide to your PowerLab may contain possible solutions. If none of the solutions here or elsewhere are of help, then consult your ADInstruments representative.

Most of the problems that users encounter are connection problems, and can usually be fixed by checking connections and starting up the hardware and software again. Very rarely will there be an actual problem with the Spirometer front-end or the PowerLab itself.

Problems and Solutions

The status indicators fail to light when the software is started, or the front-end commands and so on do not appear where they should

The I²C cable or the BNC-to-BNC cable from the front-end to the PowerLab is not connected, has been connected incorrectly (to the wrong input or output, for instance), or is loose.

• Turn everything off. Check to see that all cables are firmly seated and screwed in. The BNC cable from the Signal Output of the Spirometer must be connected to a positive input on the PowerLab. Make sure the input is the same channel from which you expect to use the front-end in the software. Start up again to see if this has fixed the problem.

You are using an early version of LabChart.

• Upgrade to the latest version of the software. Contact your ADInstruments representative for information.

The BNC or I²C cable is faulty.

• Replace the cable and try again. Immediately label all cables proved faulty so that you don’t use them again by accident.

The front-end is faulty.

• This is the least likely event. If the front-end will not work properly after the previous measures, then try using it on another PowerLab. If the same problems recur with a second PowerLab, the front-end may be faulty. Contact your ADInstruments representative to arrange for repairs.

On starting up the software, an alert indicates that there is a problem with the front-end or driver

The correct Bridge driver is not installed on your computer.

• Reinstall the software.

You are using an early version of LabChart.

• Upgrade to the latest version of the software. Contact your ADInstruments representative for information.

The BNC or I²C cable is faulty.
• Replace the cable and try again. Immediately label all cables proved faulty so that you don’t use them again by accident.

The front-end is faulty.
• This is the least likely event. If the front-end will not work properly after the previous measures, then try using it on another PowerLab. If the same problems recur with a second PowerLab, the front-end may be faulty. Contact your ADInstruments representative to arrange for repairs.

Some software settings don’t resemble those in this guide

You are using an early version of the front-end driver, or of LabChart. Some changes may have been made since then.
• Upgrade to the latest version of the software. Contact your ADInstruments representative for information.

The trace will not zero properly when using the automatic or manual zeroing controls

Variations in the signal during auto-zeroing may cause the software to fail to zero the offset properly, if it zeroes at all.
• Make sure that the apparatus is kept still and that no varying signal is applied during auto-zeroing.

The signal from the flow head is beyond the range of the Spirometer’s zeroing circuitry.
• You may need to use another, more suitable, flow head.

The signal is noisy at lower ranges

This is usually the amplified noise from the transducer and its associated circuitry, not a fault as such.
• Set the low-pass filter to remove the noise.

The signal recorded by the Spirometer is weak even at lower ranges

The tubing connection to the flow head may be leaking, or there is condensation in the tubing or on the gauze of the flow head.
• Check the connection and try again.
• Ensure that both the tubing and gauze is clean and is free from condensation, otherwise dry it. Make sure that the flow head is used with the tubes in an upward direction.

The signal is inverted and inspiration is appearing as a downwards deflection.

The two tubing connections to the spirometer may have been swapped over, or the flow head is being used in the reverse direction.
• Either swap the tubing connections over, or change the orientation of the flow head.
• If this is inconvenient, select the Invert checkbox in the Spirometer dialog to change the polarity of the signal.
Specifications

**Input**

Safety: Approved to IEC 60601-1 Standard (BF rating)

EMC: Approved to EN61326-1:2006 Standard

Connection type: Two female Luer fittings to enable connection to flow head via male Luer fittings and suitable plastic tubing

Configuration: Differential pressure input, ± 1" (2.5 cm) H₂O (1.9 mmHg, 249 Pa)

Input range: ± 20 mV to ± 500 mV full scale in 5 steps (combined PowerLab and Spirometer)

<table>
<thead>
<tr>
<th>Volts</th>
<th>inches H₂O</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>± 500 mV</td>
<td>± 1</td>
<td>± 15.6 μV</td>
</tr>
<tr>
<td>± 200 mV</td>
<td>± 0.4</td>
<td>± 6.25 μV</td>
</tr>
<tr>
<td>± 100 mV</td>
<td>± 0.2</td>
<td>± 3.125 μV</td>
</tr>
<tr>
<td>± 50 mV± 0.1</td>
<td>± 1.56 μV</td>
<td></td>
</tr>
<tr>
<td>± 20 mV± 0.04</td>
<td>± 0.625 μV</td>
<td></td>
</tr>
</tbody>
</table>

Maximum input pressure: ± 28.1" H₂O (7 kPa)

Pressure sensitivity: 0.5 V/inch (1.27 V/cm) H₂O

Temperature drift: 0.05% of full scale per °C

Warm-up time: ~ 2 minutes

Max zero pressure offset: < 1% full scale, software removable

Zero offset correction: Software removed (up to ± 10% full scale)

Response time: 1 ms (10–90% full scale) at maximum bandwidth

Linearity: ± 0.5% full scale

Repeatability: ± 0.25% full scale

Long term stability: ± 0.5% full scale

Amplifier noise: < 150 μV\text{rms} @ 100 Hz

< 50 μV\text{rms} @ 10 Hz

< 35 μV\text{rms} @ 1 Hz

**Filters**

Low-pass filtering: 1, 10 or 100 Hz (software-selectable) using fourth-order Bessel filter
Control Port

I²C port: Provides control and power. Interface communications rate of ~50 kbits/s.

Physical Configuration

Dimensions (h × w × d): 55 mm × 120 mm × 260 mm (2.2" × 4.7" × 10.2")
Weight: 1.2 kg (2 lb 11 oz)
Power requirements: 1.5 W
Operating conditions: 5–35 °C, 0–90% humidity (non-condensing)

ADInstruments reserves the right to alter these specifications at any time
Chapter 1

Warranty

Product Purchase and License Agreement
This Agreement is between ADInstruments NZ Ltd [‘ADI’] and the purchaser [‘the Purchaser’] of any ADI product or solution — software, hardware or both — and covers all obligations and liabilities on the part of ADI, the Purchaser, and other users of the product. The Purchaser (or any user) accepts the terms of this Agreement by using the product or solution. Any changes to this Agreement must be recorded in writing and have ADI’s and the Purchaser’s consent.

Responsibilities
The Purchaser and any others using any ADI product or solution agree to use it in a sensible manner for purposes for which it is suited, and agree to take responsibility for their actions and the results of their actions. If problems arise with an ADI product, ADI will make all reasonable efforts to rectify them. This service may incur a charge, depending on the nature of the problems, and is subject to the other conditions in this Agreement. ADI does not separately warrant the performance of products, equipment or software manufactured by third parties which may be provided to Purchaser as part of an overall solution. However, as further noted below, ADI will pass through to Purchaser all applicable third party warranties to the extent it has the right to do so.

ADI Product Hardware Warranty
ADI warrants that PowerLab Data Acquisition Units (PL prefix)1 and Front-ends (FEprefix)2 shall be free from defects in materials and workmanship for five (5) years from the date of purchase. Other PowerLab Data Acquisition Units3, Front-ends4 and Pods5 shall be free of defects in material and workmanship for three (3) years from their date of purchase. ADI also warrants that ADI Specialized Data Recorders6 and Instruments7 shall be free of defects in material and workmanship for one (1) year from their date of purchase. If there is such a defect, as Purchaser’s sole remedy hereunder, ADI will repair or replace the equipment as appropriate, and the duration of the warranty shall be extended by the length of time needed for repair or replacement.
To obtain service under this warranty, the Purchaser must notify the nearest ADI office, or Authorized Representative, of the defect before the warranty expires. The ADI or Representative office will advise the Purchaser of the nearest service center address to which the Purchaser must ship the defective product at his or her own expense. The product should be packed safely, preferably in its original packaging. ADI will pay return shipping costs.
Hardware Warranty Limitations
This warranty applies only to the ADI hardware specified in this document and used under normal operating conditions and within specification. Consumables, electrodes and accessories are not covered by this warranty. Third party equipment may be covered by the third party manufacturer’s warranty. To the extent that ADI has the right to pass through any third party manufacturer warranties to Purchaser it will do so to the extent it is able to do so. Copies of applicable third party manufacturer warranties, to the extent they exist, are available upon request. The warranty provided hereunder does not cover hardware modified in any way, subjected to unusual physical, electrical or environmental stress, used with incorrectly wired or substandard connectors or cables, or with the original identification marks altered. Tampering with or breaking of the Warranty Seal will also void the warranty.

Product Types & Warranty Term

ADI manufactured products covered by a five (5) year warranty
1 Data Acquisition Units: PowerLab 35 series with PL prefix
2 Front-ends: ADI Front-end Signal Conditioners with FE prefix.

ADI manufactured products covered by three (3) year warranty
3 Data Acquisition Units: PowerLab 26 series with ML prefix
4 Front-ends: ADI Front-end Signal Conditioners with ML prefix.
5 Pods: The entire range of ADI Pod Signal Conditioners.

ADI manufactured products covered by one (1) year warranty
6 Specialized Data Recorders: Metabolic Systems (e.g., ML240 PowerLab/8M Metabolic System)
7 Instruments: Blood FlowMeter, Gas Analyzers, NIBP System (excluding transducers), STH Pump Controller.

Third Party Products (Including Transducers)
Products not manufactured by ADI are covered by the manufacturer’s warranty.

Accessories and Consumables
Accessories and Consumables are not covered by any type of warranty.

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