

Medical Panel Computer

MLC-AL/MLC-KL



User's Manual

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1 Contents

1	Contents	2
1.1	List of Figures	4
2	Revision History	5
3	General Information.....	6
3.1	About this Manual	6
3.2	Environmental Responsibility.....	6
3.3	Trademarks.....	6
3.4	Warranty Information	7
3.5	Support, Problems and Failure Analysis.....	7
3.5.1	Recommended action on problems or failures.....	7
3.5.2	Procedure for returning products.....	7
3.5.3	Drivers	8
3.6	Conventions Used in this Manual	8
3.6.1	Conventions for signal words and symbols	8
3.6.2	Conventions for different user groups	8
4	Safety	9
4.1	Intended Purpose	9
4.1.1	Intended purpose of MLC-1XX-XL used as part of third-party medical device systems.....	10
4.2	Safety and Warning Instructions.....	11
4.2.1	General Electrical Hazards.....	11
4.2.2	Specific hazards caused by electrical leakage currents in medical devices	13
4.2.3	Other hazards	13
4.2.4	Hazards with regard to repair and maintenance	17
5	User Information	18
5.1	General Description	18
5.2	Features.....	18
5.3	Packing List	18
5.4	Device Overview	19
5.4.1	Interfaces	19
5.5	Operating the Device	20
5.5.1	Installing the system	20
5.5.2	Connecting Power and Patient Potential Equalization	20
5.5.3	Powering the System On/Off	20
5.6	Cleaning and Disinfection	21
5.6.1	Safety instructions for cleaning and disinfection of the device.....	22
6	Administrator Information	23
6.1	Functional Block Diagram.....	23
6.2	Technical Data of Main System Components.....	26
6.3	Detailed System Components	26
6.4	Maintenance and Service	27
6.4.1	General service intervals	27
7	Specifications	28

7.1	Mechanical Specifications	28
	MLC-133-XL Dimensions	29
7.1.1	MLC-156-XL Dimensions	29
7.1.2	Weight	30
7.2	Electrical Specifications	30
7.2.1	Power supply unit (optional)	30
7.2.2	Power consumption	31
7.3	Environmental Specifications	32
7.4	Classification	32
7.5	Markings and Labels	33
7.5.1	Part number and serial number labels	33
7.5.2	Product identification label	33
7.5.3	Explanation of symbols	34
8	Certificates and Standards	36
8.1	Verification of Compliance – EN55032	36
8.2	Verification of Compliance – EN 60601-1-2	37
8.3	Verification of Compliance – FCC Part 15 Class B	39
9	Appendix	40
9.1	EN 60601-1-2 Tables	40
9.1.1	Guidance and manufacturer's declaration – electromagnetic emissions (IEC 60601-1-2:2007 Table 1)	40
9.1.2	Guidance and manufacturer's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS (IEC 60601-1-2:2007 Table 2)	40
9.1.3	Guidance and manufacturer's declaration — electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (IEC 60601-1-2:2007 Table 4)	41
9.1.4	Recommended separation distances between portable and mobile RF communications equipment and the EUT (IEC 60601-1-2:2007 Table 6)	42
10	Getting Service	43

1.1 List of Figures

Figure 1: Bottom view of connectors.....	19
Figure 2: Power supply unit	20
Figure 3: Power supply unit connected to the Power 12VDC-In connector	20
Figure 4: MLC-1XX-KL functional block diagram.....	23
Figure 5: MLC-1XX-AL functional block diagram.....	24
Figure 6: MLC-1XX-AL USB3/PCIe*/SATA Port Mapping	25
Figure 7: Functional Block Diagram of I/O Board for MLC-1XX-XL	25
Figure 8: VESA 100 mounting hole pattern	28
Figure 9: MLC-133-XL dimensions	29
Figure 10: MLC-156-XL dimensions	29
Figure 11: Part number label	33
Figure 12: Serial number label.....	33
Figure 13: Product identification label.....	33

2 Revision History

Revision	Changes	Date
1.0	Initial release	October 23, 2020

3 General Information

3.1 About this Manual

This user manual will assist you in optimizing the use of your device. The information contained will help prolong the lifetime of the device and avoid possible hazards.

Within this document the official name ADLINK Technology Inc. will hereafter be referred to as ADLINK.

This technical manual contains all relevant and necessary information for safe and best possible failure-free operation of the device. However, this documentation does not claim to provide gap-free completeness regarding every technical detail or equipment models, nor does it include and explain every imaginable installation situation, operating mode or servicing modality. In case any further information not covered by this document is needed, do not hesitate to contact your ADLINK representative.

For further documentation and the latest utilities and drivers, please visit the ADLINK website at www.adlinktech.com or contact your local ADLINK (sales) representative.

The content of this technical manual shall not become part of or modify any prior or existing agreement, commitment or relationship between ADLINK and the owner/user of the device. The sales contract only describes the entire obligations of ADLINK Technology Inc. The warranty contained in the contract between the parties is the sole warranty of ADLINK Technology Inc.

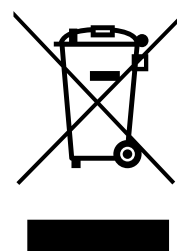
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3.2 Environmental Responsibility

ADLINK is committed to fulfilling its social responsibility to global environmental preservation through compliance with the European Union's Restriction of Hazardous Substances (RoHS) directive and Waste Electrical and Electronic Equipment (WEEE) directive. Environmental protection is a top priority for ADLINK. We have enforced measures to ensure that our products, manufacturing processes, components, and raw materials have as little impact on the environment as possible. When products are at their end of life, our customers are encouraged to dispose of them in accordance with the product disposal and/or recovery programs prescribed by their nation or company.



3.3 Trademarks

Product names mentioned herein are used for identification purposes only and may be trademarks and/or registered trademarks of their respective companies.

3.4 Warranty Information

Your ADLINK product warranty covers material defects and workmanship for the warranty period, starting with the date of shipment. The medical panel computer has an expected service life of 15,000 hours. During the warranty period, ADLINK reserves the option to either repair or replace defective products.

Within the warranty period, repair is free of charge, provided that warranty conditions were observed. Due to high expenditures for test procedures, a test fee will be charged if no fault can be found. Repair services outside of the warranty period will be charged.

For further information regarding tests and measurements made in conjunction with warranty and/or repair services, please refer to section 3.5 below.

3.5 Support, Problems and Failure Analysis

A base knowledge of standard PC technology is required to use ADLINK products, and this information will not be further explained within this manual.

3.5.1 Recommended action on problems or failures

Each ADLINK product has been tested carefully and thoroughly prior to shipment. In the unlikely event that a problem occurs during operation, please check the BIOS and operating system settings of your system. These settings are often a cause of error due to resource conflicts.

Before contacting ADLINK, please visit the website of ADLINK or the websites of the respective hard- and/or software manufactures. If the problem cannot be resolved with this documentation and/or updates alone, please contact ADLINK via e-mail or telephone.

Please be prepared to answer questions such as:

- Which ADLINK product is experiencing a problem?
- What is the serial number of the product?
- Which BIOS version is installed on your device?
- Which OS (version) is installed on your device?
- Has this problem already been reported (by whom, to whom)?
- When did the problem begin occurring?

3.5.2 Procedure for returning products

If you need to return your ADLINK device for servicing, please fill in the **Return Material Authorization (RMA)** form available on the ADLINK website before shipping. In order to repair your ADLINK device as fast as possible, the information requested on the form is required.

Repairs within the warranty period are free of charge provided that warranty conditions were observed. Due to high expenditures for test procedures, a test fee will be charged if no fault can be found. Repair services outside of the warranty period will be charged.

Your ADLINK product warranty covers material defects and workmanship for the warranty period starting with the date of shipment. During the warranty period, ADLINK reserves the option to either repair or replace defective products.

For warranty service or repair, the product must be returned to a service facility designated by ADLINK, prepaid by the customer.

3.5.3 Drivers

Drivers for your ADLINK device are available at <http://www.adlinktech.com>. If you experience any problems, always download and install the latest drivers for your system from this website before contacting ADLINK.

3.6 Conventions Used in this Manual

3.6.1 Conventions for signal words and symbols

**DANGER**

Result and cause of the hazard

indicates a hazardous situation which, if not avoided, *will* result in death or serious injury.

**WARNING**

Result and cause of the hazard

indicates a hazardous situation which, if not avoided, *may* result in death or serious injury.

**CAUTION**

Result and cause of the hazard

indicates a hazardous situation which, if not avoided, *could* result in minor or moderate injury.

**NOTICE**

is used to call special attention to important information related to the device, handling of the device or the respective part of the manual.

3.6.2 Conventions for different user groups

In this manual specific terms are used for two groups of users:

User

The term “user” is applied in this document when a user/operator of the device is using the device according to its intended purpose.

Administrator

The term “administrator” is applied in this document to a person who, in contrast to a common user, has an enhanced level of knowledge and/or has a broader level of operational authorization. For example, such a person may work as an IT administrator in a health care facility or be an authorized service technician, e.g. someone especially trained by ADLINK.

4 Safety

The MLC-AL/ MLC-KL (hereinafter also referred to as MLC-1XX-XL) devices are compliant with the market access regulations of the European Community respectively the equivalent regulations for the national transitions thereof. The devices are labelled with the relevant CE mark in accordance with the relevant provisions. Detailed compliance information and excerpts are contained in Chapters 8 and 9.

4.1 Intended Purpose

The All-in-One MLC-1XX-XL is a medical touch panel computer designed to display, monitor, and store accumulated data while processing medically relevant and/or patient data in medical environments such as:

- surgical OR theatres,
- intensive care units,
- emergency care units, and
- further point-of-care sites

in health care facilities such as hospitals, outpatient care units, and other medical care units.

Handling and operation of the MLC-1XX-XL device shall only be performed by professional personnel of the above-mentioned entities such as medical staff (surgeons, anesthetists, physicians, etc.), nursing personnel and technical personnel working in health care facilities such as IT administrators, medical engineers, and technical service technicians.

The engineering design and constructional characteristics of the device especially considers requirements for usage within the above-mentioned medical environment or other hygiene-sensitive environments with respect to:

- hygienic conditions (e.g. fanless, internal cooling concept),
- quality aspects for displayed / monitored patient data,
- operational control abilities (e.g. with user's hands double gloved),
- further technical design characteristics (e.g. isolated interface ports, etc.).

The MLC-1XX-XL device is intended for use in indoor environments in accordance with the usage environments described above. The device is not intended for outdoor use including use in mobile vehicles such as ambulance cars, helicopters, etc. or in other rough environmental conditions of non-domestic environments.

Any use not in compliance with the defined application purpose described above is not within the scope of the intended purpose.

Improper use, alterations made to the devices, or the use of (spare) parts not approved and released by ADLINK may result in unforeseeable damage. Any use of the device not in accordance with the intended purpose will result in loss of all warranty claims. The risks and possible damage resulting thereof are the full responsibility of the user/operator of the device.

4.1.1 Intended purpose of MLC-1XX-XL used as part of third-party medical device systems

Use in conformity with the intended purpose also includes applications of the MLC-1XX-XL in conjunction with and/or as an integral part of medical device systems such as anesthesia monitoring systems, respiratory monitoring systems, or various other medical system applications formed by a combination of the MLC-1XX-XL with specific medical software.

Medical systems which use an MLC-1XX-XL device as an integral part or a component are manufactured and placed on the market by third-party companies independently from ADLINK Technology Inc. The entire system configuration, technical architecture, etc. and the CE conformity procedure for the created system are then the full responsibility of the respective system manufacturer.

Consequently, the manufacturer of the created system determines the explicit intended use of the integrated MLC-1XX-XL device and/or of the entire medical system.

4.2 Safety and Warning Instructions

4.2.1 General Electrical Hazards

**DANGER**

Risk of electrical shock to the user as well as risk of property damage and damage to the device caused by use of inappropriate mains supplies:

Use an original ADLINK mains supply only and preferably the standard power supply unit delivered with the device. In case another mains supply must be used, it must follow specifications which provide an equivalent safety level as the original mains supply, as well as technical compatibility to the technical specifications of the device. Use of a mains supply not authorized by ADLINK may, in addition to the potential hazards caused, result in a loss of warranty!

**DANGER**

Risk of electrical shock to the user or others and risk of property damage caused by damaged mains connection components:

Never operate the device with a damaged mains supply cable. Damaged mains supply cables including damaged cable plugs must be withdrawn from use immediately. If the mains connection socket of the device is damaged, it must also be withdrawn from operation immediately and must be secured against any further use until the necessary repairs are performed by a trained service technician.

**WARNING**

Risk of electrical shock or other injuries to the user or others and risk of property damage caused by insufficient laid mains supply cables:

Take appropriate care in laying out mains supply cables in order to avoid any possible damage to the cable and to avoid any danger of stumbling over it.

**WARNING**

Risk of electrical shock or other injuries to the user or others and risk of property damage caused by inappropriate conditions of the mains supply socket:

Never use mains supply sockets which are damaged, dusty, or dirty. Make sure that proper connections are made between the mains connector and the mains outlet socket. Improper plug connections may result in injury caused by sparks and/or a fire hazard.

**WARNING**

Risk of electrical shock to the user or others and risk of property damage caused by insufficient (ground) protection line connection:

The device must only be operated at mains supply outlets with a protective ground connection. Intentional disruption of the ground protection line and operation of the device with damaged ground protection either in the connecting cable or the device itself are prohibited.

**WARNING**

Risk of electrical shock to the user or others and risk of property damage caused by overloaded mains supply devices:

Any additional extension cables or multiple outlet sockets being used must be regularly checked to ensure proper condition and secure operation.

Do not overload outlet sockets, extension cables, and multiple outlet socket devices. Doing so may cause electrical shocks or fire hazards.

**WARNING**

Risk of electrical shock to the user as well as risk of property damage and damage to the device caused by overvoltage:

Appropriate overvoltage protection must be provided to avoid dangerous overvoltage to the device such as those caused by thunderstorms.

**WARNING**

Risk of electrical shock to the user as well as risk of property damage and damage to the device caused by ingress of fluids or foreign objects:

Although the device is designed with a high level of protection, it is not fully protected against ingress of fluids.

To ensure proper protection of the device housing from fluid ingress, never expose the device to excessive amounts of fluids (e.g. during cleaning) and especially ensure protection of housing openings (i.e. interface sockets) from fluids of any kind.

**WARNING**

Risk of electrical shock to the user or others and as well as risk of property damage and damage to the device caused by inaccessible mains sockets:

The device does not provide a mains switch for disconnecting it from the mains supply; the mains disconnection element of the device consists of the power supply's mains cable.

Due to this fact, the mains socket and/or the mains cable must be within easy reach for the user at all times. If the device must be integrated into cabinets or other objects, the operating institution must provide a disconnection switch device at the system level (i.e. operation via an all-lines disconnecting mains switch e.g. at the system).

**WARNING**

Risk of electrical shock or other injuries to the user or others and risk of property damage caused by insufficient electrical installations:

Electrical installations must be set up by qualified personnel only. For installation and operation of the device, the responsible operating institution must ensure that the chosen personnel is sufficiently qualified with regard to physical, psychological and emotional condition. It is the responsibility of the operating institution to choose qualified personnel for installation and operation of the device.

4.2.2 Specific hazards caused by electrical leakage currents in medical devices

**WARNING**

Risk of an unacceptable high leakage current to the patient, user or others caused by device interfaces not in use:

Never touch unused interfaces such as USB or COM ports and a patient at the same time!

**WARNING**

Risk of an unacceptable high leakage current to the patient caused by insufficient system configuration:

Accessories connected to analog or digital interfaces must be compliant with the respective European or international standards (e.g. EN 60601-1 for medical devices). Furthermore, all configurations for ME systems must be compliant with the EN 60601-1-1 standard. Users connecting additional devices to a signal input or output are configuring a medical system and are therefore responsible for the system being compliant with the applicable version of the system standard EN 60601-1-1.

In case of doubt, please contact the technical customer support or your local representative.

4.2.3 Other hazards

**WARNING**

Risk of injury to the user or others as well as risk of property damage and damage to the device caused by inappropriate operation conditions:

The device must only be operated within the operation conditions specified by ADLINK.

Never place the device onto heat emitting objects such as radiators or heating ventilators. The environmental temperature must not exceed the maximum temperatures indicated in this documentation. Never place the device into an enclosed housing unless it is ventilated enough to ensure an operational temperature below the allowed maximum.

**WARNING**

Risk of injury to the user or others caused by laser emissions in accessory components:

If your ADLINK device is being operated in combination with a product emitting laser light, (e.g. a barcode reader as accessory), never look into the laser beam. This may result in irreversible damage to the eye. Never use settings or functions other than those described in the documentation of the device and never try to repair or disassemble such accessory devices.

**WARNING**

Risk of injury to the patient caused by inappropriate handling of ceiling mounting equipment:

If the device is mounted to manually adjustable swiveling ceiling supports, always ensure that no collisions with other objects occur when adjustments are made. Harsh collisions may result in damage to the device housing surface by particles that get stripped off thus creating a potential hazard for a patient being present with an open wound.

**WARNING**

Risk of injury to the user or others caused by substances hazardous to health:

Please note that the device may emit substances hazardous to health (gases, fluids) in case of a fire.

**WARNING**

Risk of physical injury to the user or others and danger of damage of the device caused by insufficient mechanical mounting:

When mounting the device, use all four VESA 100 threads on the rear of the device with appropriate screws depending on the thickness of the counterpart. Tighten all four screws firmly to support the weight of the device. Make sure that the suspension system is capable of carrying the device!

**CAUTION**

Risk of burns to the user caused by hot surfaces:

Turn off power and allow the device to cool down prior to connecting/disconnecting peripheral devices or performing any mounting/demounting operations. Do not touch the enclosure for over 10 seconds when the device is in operation or is still hot from previous use.

**CAUTION**

Risk of injury to the user or others, danger of damage to property and danger of damage of the device caused by insufficient mounting or operating places:

The user is responsible for ensuring safe mounting conditions of the device to or on transport devices as well as for observing the safety instructions for the transport vehicles itself. Improper handling may lead to injuries or property damage.

Ensure that the carts, trolleys, surfaces, vehicles, or tables the device is being attached to or onto are stable enough and are able to bear the applied weight.

Secure the device against accidental movement and from falling down.

Please contact your ADLINK partner for further information about appropriate mounting devices.

**CAUTION**

Risk of injury to the user or others as well as risk of damage to the device caused by lifting and manual transport of the device:

When lifting and transporting the device, consider the product's weight. Move, carry, and put down the device carefully in order to avoid back or other injuries.

**CAUTION**

Health hazard to the user caused by allergenic substances:

As with all industrial products, the device may contain substances (e.g. nickel, aluminum) which may induce an allergic reaction. If you suspect an allergic reaction (i.e. skin reaction, frequent sneezing, red eyes, inhalation restrictions or any other similar symptom), immediately consult a physician to determine the cause.

**CAUTION**

Risk of damage to the device caused by inappropriate usage aids:

If your device is equipped with a touchscreen display, operate this touchscreen only with your finger(s) or an input pen specifically designed for this purpose.

Never use hard, sharp, or tapered objects, e.g. pencils, ball pens, knives, etc. to avoid damage to the touchscreen.

**CAUTION**

Risk of damage to the device caused by environmental influences:

Never expose your device to excessive vibration, heat or mechanical force. This may lead to damage of your device or parts of it.

**CAUTION**

Risk of damage to the device caused by aggressive chemical substances:

Although your device is resistant against many aggressive chemical substances, some substances such as acids, chlorine and chlorine dissipating solutions may damage the housing, seals and/or the display.

Please contact your ADLINK representative for further information.

**CAUTION**

Risk of damage to the device caused by climatic influences:

Never operate your device under condensing conditions which may occur e.g. if the device is brought directly from a cold to a warm surrounding.

**CAUTION**

Risk of damage to the device itself or devices connected to it caused by influences of electromagnetic fields resulting in the device becoming inoperable:

The device is comprehensively protected against influences of electromagnetic fields by constructional measures (see Chapter 9 regarding electromagnetic immunity). However, the device is not capable of operating in close proximity to electromagnetic radiation sources which may emit especially high electromagnetic radiation, e.g. certain HF surgery devices, MR devices or cell phones. Ensure a minimum distance of 2 meters from these kinds of devices when operating the MLC-1XX-XL.

**CAUTION**

Risk of damage to the device itself or devices connected to it caused by incorrect handling of peripheral devices:

Before connecting your device to additional peripheral devices (e.g. additional monitor screens or other patient monitoring devices), the device must be switched off and disconnected from the mains supply! Disconnect the mains cable from the mains outlet before connecting peripheral devices to your MLC-1XX-XL computer.

After connection of peripheral devices, the system must only be operated with appropriate potential equalization. Connect the potential equalization pins provided, both the one belonging to the MLC-1XX-XL, as well as those of the peripheral devices with the potential equalization of the room in which the system is operated in.

**CAUTION**

Risk of property damage and damage to the device caused by inappropriate system configuration:

Inappropriate changes to the device settings may damage the device or peripheral devices connected to it and may cause the devices or the entire system to function incorrectly. All damage caused by inappropriate settings and/or system configurations will not be covered by warranty!

**CAUTION**

Risk of property damage respectively environmental damage caused by inappropriate disposal methods:

At the end of the life span of the device it must not be discarded into the general waste, as electronic elements of the device may cause environmental damage if disposed of inappropriately. Please observe the relevant national disposal restrictions valid for your region.

Please contact your local ADLINK partner for further information about device disposal.

**California Proposition 65 Warning**

This product can expose you to chemicals including acrylamide, arsenic, benzene, cadmium, Tris(1,3-dichloro-2-propyl)phosphate (TDCPP), 1,4-Dioxane, formaldehyde, lead, DEHP, styrene, DINP, BBP, PVC, and vinyl materials, which are known to the State of California to cause cancer, and acrylamide, benzene, cadmium, lead, mercury, phthalates, toluene, DEHP, DIDP, DnHP, DBP, BBP, PVC, and vinyl materials, which are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

4.2.4 Hazards with regard to repair and maintenance

**DANGER**

Risk of electrical shock to the user or others as well as risk of property damage and damage to the device caused by dangerous currents:

Hazardous currents are present during operation of the device. Improper operation or maintenance may result in death, severe injuries, or significant damage to property. Strictly observe all instructions being given in this chapter.

**WARNING**

Risk of electrical shock to the user, patient or others caused by inappropriate repair methods or maintenance:

All repair or maintenance actions must be performed by qualified, ADLINK authorized personnel only! Local respectively national safety regulations and accident prevention regulations must be strictly observed for all servicing activities.

Every change to the device performed by the user or other, not authorized third parties are not allowed and will lead furthermore to loss of device warranty.

**WARNING**

Risk of electrical shock to the user or others as well as risk of property damage and damage to the device caused by insufficient preparation for repair or maintenance:

Before starting any repair or maintenance procedures, the device must always be disconnected from the mains supply and must be connected to ground.

**CAUTION**

Risk of electrical shock to the user or others as well as risk of property damage and damage to the device caused by inappropriate spare components:

For any kind of repair or changes to the device (e.g. for post-manufacture upgrades) original spare parts or ADLINK authorized spare parts or components must be used.

**CAUTION**

Risk of damage to device caused by electrostatic discharge:

Medical computers, monitors, and their components are highly delicate devices. ESD (electrostatic discharges) and incorrect handling may seriously damage your device.

Only qualified service personnel may handle the device hardware. Connect yourself to ground before opening the device or before touching internal parts!

5 User Information

All information in this chapter is addressed to the user (operator) of the device. It describes all system characteristics, components, and control actions including the maintenance of the device that can be performed by the user.

Additional information addressed to administrators is provided in Chapter 6 Administrator Information“.

5.1 General Description

The MLC-AL/ MLC-KL is a medical touch panel computer based on the Intel® Atom® x5-E3930 processor and the Intel® Core™ i3-7100U processor. It can be used to display and record medical information in a variety of clinical settings. Patient and surgery data can be stored locally or exported to external systems.

The MLC-AL/ MLC-KL series is available in two sizes all equipped with a multi-touch projected capacitive touchscreen panel with safety glass and anti-glare coating. The effective diagonal dimensions of MLC-133-XL and MLC-156-XL models are 13.3" and 15.6" respectively. The projected capacitive touchscreens support multi-touch operation to provide easy operations such as turning, swiping, and zooming of elements on the display, as found on modern smart phones (dependent on software support).

The touchscreen display's sensitivity is sufficient to provide operation of the touch functionality for a user wearing protective gloves as commonly used in medical environments.

The mains supply of the device is provided by an external 'medical grade' power supply unit suitable for all mains voltages worldwide. ADLINK supplies the corresponding desktop medical grade power supply unit with standard mains cable at primary side and adapted connection cable at secondary side (for further electrical specifications, refer to Section 7.2.1).

At the rear of the device housing, there is a VESA 100 interface allowing the device to be mounted to support units such as pedestals (accessory not included as standard equipment) or ceiling support units, etc.

5.2 Features

- Intel® Atom® x5-E3930 @ 1.8GHz / Intel® Core™ i3-7100U @ 2.4GHz processors
- Multi-touch projected capacitive touchscreen
- Screw-less design for easy cleaning
- Compliant with the relevant medical safety standards
- 1x USB 3.0 port and 1x USB 2.0 port
- 1x Gigabit Ethernet (isolated)
- 1x RS232/422/485 (isolated)
- Onboard SSD via M.2
- Windows 10 IoT Enterprise 64-bit

5.3 Packing List

- MLC-AL/ MLC-KL device
- Power adapter (optional)
- Power cord (optional)

5.4 Device Overview

5.4.1 Interfaces

At the bottom of the device, there are power and I/O interfaces allowing connections with other systems/devices via respective cables and/or connectors.

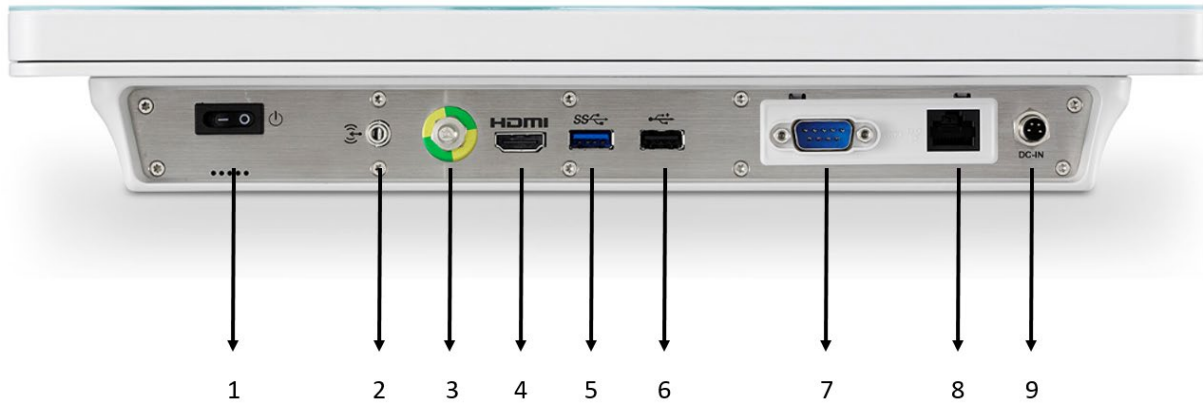


Figure 1: Bottom view of connectors

1. **Power-On switch**
2. **Audio**
3. **Potential equalization connecting pin** ($\varnothing$ 6mm), according to DIN 42801 with color coding yellow/green for connecting a potential equalization cable
4. **HDMI**
5. **USB 3.0 port** (blue)
6. **USB 2.0 port**
7. **COM interface**, galv. isolated up to 4 kV
8. **GbE network interface**, galv. isolated up to 4 kV (RJ45 connector)
9. **DC-In connector**

NOTICE

The equalization pin of the device must be connected to the potential equalization panel of the respective OR theatre (see IEC 60601-1/EN 60601-1 or the respective national standards).



CAUTION

Risk of burns to the user caused by hot surfaces:

Turn off power and allow the device to cool down prior to connecting or disconnecting peripheral devices. Do not touch the enclosure for over 10 seconds when the device is in operation or is still hot from previous use.

5.5 Operating the Device

5.5.1 Installing the system

Install the device using the VESA mounting holes shown in Section 7.1 Mechanical Specifications.

5.5.2 Connecting Power and Patient Potential Equalization

Connect the power supply unit (power cord and power adapter) to the Power VDC-In connector (9) of the device and then to the mains supply.



Figure 2: Power supply unit



Figure 3: Power supply unit connected to the Power 12VDC-In connector

Connect the patient potential equalization connecting pin (3) to the potential equalization of the room in which the system is operated (in acc. with IEC 60601-1).

Power supply units:

Vendor	Model name	Rating
Sinpro	MPU60A-105-P66W101-E3A033-12V00 (M3.1),(L5) V2.0	63W, Medical Adapter, 12V/5.25A, M8 4P
FSP	FSP, FSP065M-DBA(9NA0656405)	65W, Medical Adapter, 19V/3.43A, M8 4P

5.5.3 Powering the System On/Off

Turning On the System

To turn on the device, press the Power-On switch (1) for approx. 2 seconds until the Power LED lights up green. The device will begin the boot routine.

Turning Off the System

To turn off the device, use the shutdown procedure of the operating system (for Windows select the "Start" button and click on "Shut Down").

NOTICE

Pressing the Power-On switch for more than 5 seconds while in operation, a hard shutdown of the device is forced. This may cause a loss of data if it hasn't been saved or finished processing before shut down.

5.6 Cleaning and Disinfection

ADLINK recommends product cleaning and disinfecting according to the guidelines and specifications of the Robert Koch-Institute (RKI) in Germany. These guidelines apply to the device. For cables, sensors and other peripheral items, follow the cleaning instructions in the Directions for Use document that accompany these accessories.

The following germicidal products are ADLINK-approved disinfectants for use on your ADLINK product, especially for the touchscreen or glass front panel:

- Incidin Plus
- Skinman soft
- Cutasept G & F
- Sterilium
- Aseptoman

In general, disinfectants based on alcohol, aldehydes, guanidine derivatives or quaternary compounds are suitable for use as surface disinfectants.

Disinfectants based on chlorine, chlorine-releasing substances, or peroxide compounds must not be used for device decontamination, as these ingredients can lead to material damage of the device, especially if the surface has prior damage (e.g. an accidentally caused scratch) and/or especially over long-term use of these type of disinfectant solutions.

While there are many other products available for disinfection, their effectiveness has not been tested on your ADLINK product. If you use a product or method other than those recommended substances above, this should be documented accordingly in your hygiene protocol.

For a wipe disinfection, use a spray applicator to apply any of the approved liquids from the list above and use a soft, lint-free cloth to clean the screen. Thoroughly follow the specifications and usage guidelines of the manufacturers of the disinfecting solutions for cleaning your device.

If due to the nature of the device application or its location a cleaning of the device should be sufficient, please use a soft, damp and lint-free cloth only to clean the device's surface. If the device was lightly soiled only, it would be best to refrain completely from water and use a dry cloth providing anti-static characteristics instead.

For cleaning the glass/touch front of the device, a simple household glass cleaner available in consumer markets may be used. After spray application of the glass cleaner, use a soft, lint-free cloth to wipe the device front until all liquid films are removed.

As a general safety precaution, your ADLINK product should undergo decontamination before returning the device to ADLINK for service, repair, inspection, or disposal.

NOTICE

Contaminated items must not be returned without prior written agreement.

5.6.1 Safety instructions for cleaning and disinfection of the device

**WARNING**

Risk of electrical shock to the user caused by presence of potentially conductive liquids:

Prior to any cleaning and disinfection procedure, the mains cable must be disconnected from the mains supply at all times.

**WARNING**

Risk of unintended operation of the device due to touchscreen functionality:

Before cleaning and/or disinfecting your device, turn off the device.

**WARNING**

Risk of electrical shock to the user and risk of damage to the device caused by inappropriate processing procedures:

The device is **not** suited for any kind of mechanical and/or thermal decontamination procedures such as autoclaving, steam sterilization, etc.

**WARNING**

Risk of electrical shock to the user and risk of damage to the device caused by over-dosed amounts of liquids:

Never apply heavy amounts of liquids to your device nor immerse it into liquids of any substance. Be conservative with all cleaning and disinfection solutions used to clean the device and never apply liquids into given openings such as I/O interface ports.

**CAUTION**

Risk of damage to the device caused by usage of abrasive materials:

Your ADLINK device provides a surface finishing that is sufficiently protected during use within the intended purpose. However, do not use any abrasive materials for cleaning processes, e.g. brushes, sponges, or other objects with hard and/or rough characteristics. Doing so may lead to damage to the front side, the touch surface or the housing surface. Never use e.g. sponges made of metal grafts or similar, nor any sharp or hard objects like knives, pencils etc. for cleaning purposes. Thoroughly follow all instructions provided in this chapter.

6 Administrator Information

The information in this chapter is directed to administrators (e.g. employees in the IT department) requiring broader technical information beyond the simple operation/handling of the device.

6.1 Functional Block Diagram

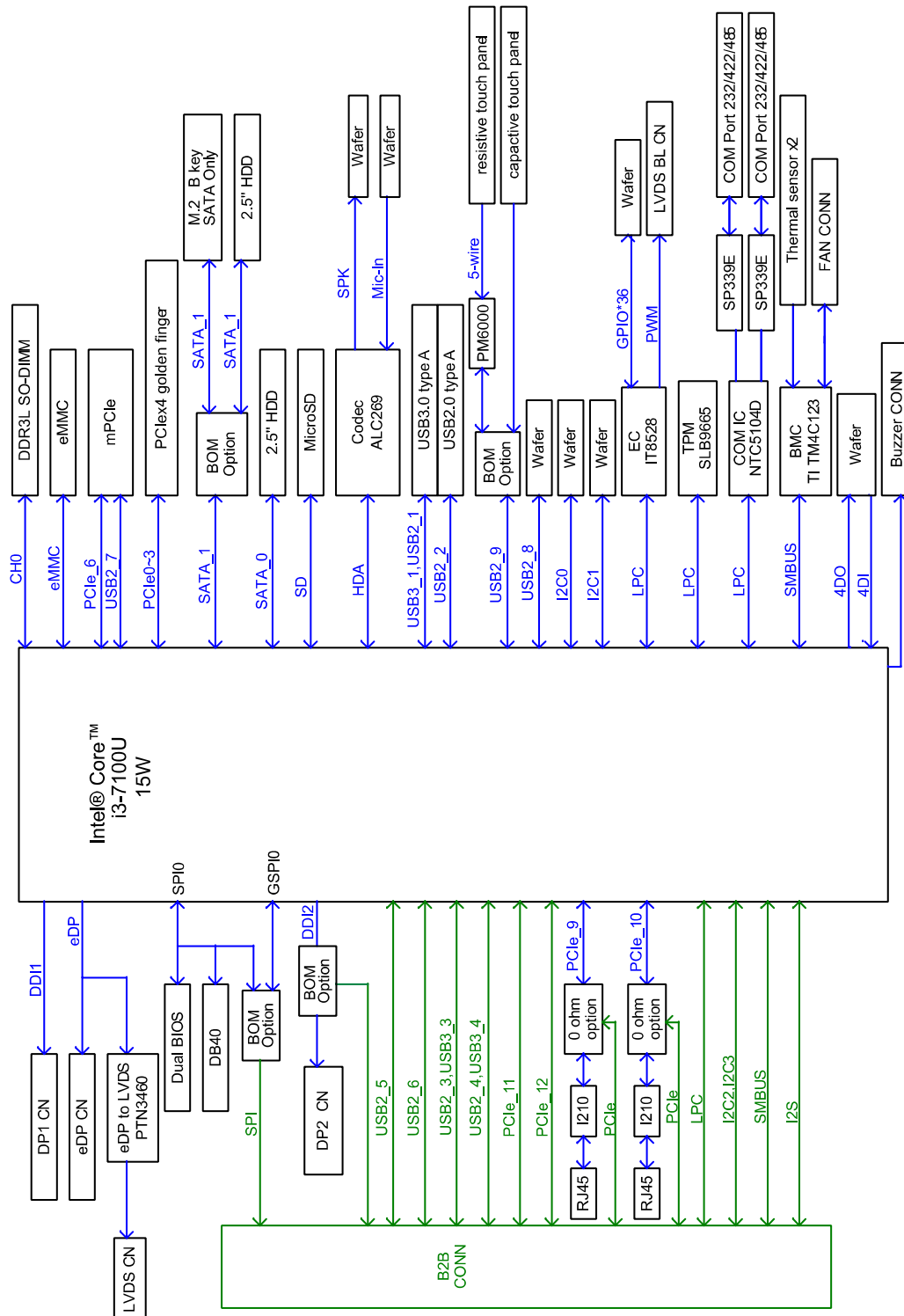


Figure 4: MLC-1XX-KL functional block diagram

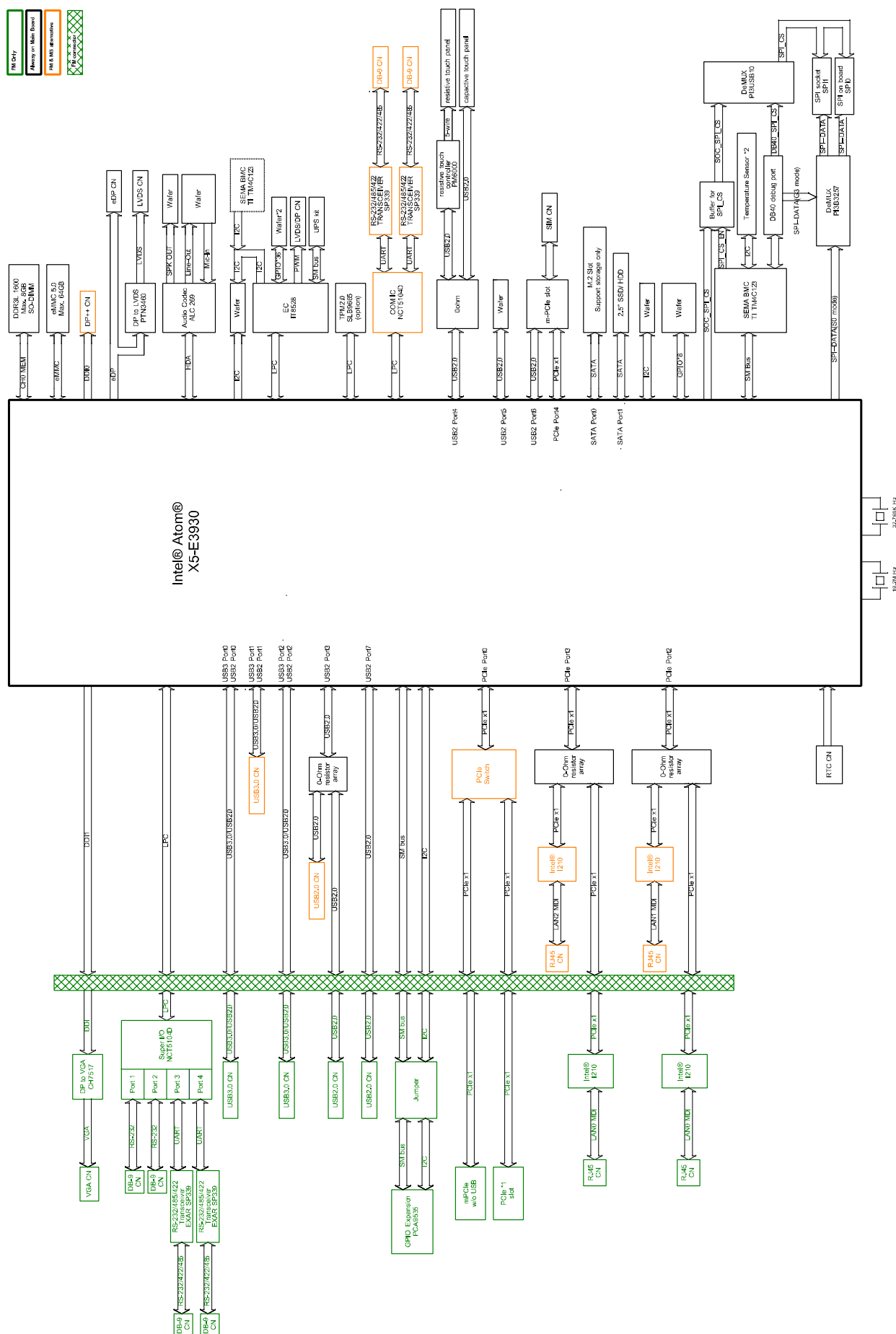


Figure 5: MLC-1XX-AL functional block diagram

USB3/PCIe*/SATA Port Mapping

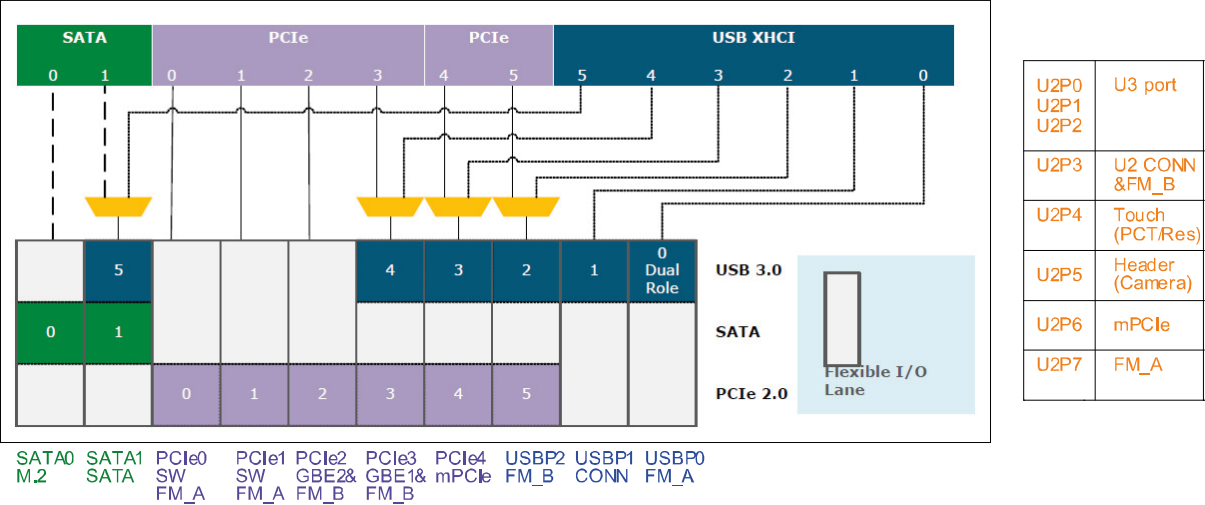


Figure 6: MLC-1XX-AL USB3/PCIe*/SATA Port Mapping

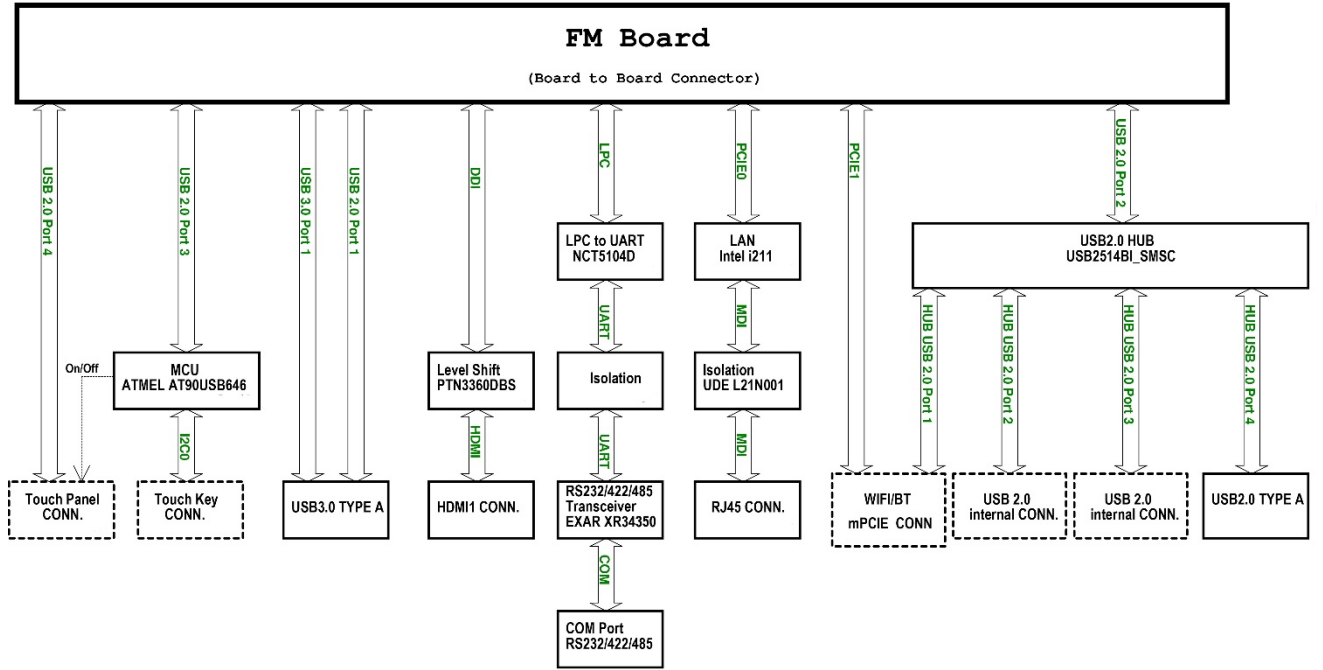
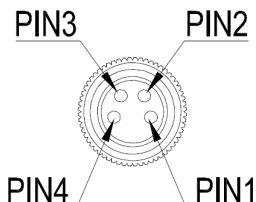


Figure 7: Functional Block Diagram of I/O Board for MLC-1XX-XL

6.2 Technical Data of Main System Components

Component	Technical Data
Processor (AL)	Intel® Atom® x5-E3930 @ 1.8GHz, dual-core, 2 MB cache
Processor (KL)	Intel® Core™ i3-7100U @ 2.4GHz, dual-core, 3 MB cache
Memory	One SO-DIMM slot to support 4GB DDR3L non-ECC 1866MHz (up to 8GB)
Graphics	Intel® HD Graphics
Mass Storage	SSD via internal M.2 2280 slot
Operating System	Windows 10 IoT Enterprise 64-bit

6.3 Detailed System Components

Device Features	
Display	MLC-133-AL/KL Max. resolution 1920 x 1080, brightness 360 cd/m², dimensions 13.3" (338 mm), viewing angle v/h 178°/ 178° MLC-156-AL/KL Max. resolution 1920 x 1080, brightness 270 cd/m², dimensions 15.6" (396 mm), viewing angle v/h 178°/ 178°
Touchscreen	Multi-touch projected capacitive (PCAP) touchscreen with safety glass and anti-glare coating
Power Supply (optional)	Medical power supply (FSP Technology Int. / FSP065M-DBA(9NA0656405)) Input: AC 100V to 240V, 47-63Hz; Output: DC 19V, 3.43A Meets the following certifications: • IEC 60601-1: 2005 + CORR. • EN 60601-1: 2006 + A11: 2011 + A1: 2013 + A12: 2014 • ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) • CAN/CSA-C22.2 No. 60601-1:14
Power Supply Connector	Pins 1, 2: Ground Pins 3, 4: +19V 
Power Supply Cord	A power supply cord meeting the following specifications must be used (such as the one provided with the device): Listed, Detachable, Type SJT or above. 125/250 V minimum, 18 AWG/3C minimum, 3.0 m long maximum. Mains end terminates in 250 V, 10 A with cold-device connector IEC 60320 type C13; the other end with mains plug, e.g. type F, CEE 7/4 or an equivalent type of mains plug.

Interfaces	
USB 3.0 Port	1x USB 3.0, type A, OCP, 1600 mA, SuperSpeed (5Gbit/s) interfaces (blue), compatible with USB 1.1 low (1.5Mbit/s) and full (12Mbit/s), and USB 2.0 high speed (480Mbit/s)
USB 2.0 Port	1x USB 2.0, type A, OCP, 1000 mA, high speed (480Mbit/s), compatible with USB 1.1 low (1.5Mbit/s) and full (12Mbit/s)
Network	1x Gigabit Ethernet, 10/100/1000Mbit/s (10/100/1000BASE-T), RJ-45, galvanic isolation up to 4 kV
COM	1x RS232/422/485 galvanic isolation up to 4 kV
HDMI	1x HDMI type A support HDMI1.4
Switch	Power-On switch
Audio	Audio Connector supporting: • 1x Mic-In • 1x Speaker-Out

6.4 Maintenance and Service

6.4.1 General service intervals

ADLINK devices do not require servicing or maintenance at regular intervals due to the usage of high-quality industrial standard components. Devices, medical panel computers, or monitors rarely require servicing when used for their intended purpose.

If your ADLINK system does not operate properly and needs to be returned for servicing, please refer to the instructions in the Sections 3.5.2 and 5.6 above.

7 Specifications

7.1 Mechanical Specifications


WARNING

Risk of physical injuries and/or property damage:

When mounting the device, use four M4 x 6mm screws to mount the VESA bracket to the rear of the device. Tighten all four screws firmly to support the weight of the device. Make sure that the suspension system is capable of carrying the device!

Note: The VESA 100 mounting hole pattern is shown in the Figure 8 below (all dimensions are in millimeters). All I/O ports **must** face down.

Note: It is recommended to mount the device not higher than 2 m above floor level.

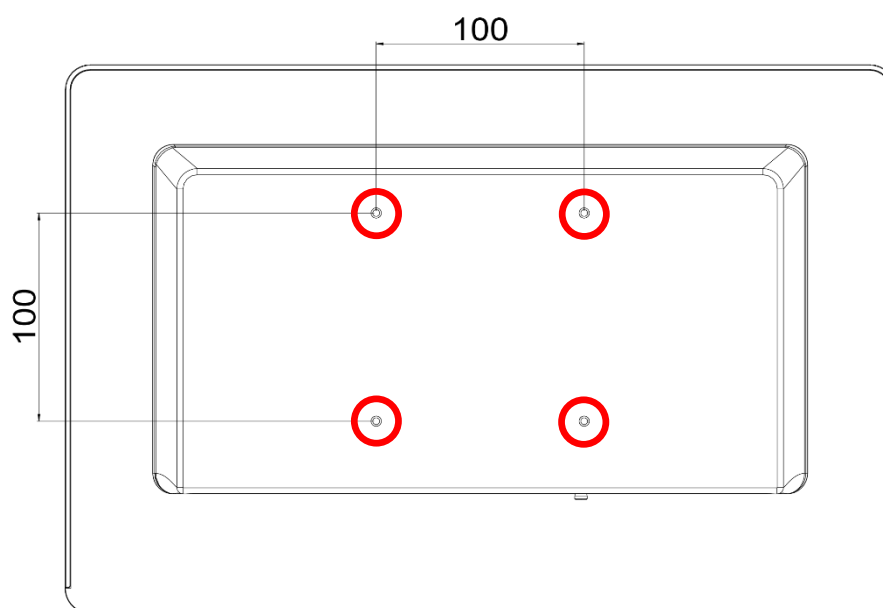


Figure 8: VESA 100 mounting hole pattern


CAUTION

Risk of burns to the user caused by hot surfaces:

Turn off power and allow the device to cool down prior to performing any mounting or demounting operations. Do not touch the enclosure for over 10 seconds when the device is in operation or is still hot from previous use.

MLC-133-XL Dimensions

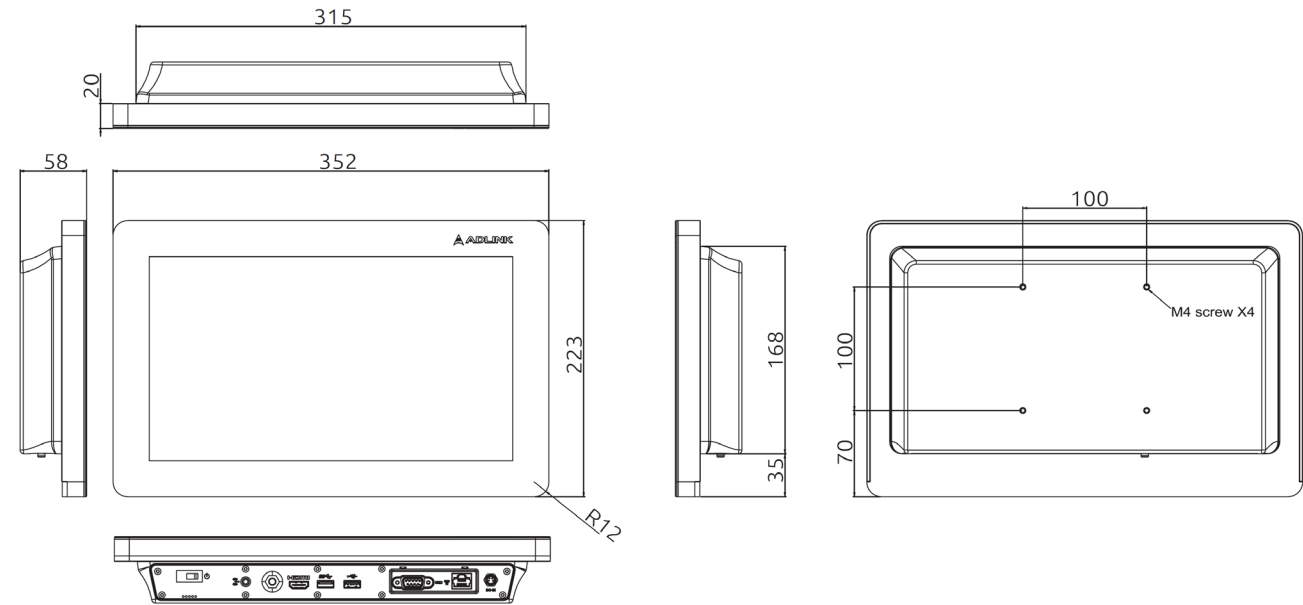


Figure 9: MLC-133-XL dimensions

All dimensions above are in millimeters.

7.1.1 MLC-156-XL Dimensions

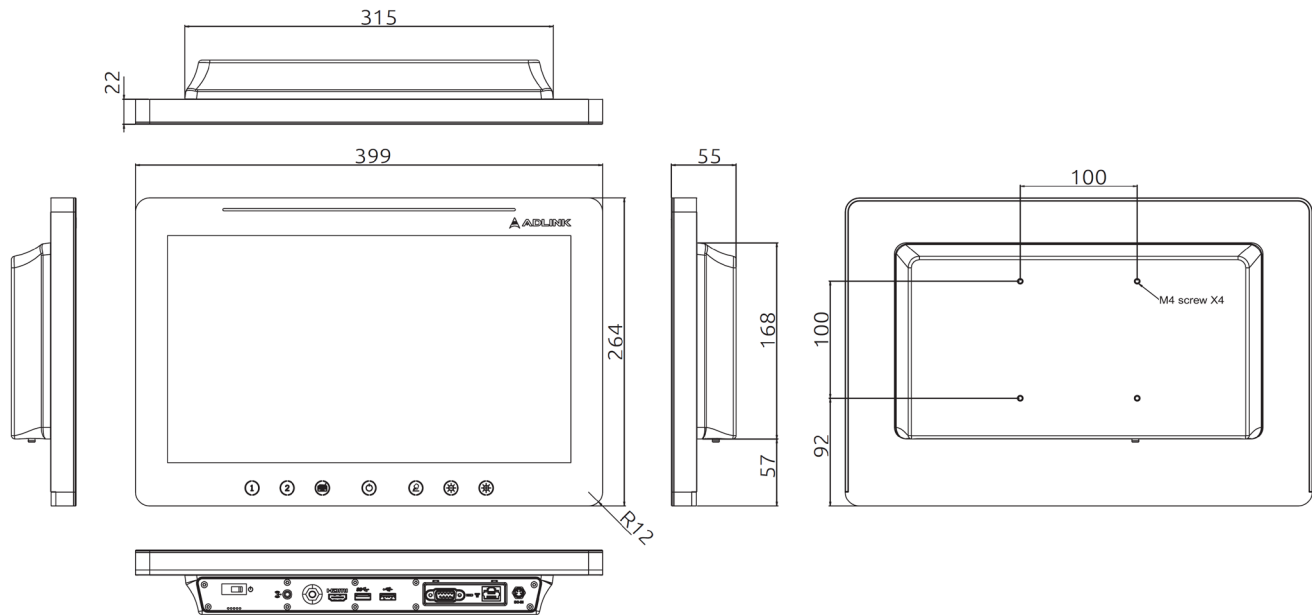


Figure 10: MLC-156-XL dimensions

All dimensions above are in millimeters.

7.1.2 Weight

Maximum weight without optional components:

Device version	[kg]	[lbs]
MLC-133-XL	3.2	7
MLC-156-XL	4.3	9.5

7.2 Electrical Specifications

7.2.1 Power supply unit (optional)

Input voltage	100...240 V~
Input frequency	47/63 Hz
Output voltage	+ 19 V ==

7.2.2 Power consumption

Test configuration:

Intel® Atom® x5-E3930, clock speed 1.8GHz, 4GB RAM, 64GB mSATA, 1x USB 2.0 port, either open or loaded with 0.5A ceramic resistor and 1x USB 3.0 port either open or loaded with 0.9A ceramic resistor;

Intel® Core™ i3-7100U, clock speed 2.4GHz, 4GB RAM, 64GB mSATA, 1x USB 2.0 port, either open or loaded with 0.5A ceramic resistor and 1x USB 3.0 port either open or loaded with 0.9A ceramic resistor;

OS Windows 10 IoT Enterprise, 64bit, Intel HD Graphics;

if applicable, 'High Performance' power plan means display brightness set to 100%;

if applicable, BurnIn means usage of test SW 'PassMark BurnIn Test Pro 8.1

MLC-1XX-AL:

Test #	System Condition	P _{avg} [W]		Description
		13.3"	15.6"	
1	power off (S5)	1.9	1.9	standby power: m.2 SSD
2	hibernate (S4)	1.9	1.9	power plan: High Performance config: m.2 SSD SW: None
3	sleep (S3)	2.0	2.0	power plan: High Performance config: m.2 SSD SW: None
4	idle (S0)	22.3	23.1	power plan: High Performance config: m.2 SSD SW: None
5	loading (S0)	27.9	29.3	power plan: High Performance config: m.2 SSD SW: BurnIn test: CPU+RAM+2D+3D+video+disk tests
6	loading (S0)	37.2	39.8	power plan: High Performance config: m.2 SSD +1*0.5A ceramic resistor (USB 2.0 interface) + 1* 0.9A ceramic resistor (USB 3.0 interface) SW: BurnIn test: CPU+RAM+2D+3D+video+disk tests

MLC-1XX-KL:

Test #	System Condition	P _{avg} [W]		Description
		13.3"	15.6"	
1	power off (S5)	1.7	2.1	standby power: m.2 SSD
2	hibernate (S4)	2.0	2.0	power plan: High Performance config: m.2 SSD SW: None
3	sleep (S3)	2.3	2.4	power plan: High Performance config: m.2 SSD SW: None
4	idle (S0)	21.2	21.4	power plan: High Performance config: m.2 SSD SW: None
5	loading (S0)	41.5	41.7	power plan: High Performance config: m.2 SSD SW: BurnIn test: CPU+RAM+2D+3D+video+disk tests
6	loading (S0)	50.1	51.5	power plan: High Performance config: m.2 SSD + 1*0.5A ceramic resistor (USB 2.0 interface) + 1* 0.9A ceramic resistor (USB 3.0 interface) SW: BurnIn test: CPU+RAM+2D+3D+video+disk tests

7.3 Environmental Specifications


CAUTION

Risk of device malfunctioning caused by violation of environmental specification limits:

Your ADLINK device is specified for proper operation within the environmental conditions mentioned below. Exceeding these limits can lead to unexpected device behavior and malfunctions.

Always make sure that you operate the device within the environmental conditions specified in this section.

Ambient temperature range for operation	0°C...+35°C
Ambient temperature range for storage and transport	-20°C...+60°C
Ambient humidity range for operation	5...90%@35°C (non-condensing)
Ambient humidity range for storage and transport	5...90%@35°C (non-condensing)
Ambient air pressure for operation, storage and transport	700...1013 hPa

7.4 Classification

1. Type of protection against electric shock: Class I equipment
2. Class I: No applicable parts, not AP/APG-compliant

7.5 Markings and Labels

7.5.1 Part number and serial number labels

The part number and the serial number of the device are provided on separate labels attached to the rear of the device. The following figures provide generic examples of the part number and serial number labels. The textual content may differ depending on the respective device characteristics.



Figure 11: Part number label



Figure 12: Serial number label

7.5.2 Product identification label

The product identification label is attached to the rear of the device and contains main technical data about the device. The following figure provides a generic example of the product identification label. The textual content may differ depending of the respective device characteristics.

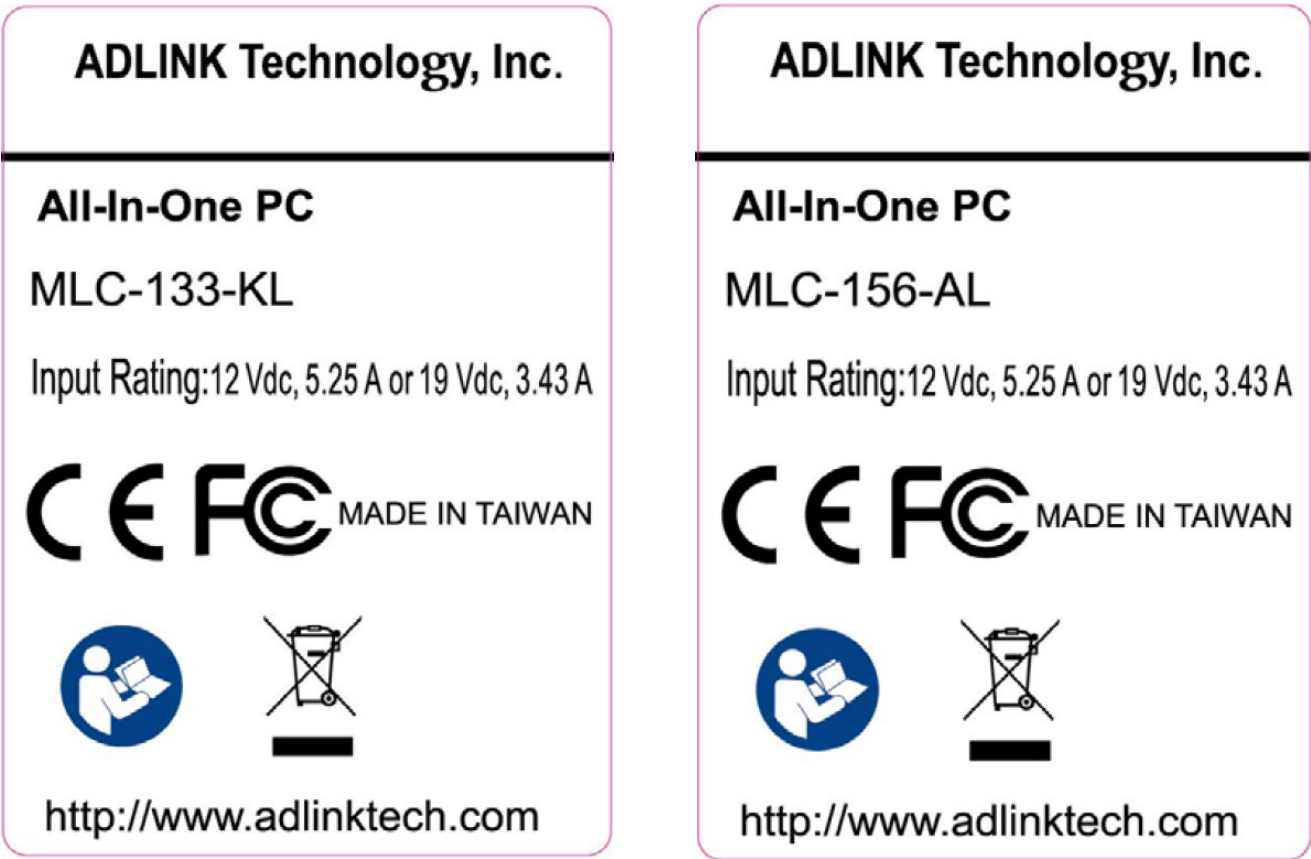


Figure 13: Product identification label

7.5.3 Explanation of symbols

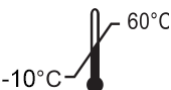
7.5.3.1 Explanation of symbols used on labels

Symbol	Meaning
	Read the user's manual and follow all handling and safety instructions.
	CE labelling: the CE symbol confirms compliance with all relevant guidelines and regulations
	Do not dispose of this device or its parts with conventional domestic waste. Observe your national regulations regarding disposal of electrical and electronic devices. For further information, refer to: DIRECTIVE 2012/19/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)
	Medical – General Medical Equipment as to Electrical Shock, Fire and Mechanical Hazards only in Accordance with ANSI/AAMI ES60601-1 (2005) + AMD (2012) and CAN/CSA-C22.2 No. 60601-1 (2008) + (2014).
	FCC labelling: the FCC symbol confirms compliance with all relevant communication requirements This device complies with Part 15 FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation.
	Do not use at an altitude exceeding 2000m above sea level.

7.5.3.2 Explanation of symbols used on the device

Symbol	Meaning
	Power-On Switch
	USB 2.0 port
	USB 3.0 port
	GbE network port
	ESD warning symbol
	Connector pin for potential equalization

7.5.3.3 Explanation of symbols used on the packaging

Symbol	Meaning
	Upright position
	Fragile, handle with care
	Keep away from rain
	Atmospheric pressure limitation for storage and transport (700 to 1013 hPa)
	Humidity limitation for storage and transport (5 to 95%)
	Temperature limitation for storage and transport (-10°C to 60°C)

8 Certificates and Standards

8.1 Verification of Compliance – EN55032



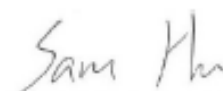
Ref. No. VXD0516A/2020
Page: 1 of 1

VERIFICATION OF COMPLIANCE

Issue Date: August 4, 2020
Applicant: ADLINK TECHNOLOGY INC.
Address: 9F, No.166, Jian Yi Rd., Zhonghe Dist.,
New Taipei City, 235 Taiwan
Manufacturer: ADLINK TECHNOLOGY INC.
Address: 9F, No.166, Jian Yi Rd., Zhonghe Dist.,
New Taipei City, 235 Taiwan
Contact Information: Web: <https://www.adlinktech.com/en/index>
TEL#: 02-8226-5877#8361
E-mail#: sean.ba@adlinktech.com
Product: All in one PC
Brand Name/Trade Mark: 
Model/Type: MLC-156-KL
Added Model(s): MLC-133-AL; MLC-133-KL; MLC-156-AL
Applicable Standards: EN 55032: 2015 / AC: 2016
CISPR 32: 2015 (Ed 2.0) / C1: 2016
EN 61000-3-2: 2014
EN 61000-3-3: 2013
EN 55035: 2017
IEC 61000-4-2: 2008; IEC 61000-4-3: 2006 + A1: 2007 + A2: 2010;
IEC 61000-4-4: 2012; IEC 61000-4-5: 2014 + A1: 2017;
IEC 61000-4-6: 2013 + COR1: 2015; IEC 61000-4-8: 2009;
IEC 61000-4-11: 2004 + A1: 2017
Test Laboratory: Compliance Certification Services Inc.
Xindian Lab
No. 163-1, Jhongsheng Rd., Xindian Dist.,
New Taipei City, Taiwan
Test Report No.: T200701D07-E, dated on August 4, 2020
Conclusion: Based upon a review of the Test Report(s), the tested sample of the product mentioned above is deemed to comply with the requirements of the above standards.

Note: This verification is only valid for the product and configuration described and in conjunction with the test report as detailed above.

Authorised Signatory:



Compliance Certification Services Inc.
Sam Hu
Assistant Manager

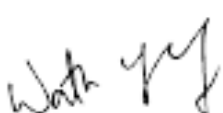
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Compliance Certification Services Inc.
聯智科技股份有限公司

No.163-1, Jhongsheng Rd., Xindian Dist., New Taipei City, Taiwan / 新北市新店區中生路 163-1 號
t: (886-2) 2217-0894 f: (886-2) 2217-1029 www.sgs.com.tw www.ccsrf.com

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8.2 Verification of Compliance – EN 60601-1-2

		Ref. Certif. No. SG PSB-MD-00415
IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME		
CB TEST CERTIFICATE		
Product	Other IT and business equipment (All-in-One PC)	
Name and address of the applicant	ADLINK Technology, Inc. 9F., No.166, Jian Yi Rd. Zhonghe Dist. 235 New Taipei City TAIWAN	
Name and address of the manufacturer	ADLINK Technology, Inc. 9F., No.166, Jian Yi Rd., Zhonghe Dist., 235 New Taipei City, TAIWAN	
Name and address of the factory	ADLINK Technology Inc. Jian Yi Factory 4F and 15F., No.166, Jian Yi Rd., Zhonghe Dist., 235 New Taipei City, TAIWAN	
Ratings and principal characteristics	Rated input voltage: <u>Power Adapter</u> I/P: 100-240 V~, 47-63 Hz, 1.62-0.72 A or 100-240 V~, 50-60 Hz, 2.0-1.0 A O/P: 12 Vdc, 5.25 A or 19 Vdc, 3.43 A <u>All-In-One PC</u> I/P: 12 Vdc, 5.25 A or 19 Vdc, 3.43 A Protection class: I	
Trade mark	ADLINK	
Model/type Ref.	MLC-133-AL, MLC-133-KL, MLC-156-AL, MLC-156-KL	
Additional information (if necessary)	All applicable Clauses of IEC 62366 have been addressed. See test report for details.	
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1-6:2010 IEC 60601-1-6:2010/AMD1:2013	
as shown in the Test Report Ref. No. which forms part of this certificate	081-200918-000	
This CB Test Certificate is issued by the National Certification Body		
CB# 075377 0021 Rev. 00 Date, 2020-10-14		
 (Watson Yang)		 PSB Singapore
Page 1 of 2 TÜV SÜD PSB Pte Ltd • 1 Science Park Drive • Singapore 118221		

	Ref. Certif. No.
	SG PSB-MD-00415

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

Name and address of the factory (continued)

ADLINK Technology (China) Co., Ltd.
No. 300, Fang Chun Road, China (Shanghai) Pilot Free Trade Zone,
201203 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Brief description of the test sample:

- The product is an All-In-One PC Intended for transfer, store, convert formats and display medical device data in hospital environment, is designed for use in practices and operating theaters by qualified personnel.
- The EUT power supplied by external Power Adapter: Sinpro Electronics Co., Ltd. type MPU60A-105, which has been approved by TÜV/Rh according to IEC 60601-1:2005 + A1, 2MOPP provided between primary circuit and secondary circuit, certified as Class I equipment in TÜV /Rh CB report.
The EUT alternative power supplied by external Power Adapter: FSP Group Inc. type FSP065M-DBA, which has been approved by TÜV/Rh according to IEC 60601-1:2005 + A1, 2MOPP provided between primary circuit and secondary circuit, certified as Class I equipment in TÜV /Rh CB report.
- The equipment provides Means of Patient Protection (MOPP).
- The equipment is evaluated for operating in altitude up to 2,000 m.

This CB Test Certificate is issued by the National Certification Body

CB0 075377 0021 Rev. 00
Date, 2020-10-14

Page 2 of 2
TÜV SÜD PSB Pte Ltd • 1 Science Park Drive • Singapore 118221

Watson Yang
(Watson Yang)



PSB Singapore

8.3 Verification of Compliance – FCC Part 15 Class B



Ref. No. VXD0514A/2020

Page: 1 of 1

VERIFICATION OF COMPLIANCE

Issue Date: August 4, 2020
Applicant: ADLINK TECHNOLOGY INC.
Address: 9F, No. 166, Jian Yi Rd., Zhonghe Dist.,
 New Taipei City, 235 Taiwan
Manufacturer: ADLINK TECHNOLOGY INC.
Address: 9F, No. 166, Jian Yi Rd., Zhonghe Dist.,
 New Taipei City, 235 Taiwan
Contact Information: Web: <https://www.adlinktech.com/en/index>
 TEL#: 02-8226-5877#8381
 E-mail#: sean.ba@adlinktech.com
Product: All in one PC
Brand Name/Trade Mark: 
Model/Type: MLC-156-KL
Added Model(s): MLC-133-AL; MLC-133-KL; MLC-156-AL
Applicable Standards: FCC 47 CFR Part 15 Subpart B
 ANSI C63.4: 2014
 ISD ICES-003 (Issue 6)
Test Laboratory: Compliance Certification Services Inc.
 Xindian Lab
 No. 163-1, Jhongsheng Rd., Xindian Dist.,
 New Taipei City, Taiwan
Test Report No.: T200701D07-D, dated on August 4, 2020
Conclusion: Based upon a review of the Test Report(s), the tested sample of the product
 mentioned above is deemed to comply with the requirements of the above
 standards.
Note: This verification is only valid for the product and configuration described and in conjunction
 with the test report as detailed above.

Authorised Signatory:

Compliance Certification Services Inc.

Sam Hu

Assistant Manager

FM-023A-R01

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9 Appendix

9.1 EN 60601-1-2 Tables

9.1.1 Guidance and manufacturer's declaration – electromagnetic emissions (IEC 60601-1-2:2007 Table 1)

The MLC-1XX-XL is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

9.1.2 Guidance and manufacturer's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS (IEC 60601-1-2:2007 Table 2)

The MLC-1XX-XL is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

9.1.3 Guidance and manufacturer's declaration — electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (IEC 60601-1-2:2007 Table 4)

The MLC-1XX-XL is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

9.1.4 Recommended separation distances between portable and mobile RF communications equipment and the EUT (IEC 60601-1-2:2007 Table 6)

The MLC-1XX-XL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

10 Getting Service

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