

PUBLIC

MED-TAB v.2

INSTRUCTIONS FOR USE

PUB INT EN – 002TR

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Release date: 22.05.2017

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1 Introduction

1.1 Manual Overview

This document represents the MED-TAB v.2 instructions for use by PLUM Medical Solutions GmbH.

Disclosure level of this document is PUB, which means that this document is freely available to resellers, end users as well as potential customers.

NOTICE:

The provided data was researched with the utmost care. Nevertheless, the author does not accept any liability for the correctness, completeness and up-to-date nature of the information contained in this document. It is the responsibility of the user or the local administrator to verify the details by considering suitable sources.

⚠ CAUTION

*Please make sure to utilize the latest version of the instructions for use.
(H-No.: HW4.1.1)*

1.2 Summary

MED-TAB is a 13.3" color LCD monitor including a built in tablet computer for viewing and analyzing of medical images aside from those of mammography from a picture archiving and communication system (PACS). The color panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 1920 x 1080 pixels (2MP). There is one REGULAR display MODE to visualize non-medical images and one DICOM MODE factory calibrated display mode to display medical images according to DICOM GSDF regulations.

CALCON is an application software which is preinstalled in each tablet offering quality control over the monitor. The software supports quantitative and visual tests.

The MED-TAB has been precisely calibrated to comply with DICOM Part 14 at factory. With built-in brightness stabilization circuit, USB adjustment tool and ambient light sensor, stable brightness and persistent calibration can be guaranteed. The MED-TAB can support both landscape and portrait mode. The anti-reflection coated protective screen can prevent display from damage under heavy operating conditions. The tablet-PC is designed in conformity with IEC60601-1, IEC60601-1-2 and CCC standards.

⚠ CAUTION

Danger of incorrect image analysis results.

Read the entire manual in full detail to ensure safe and proper use, before using the device for the first time.

(H-No.: HW4.2.1)

Incorrect use due to insufficient environmental conditions or incompatible software may lead to incorrect image analysis results.

(H-No.: HW4.3.1)

1.2.1 Intended medical indication

MED-TAB is a 13.3" color LCD monitor including a built in tablet computer for viewing and analyzing of medical images, except of mammography, from a picture archiving and communication system (PACS).

1.2.2 Intended patient population

The MED-TAB is intended for use by medical healthcare professionals only. This device is not intended for use or operation by a patient.

1.2.3 Intended users and user groups

Users of the MED-TAB are medical healthcare professionals such as, trained medical practitioners or veterinarians. Patients should not touch or operate this device. This device should not be used by people with a known allergy to plastic as it can cause an allergic reaction (H-No.: HW2.3.1).

1.2.4 Designated Conditions of Use

Designated conditions of use are:

- Only intended for medical healthcare professionals.
- It is recommended to place the device on a desk using the rotating case stand either in portrait or landscape mode without direct flare on the screen.
- The ambient should be less than 100 lux for image analysis.
- The intention of the device is for repeated but not continuous use.
- The operating Temperature is +10°C to +35°C.
- The operating air pressure is 600 hPa to 1100 hPa.

1.2.5 Contraindications

The MED-TAB is not intended for:

- Mammography for diagnostic purposes (H-No.: HW4.1.3, HW4.1.4).
- Usage at ambient light of more than 1000 lux.
- Sterile use.
- Usage in an infectious environment (H-No.: HW2.1.1 – HW2.1.4, HW2.2.2 – HW2.2.6, HW2.2.8).

1.2.6 Exclusions, warnings and precautions

- Perform a medical display acceptance test with the PACS before clinical use according to local laws and regulations using a calibrated luminance meter.
- No use for emergency procedures in case of unreliable data connections.
- No handheld use for image analysis.
- Regularly clean the device to remove dirt.
- Only use a pen or a mouse to perform measurements using a PACS. Do not use fingers (H-No.: HW4.2.1).

2 First steps

2.1 Unpacking your new MED-TAB

Please check the product box for the following items:

- MED-TAB v.2
- MED-TAB USB-Adjustment Tool with a Micro USB plug
- Leather case with rotating stand
- Touch pen
- Switching Power Adaptor for MED-TAB v.2 incl. plugs for US, UK, EU and CN
- Micro USB to USB cable
- Quick start guide

We recommend operating the MED-TAB using the leather case to protect the device.

CAUTION

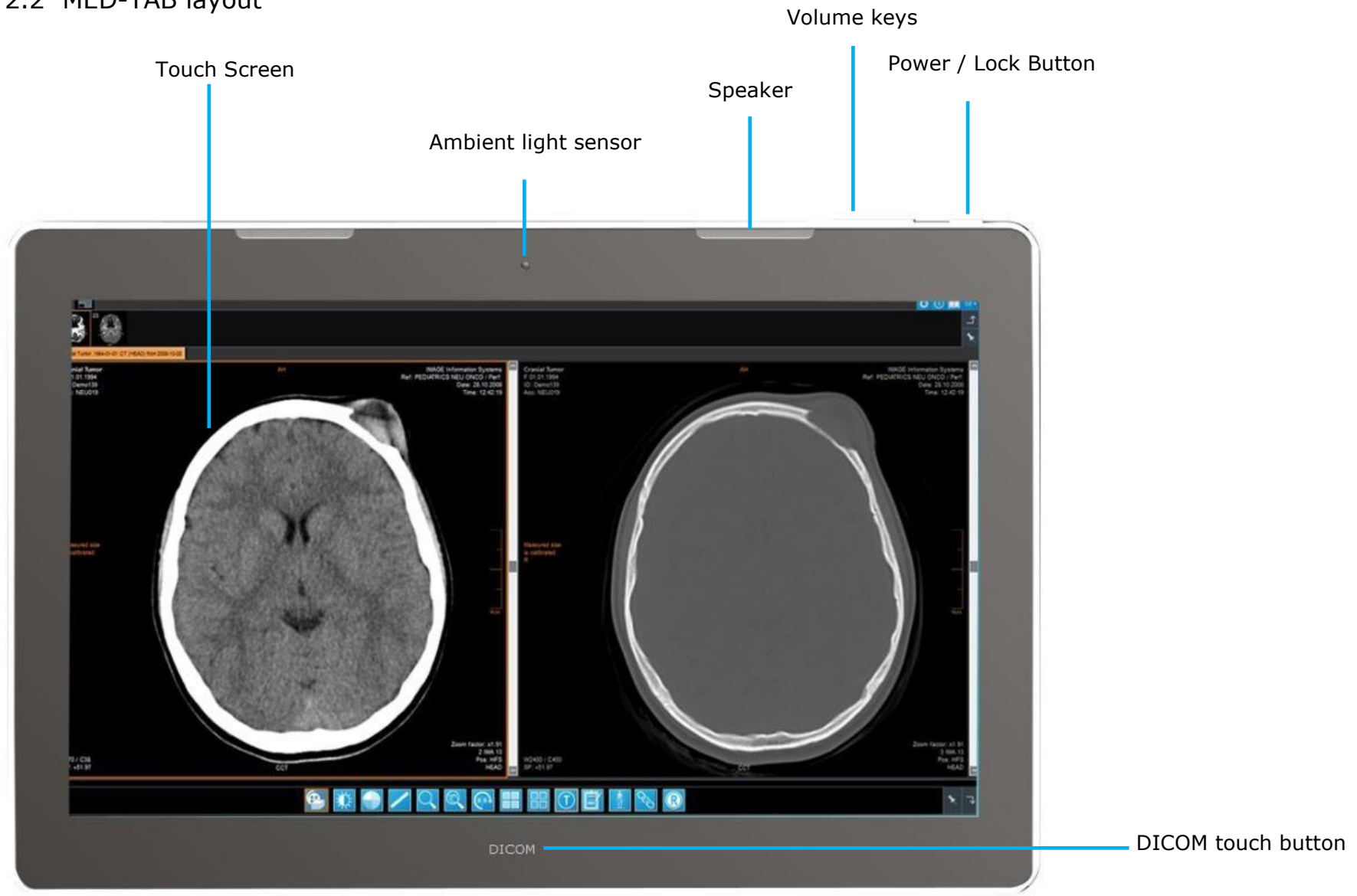
Danger of incorrect image analysis results.

Always transport MED-TAB in the original case or in the original packaging box.

The antiglare sheet on the surface of the tablet is soft. Scratches can impair the image quality.

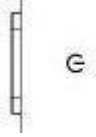
(H-No.: HW3.1.1, HW3.1.3)

2.2 MED-TAB layout





Keys and Buttons

Key	Action	
	Power/Lock	To power on/off the device (press and hold); to lock/unlock (press)
	Volume	For adjusting the volume of the device
	DICOM-Touch button	Hold to activate/deactivate the DICOM-Mode

2.3 Charging the battery for initial use

Before using the MED-TAB for the first time, charge the battery for 8 hours.

WARNING

Danger of electrical shock, fire and device malfunction.

Always use the Switching Power Adaptor for MED-TAB v.2 for charging and operation. Make sure the power connector is fully connected to the power socket.

The power adaptor must be used at specified electric voltage, only.

(H-No.: HW1.1.1)

CAUTION

Danger of delayed treatment due to unavailable image analysis device.

A warning will appear along with an alert when the battery charge is low. The battery must be charged for wireless operation. Once the battery is completely discharged, the device cannot be turned on until the battery has been charged or the device is connected to a power source.

(H-No.: HW3.1.2)

2.4 Care and cleaning instructions

CAUTION

Danger of incorrect image analysis results.

Frequent cleaning of the display using a display cleaner is recommended.

Finger prints and dirt may lead to incorrect image analysis results.

Use of rough tissues for cleaning may damage the surface which can impair the image quality.

Incorrect display cleaners may dull the surface and impair the image quality.

Do a new image acceptance test if you are unsure after any damage to the surface.

(H-No.: HW3.1.1, HW3.1.3, HW3.2.3, HW3.2.4)

Periodic cleaning is recommended to keep the display clean and to prolong its operational lifetime.

Never use thinner, benzene, alcohol (ethanol, methanol, or isopropyl alcohol), abrasive cleaners, acid, steel wool or other strong solvents, as these may cause damage to the cabinet or LCD panel.

The surface can be cleaned with a soft display-cloth, such as cotton or lens paper and special display cleaner. If necessary, stubborn stains can be removed by moistening part of a cloth with water to enhance its cleaning power.

CAUTION

Danger of incorrect image analysis results.

Do not scratch the display surface. Be careful with rings, keys or jewelry which could scratch the display surface. Do not use touch pens other than the original one.

Scratches may damage the display and impair the image quality.

Do a new image acceptance test if you are unsure after damaging the surface.

(H-No.: HW4.2.1)

2.5 Usage of a memory card (optional)

The MED-TAB only accepts microSD™ and microSDHC memory cards with a maximum capacity of 128GB. Not all memory cards are compatible with MED-TAB. MED-TAB only supports the FAT file system.

If you insert a card with a different file structure, the device will ask to reformat the memory card before use. The file directory of inserted memory cards appears in the extSdCard folder of the MED-TAB.

If you want to remove a memory card, please be sure that the device is not currently accessing the memory card. Open "**Settings**" in the application list, choose the category "**Storage**" and select "**Unmount SD card**". After confirming this process, you can unmounts or remove the memory card.

2.6 Leather Case

The MED-TAB should be used while sheltered in its leather case (H-No.: HW1.4.1, HW1.4.2). The business card cover is thought to identify the owner or user of a device, e.g. by inserting a business card.

The rotating stand of the MED-TAB can be turned over 360° to enable both landscape and portrait views.



2.7 Touch Pen

The supplied touch pen allows a dirt-free usage of the MED-TAB and hence preserves its image quality. The supplied touch pen will provide the most accurate measurements for diagnostic purposes.



⚠ CAUTION

Danger of incorrect image analysis results.

Use the original touch pen to control the MED-TAB for image analysis in order to avoid image quality impairment by finger prints.

Wash your hands before using MED-TAB to reduce oil remaining on the surface.

(H-No.: HW4.2.1)

⚠ WARNING

Be aware that PLUM Medical Solutions GmbH cannot be held responsible for any use of the Touch Pen other than described in this document!

(H-No.: HW4.2.1)

2.8 Grayscale adjustment according to DICOM Part 14 GSDF

The MED-TAB Calibrator is a grayscale adjustment tool. The combination between the grayscale adjustment tool and the MED-TAB CALCON app helps to ensure that the MED-TAB complies with the DICOM Part 14 GSDF specification (see chapter "4 CALCON - Grayscale adjustment tool").



2.9 Climatic and ambient conditions

Key	Action
Operating Temperature	+10°C~+35°C
Air pressure	600 hPa ~ 1100 hPa
Operating Humidity	30% ~ 95% Non-condensing
Storage Temperature	-10°C ~ +55°C
Storage/Transportation Humidity	10% ~ 95% Non-condensing
Magnetic resistance	< 0,25 T
Ambient light	0 ... 1000 lux

2.10 MED-TAB Characteristics

Key	Action
Luminance	350 Candela/m ² (+/- 10%)
Battery runtime	3,5h in DICOM mode, 10h in regular color mode
RAM	8 GB
CPU	Quad Core

(H-No.: HW4.1.2)

3 Getting started

3.1 Working position

CAUTION

Danger of incorrect image analysis results.

Use a viewing angle of around 90° for image analysis.

Do not operate in direct light to avoid glary reflections which can impair the image quality.

Verify that the ambient light is less than 100 lux for therapeutic decisions. Use a 3rd party calibrated lux meter to determine ambient light. The CALCON app is not calibrated and provides an estimated indicator for the ambient light by using the built in ambient light sensor.
(H-No.: HW3.2.5)

3.2 Powering on or off

To power on the MED-TAB, please press and hold the Power button.

To power off the MED-TAB, please press and hold the Power button for 3 seconds and then select "Power off". Confirm the shutdown by "OK".

3.3 Switching between DICOM and regular display modes

Push the DICOM label at the bottom centre and hold it for ~3 sec to switch the DICOM mode on or off.

CAUTION

Danger of incorrect image analysis results.

Use the DICOM mode for grayscale image analysis and the REGULAR mode for any non-DICOM applications.

Use of the incorrect display mode will impair the image quality.

(H-No.: HW4.1.1)

3.4 Optimizing the display lifetime

In case of working with the same image or an application with static image elements for more than 4 continuous hours, it is recommended to change the image content regularly to avoid image retention of the static elements.

NOTICE:

*Risk of display damage if continuously displaying the same image for more than a few hours.
We recommend to set the display sleep timer to 5 minutes of nonuse to protect the screen.*

3.5 Using the touch screen

The Med-TAB touch screen provides an easy possibility to select items or perform functions with the touch of your finger. However, when conducting measurements for diagnostic purposes, use the original touch pen or a mouse in order to avoid inaccuracies.

CAUTION

Danger of incorrect image analysis results.

Exclusively use the original supplied touch pen with the device.

Only use the supplied touch pen or a mouse for any measurements with a connected PACS.

Never use fingers or other tools due to inaccurate measurements.

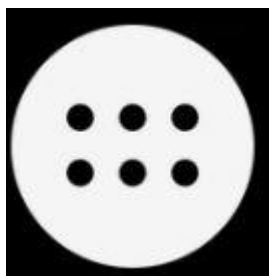
(H-No.: HW4.2.1)

3.6 Locking and unlocking the touch screen and the keys

To lock/unlock the touch screen and the buttons manually, press the Power button.

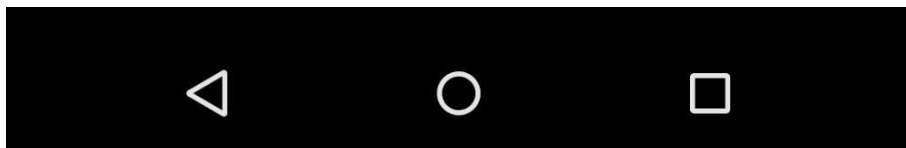
3.7 Opening App overview

For opening the overview about all installed apps, please click on the circle with the 6 dots within on the bottom of the screen. It is right above the navigation bar on your home screen.



3.8 Navigation bar

The navigation bar will be found on the bottom center of the screen.



3.8.1 Go one step back

To go one step back please click on the arrow pointing to the left on the bottom left navigation bar.

3.8.2 Jump to home screen

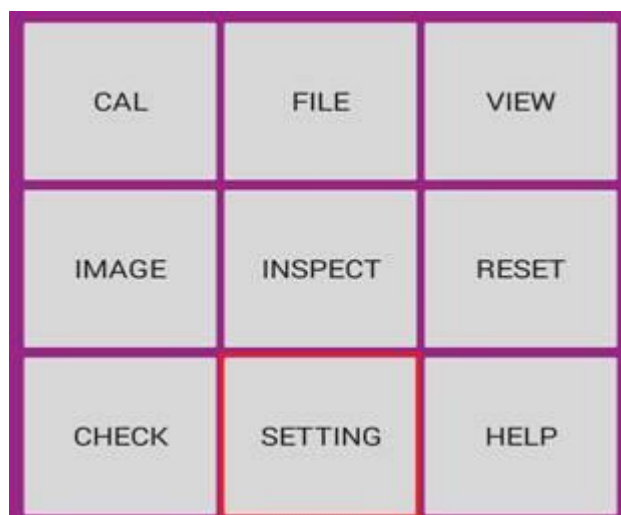
By pressing the circle button on the bottom center on the navigation bar the home screen will be shown.

3.9 Close background apps

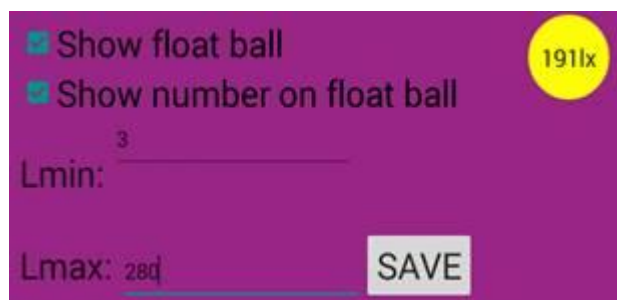
By pressing the square button on the bottom right on the navigation bar all background apps will be shown. Simply swipe an app to the side to close it.

3.10 Opening the ambient light indicator

MED-TAB CALCON is pre-installed on every MED-TAB. To open this app, please look in the total app overview.



Then please click on "Setting" and tick the two boxes in the upper left corner.



Afterwards you'll get the ambient light displayed in lux. This dot can be moved to any location on the screen. To close it please uncheck the boxes or close the app completely.

3.11 Connecting to a Wi-Fi network

1. From the home screen, tap the **Apps** icon at the bottom (it is a circle containing a grid of dots, and you can find it just above the **Home** icon)
2. Swipe across the app overview and open **Settings**.
3. Click on **Wi-Fi** at the top of the list and open the settings.
4. The screen list all nearby wireless networks. If not, please disable and re-enable the Wi-Fi-switch at the top.
5. Look up your network name and click on it.
6. Please enter the appropriate **wireless password**.
7. To ensure you have entered it correctly, you can tick the box for **Show password** to check it is correct before tapping **Connect** to continue.
8. If your password is accepted and the MED-TAB connects, your network name should show *Connected* written beneath it, and there should be a **Wi-Fi symbol** on the top line of the display, right next to the signal bars.

4 Safety information

- We intend to keep this manual as updated as possible, however information in this manual is subject to change without prior notice. It is the responsibility of the user or the local administrator to verify the details by considering suitable sources.

4.1 Precautions

- To reduce the risk of fire or electric shock, do not expose this device to rain or moisture, thunderbolts or current fluctuation, or the magnetic field of an MRI (H-No.: HW1.1.2 – HW1.1.5).
- Do not leave the device in an area with radiation as it could activate the semiconductors leading to improper diagnosis. (H-No.: HW1.2.1)
- To reduce risk of device malfunction do not be close to construction sites or any other environments creating strong vibrations. (H-No.: HW1.4.3)
- To reduce risk of faulty display rendering do not try to bend or lean on the device. (H-No.: HW1.4.4)
- Do not connect this device to other household or consumer devices.
- The MED-TAB is primarily for use in health care facilities without direct contact to patients (no applied part).
- If the device emits smoke, smells like something is burning, or makes a strange noise, disconnect all power connections immediately and contact your dealer for advice. Attempting to use a malfunctioning unit may result in fire, electric shock, burn or damage to the device.
- Do not open the case or modify it. Opening the case or modifying the device may result in fire, electric shock, burn or damage to the device.
- Refer all service to manufacturer authorized qualified service personnel. Do not attempt to service this product yourself as opening or removing covers may result in fire, electric shock, burn, or damage to the device.
- If an object or liquid falls/spills into the cabinet, unplug the unit immediately. Have the unit checked by a qualified service engineer before using it again. (H-No.: HW1.4.2)
- Do not let the device fall to the ground as it could be damaged itself or could cause injury to the user carrying it. (H-No.: HW1.4.1)
- Set up the unit in an appropriate location. Not doing so may result in fire, electric shock, burn or damage of the device.
 - Do not place the unit in a dusty or humid environment.

- Do not place the unit in a hot environment leading to too high operating temperatures. (H-No.: HW1.3.1)
 - Do not place the unit in a location where steam flows directly to the device.
 - Do not place the unit near heat generating devices or a humidifier. (H-N.: HW1.3.1)
 - Do not place the unit in an inflammable gas environment. (H-No.: HW2.2.7)
- To avoid danger of suffocation, keep the plastic packing bags away from newborns and children.
- To disconnect the power cord, grasp the plug firmly and pull. Tugging on the cord may damage and result in fire, electric shock or burn.
- Use the correct voltage.
 - The unit is designed for use with a specific voltage only. Connection to another voltage than specified in this User Manual may cause fire, electric shock, burn or equipment damage.
 - Do not overload your power circuit, as this may result in fire, electric shock or burn.
- Handle the power cord with care. If the power cord is broken, stop using it immediately. Using a broken power cord may result in fire, electric shock or burn.
 - Do not put the power cord under the unit or heavy objects.
 - Do not pull up or twist the power cord.
- Never touch the plug and power cord if it begins to thunder. Touching them may result in electric shock or burn.
- Do not touch a damaged LCD panel directly with bare hands. The liquid crystal that may leak from the panel is poisonous. Prevent to get it into the eyes or mouth. If any part of the skin or body comes in direct contact with the panel, please wash thoroughly. If some physical symptoms result, please consult your doctor.
- Follow local regulations or laws for safe disposal.
- Handle with care when carrying the unit. Disconnect the power cord and data cables and remove the optional unit. Moving the unit with the cord or the option attached is dangerous. It may result in injury. (H-No.: HW1.4.1)
- Do not block the ventilation slots of the cabinet.
 - Do not place any objects on the ventilation slots.
 - Do not install the unit in a closed space.
 - Do not use the unit laid down or upside down.
 - Blocking the ventilation slots prevents proper airflow and may result in fire, electric shock, burn or equipment damage. (H-No.: HW1.3.2, HW4.3.1)
- Do not touch the plug with wet hands. Doing so may result in electric shock.

- Periodically clean the area around the plug. Dust, water, or oil on the plug may result in fire.
- Unplug the unit before cleaning it. Cleaning the unit while it is plugged into a power outlet may result in electric shock.
- If you plan to leave the unit unused for an extended period, disconnect the power cord from the wall socket after turning off the power switch for safety and power conservation.
- When the MED-TAB is cold and brought into a room or the room temperature goes up quickly, dew condensation may occur inside and outside the display. In that case, do not turn the MED-TAB on and wait until dew condensation disappears, otherwise it may cause some damages to it. (H-No.: HW1.3.3)
- Do not scratch or press on the panel with any sharp objects, such as a pencil or pen (except the supplied Touch Pen) as this may result in damage to the panel. Do not attempt to brush with tissues as this may scratch the LCD panel.

NOTICE:

Danger of patient data breach.

We recommend you do not store patient data on the MED-TAB or an inserted memory card. The MED-TAB file system must be encrypted if patient data will be stored on the device. Ask the manufacturer for further details.

We recommend you use up-to-date anti-virus software on the MED-TAB. The virus definitions must be updated regularly (they should not be older than 2 weeks). Older virus definitions might lead to data breaches.

4.2 Environmental information

The MED-TAB and its battery must not be disposed of with other municipal waste. Please dispose the device and its accessories by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

For more information about recycling of this product, please contact your municipal waste disposal service or local city office.

FCC Warning:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- o Reorient or relocate the receiving antenna.
- o Increase the separation between the equipment and receiver.
- o Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- o Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies with part 15 of the 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.

RF Exposure Information

The device has been evaluated to meet general RF exposure requirement.

The device can be used in portable exposure condition without restriction.



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