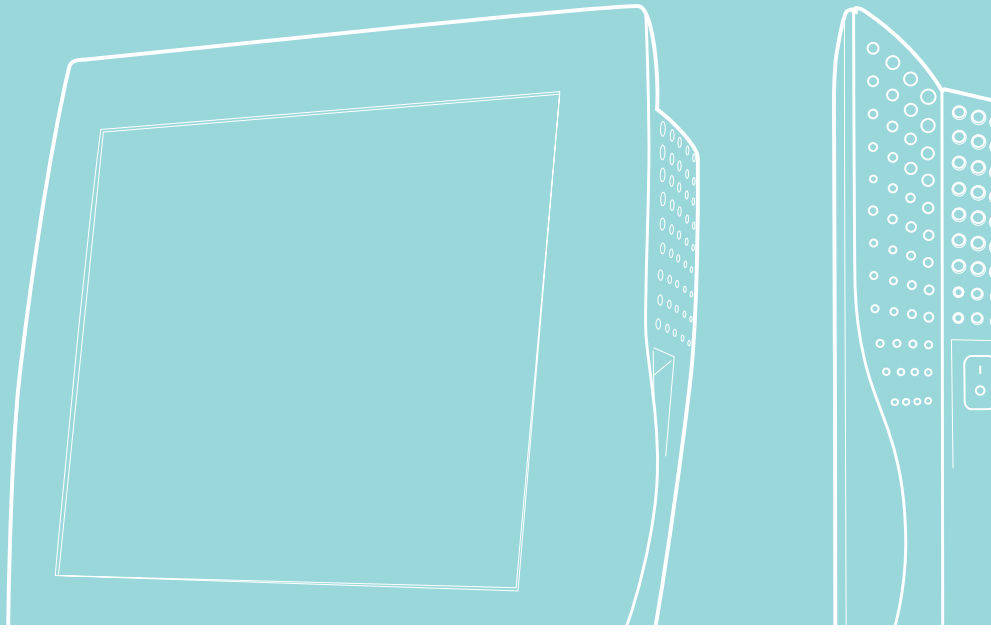
invitium™



OPERATIONS MANUAL

PLANAR®

Invitium™ Medical Workstation

OPERATIONS MANUAL

Please address any questions, comments, and suggestions to:

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Invitium™ Medical Workstation Operations Manual

About this manual

This manual is intended to assist you in setting up and using your new Invitium™ Medical Workstation. This information has been carefully checked for accuracy; however, no guarantee is given to the correctness of the contents. The information in this manual is subject to change without notice. This manual contains proprietary information protected by copyright. All rights are reserved. No part of this manual may be reproduced by any mechanical, electronic or other means, in any form, without prior written permission of the manufacturer.

This manual includes the following sections:

Section 1 About the Invitium Medical Workstation, explaining its features and key specifications.

Section 2 Getting Started, includes instructions on mounting the Invitium workstation and connecting its modules, making display adjustments and calibrating the optional touchscreen.

Section 3 Invitium System Setup, helps you define hardware and software options in the system's BIOS utility.

Section 4 Troubleshooting the Invitium Medical Workstation, provides guidance in identifying potential problems you could encounter. This section also has instructions for reinstalling Windows® and several device drivers

Section 5 Invitium Medical Workstation Technical Specifications, provides extensive system details provided for your reference.

We encourage you to look through the entire Operations Manual to familiarize yourself with its contents before you begin to set up or use your Invitium Medical Workstation.

Regulatory Information

U.S. Federal Communications Commission (FCC) Requirements

The Planar Invitium™ Medical Workstation 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.

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

To comply with the limits for an FCC Class B computing device, always use the shielded signal cord supplied with this unit. The Federal Communications Commission warns that changes or modification of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Canadian Doc Notice

For Class B Computing Devices

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the Radio Interference Regulation of the Canadian Department of Communications.

"Le present appareil numerique n'emer pas de bruits radioelecinques depassant les limires applicables aux appareils numeriques de la class B prescrites dans le Reglement sure le brouiliage radioelectrique edicte par le minstere des Communications du Canada"

Regulatory Compliance

This system has been tested and found to comply with IEC/EN 60601-1, IEC/EN 60601-1-2, UL 2601-1 and CAN/CA C22.2 No. 601.1 medical standards by Underwriters Laboratories, Inc.

Because many medical offices are located in residential areas, the Invitium workstation, in addition to meeting medical requirements, has also been tested and found to comply with the limits for Federal Communications Commission (FCC) Class B computing devices in a typically configured system. It is the system integrator or configurer's responsibility to test and ensure that the entire system complies with applicable electromagnetic compatibility (EMC) laws. Planar Systems, Inc. has made great efforts to support the medical device industry, in particular medical device manufacturers and medical device system integrators. We offer state-of-the-art systems that are compliant with worldwide accepted medical device safety standards, and for the

European market, EC-marked displays based on compliance with counsel directive 93/42/EEC — commonly referred to as the Medical Device Directive (MDD). The following summarizes our qualification of these displays as it relates to compliance with the MDD.

The European MDD requires that the intended use of the device be defined. The intended use of the Invitium workstation is "to display alphanumeric, graphic, and image data as inputted from any type of medical device." This system does not provide a measurement function in any way, and it is the device and systems manufacturers responsibility to verify its function in the integrated device or system. The workstation was classified as required by the MDD according to Annex IX of the directive and the medical device (MEDDEV) guidance available at the time of classification.

Because the workstation uses electrical energy and has no direct patient connections and- — by itself — no medical utility, the workstation is classified according to Rule 12 as an MDD Class I device-component or accessory.

The MDD states that manufacturers of Class I medical devices or accessories shall satisfy the requirements in regard to design and manufacturing controls; i.e., the applicable assessment route to be used for CD-marking under the MDD, and it shall carry the CD-mark according to Annex XII for the directive, with no notified body annotation.

The applicable safety standards for an MDD Class I device are IEC/EN60601-1: 1990 along with Amendments 1 and 2. To help the medical device designer evaluate the suitability of these workstations, Planar has also conducted EMC testing to IEC 60601-1-2 as it can be applied. The display with its power supply alone does not represent a functional medical device. Hence, Planar configured a minimal operating system to exercise the display. The resulting data is made available to interested parties.

The data is informative data, not certification data. Certification data must be obtained by the device or system integrator according to Article 12 of the MDD titled "Particular procedure for systems and procedure packs." Paragraph 2 clearly outlines the device or system integrator's responsibility in this matter.

In summary, Planar Systems, Inc. is CE-marking theses workstations under the Medical Device Directive, which establishes compliance to the basic medical safety standards. However, EMC compliance can only be accomplished in the configured medical device or system and is the responsibility of the device or system manufacturer. Planar has the necessary documentation such as IEC 60601-1 notified body and other third-party test reports and certifications, a risk/hazard analysis, and essential requirements checklist, and Planar's International Electrotechnical Commission (IEC) declaration of conformity.

Planar Systems, Inc. located in Beaverton, OR, USA is the manufacturer of these workstations in the meaning of the directive. As required by the MDD in Article 14, Planar Systems, Inc. not residing in the European Economic Area (EEA) has a European Representative, Planar Systems, Inc. –Espoo, Finland.

In the opinion of Planar Systems, Inc. registration required to put its device into commerce is the responsibility of the medical device/system manufacturer, and Planar supports this requirement by providing a European Commission (EC) declaration of conformity. If Planar supplies a workstation to an end user, rather than a device manufacturer, it is the end user's responsibility to ensure continued compliance with the MDD of the system in which the workstation is inte-

grated. For vigilance reporting as required under Article 10 of the MDD, Planar Systems, Inc. will provide any information requested by competent authority to support any reported incident investigation by such an authority.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Invitium system is intended for use in the electromagnetic environment specified below. The customer or the user of the Invitium System should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT — GUIDANCE
RF emissions CISPR 11	Group 1	The Invitium System 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 Invitium System 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-	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Invitium System is intended for use in the electromagnetic environment specified below. The customer or the user of the Invitium System should assure 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	+/- 6KV contact +/- 8KV air	+/- 6KV contact +/- 8KV 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	+/- 2KV for power supply lines +/- 1KV for input/output lines	+/- 2KV +/- 1KV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1KV differential mode +/- 2KV common mode	+/- 1KV +/- 2KV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short 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 seconds	No discernable effect No discernable effect No discernable effect Unit will power down and recover normally	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Invitium System requires continued operation during power mains interruptions, it is recommended that the Invitium System be powered from an uninterruptible power supply or 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Invitium System is intended for use in the electromagnetic environment specified below. The customer or the user of the Invitium System should assure 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	3 Vrms 150 KHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Invitium System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.16 eP d = 1.16 eP 80 MHz to 800 MHz d = 2.33 eP 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 recommend 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propogation 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 Invitium System is used exceeds the applicable RF compliance level above, the Invitium System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Invitium System.*

[b] *Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.*

European Union Declaration of Conformity for Medical Applications

A Declaration of Conformity has been filed for this product. For additional copies of the Declaration of Conformity document, please contact Planar Systems, Inc. and request document number 001-0014-04 "Declaration of Conformity."

Symbol explanations

Following are explanations of the symbols found on the Invitium Medical Workstation:

CE Indicates proof of conformity to applicable European Economic Community Council directives and two harmonized standards published in the official journal of the European Communities.

E 226863

UL 2601-1
CAN/USA C22.2
NO.601.1
IEC 60601-1

Indicates that the product has been tested and certified with respect to electric shock, fire, mechanical and other specified hazards only in accordance with US 2601-1 and CAN/CSA C22.2 No. 601.1 and IEC 60601-1 for medical equipment. If this mark appears with the indicators "C" and "US", the product is certified for U.S. Canadian markets, meeting the applicable U.S. and Canadian standards.

Indicates that it has been tested to comply with FCC Class B standards.

Consult accompanying documents.

Indicates protective earth ground.

Indicates indoor use only.

Warranty Information

Planar Systems, Inc. warrants that the goods sold hereunder will be free of defects in materials and workmanship, and such goods will substantially conform to the specifications furnished by Planar. This warranty shall be effective only if Planar receives notice of such defect or nonconformance during the period of the warranty. Planar's sole and exclusive liability for breach of warranty shall be, at Planar's option, to repair or replace the Planar product(s) with refurbished units or provide a credit to buyer in the amount of the purchase price.

Commencement of Warranty

The warranty period begins on the date of shipment.

Duration of Warranty

The goods sold hereunder are warranted for a period of one year from the date of shipment unless otherwise agreed to by Buyer and Planar. No extension of the warranty will be given during the time the goods are in Planar's possession.

Place of Repair or Replacement

In order to obtain service under this warranty, Buyer must notify Planar of the defect before expiration of the warranty period and request a "Return Material Authorization Number." If the configuration has been modified in any manner, the product must be returned to its original configuration before any warranty service will be performed by Planar. No goods are to be returned to Planar without prior authorization. Buyer will be responsible for packaging and shipping the defective goods to the nearest Planar Service Facility located in either Beaverton, Oregon, or in Espoo, Finland, with shipping charges prepaid.

Limitation of Warranty

The foregoing warranty shall not apply to defects resulting from (a) improper or inadequate maintenance by Buyer; (b) unauthorized modification of the goods; (c) operation of the goods outside of the environmental specifications of the goods; (d) neglect, misuse or abuse of the goods; or (e) modifications or integration with other goods not covered by Planar's warranty when such modifications or integration increases the likelihood of damage to the goods.

THE WARRANTY IS GIVEN BY PLANAR IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED. PLANAR DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PLANAR'S RESPONSIBILITY TO REPAIR OR REPLACE DEFECTIVE PRODUCTS IS THE SOLE AND EXCLUSIVE REMEDY PROVIDED TO THE BUYER FOR BREACH OF THIS WARRANTY. PLANAR WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES IRRESPECTIVE OF WHETHER PLANAR HAS ADVANCE NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

Technical Assistance

The warranty set forth above shall not be enlarged, diminished or affected by, and no obligation or liability shall arise from Planar, any authorized dealer, or any other person's rendering of technical advice, assistance, or services in connection with the buyer's order of the good furnished hereunder. The Buyer is not relaying on Planar's skill or judgment to select or furnish suitable goods.

Installation

Planar makes no warranty with respect to any installation of Planar's product(s) by Planar, any authorized dealer, or any other person.

Table of Contents

SECTION 4 Troubleshooting the Invitium™ Workstation

SECTION 5 Technical Specifications

SECTION 1

About the Invitium™ Medical Workstation

Before you begin

Welcome to the Planar Invitium™ Medical Workstation — the modular platform designed specifically to provide clinical information and patient monitoring applications in the point-of-care environment.

These items are shipped in the typical Invitium box. Please ensure that your Invitium box contains them:

- Document package containing this *Invitium Operations Manual* and software CDs
- Invitium *Quick Setup Guide*
- Invitium computer and attached monitor
- Power supply and cable
- Keyboard and mouse (if this is not a touchscreen system)

If anything is missing from the box, please contact us in the U.S. at **(866) 475-2627** or **(503) 748-1100** or in Finland at **358 9 42001**. Optional equipment and parts will be shipped separately.

1.1 — About the Planar Invitium™ Medical Workstation

The Planar Invitium Medical Workstation is an IBM-compatible computer, based on Intel Celeron® or Pentium® III processors. The basic system consists of a computer, monitor and power supply. A separate battery pack is available as an option.

The Invitium system supports memory configurations up to 256MB 100MHz SyncDRAM (PC-100 memory) at 3.3VDC. It supports EIDE and Ultra DMA/33 hard drives in the 3.5-inch form factor. The unit provides two USB ports, four serial ports, one PS2 keyboard port, one PS2 mouse port, and two Type II — or one Type III — Cardbus sockets.

The Invitium system provides onboard Ethernet connectivity with either 10- or 100-base-T support. It supports sound, with speakers and integrated power amplifiers mounted in the monitor. The unit does not have an internal floppy disk or CD-ROM drive.

You can boot the computer via the internally mounted hard drive or an external floppy disk drive connected via USB. The computer supports the Windows® 98 or 2000 operating systems.

The Invitium computer is passively cooled. No fans are used to cool the computer. Convection cooling is the primary method of cooling, via an array of cooling vents.

The monitor is a 15-inch AMLCD-TFT with a resolution of 1024x768 at 262,144 colors (18 bit). A resistive touchscreen option is available.

The Invitium system is powered by a single external power supply or by an optional battery pack. Each provides a regulated 12 volts as the main system voltage.

The computer and monitor can be mounted together to form a single integrated unit, or they can be mounted separately with the monitor as a standalone unit. A standard VESA mounting pattern is provided to allow use of standard mounting hardware for commercial carts, poles and wall-mounts.

The Invitium Medical Workstation is certified:

- In accordance with IEC/EN 60601-1:1990 + A1 + A2 for sale to the medical market
- By Underwriters Laboratory to medical standards UL 2601-1 and C22.2 No. 601.1 M1990 for sale in the U.S. and Canada.

The system also carries the CE marked for sale into the European Community. Declarations of conformity are in Section 5 of this manual.

For a full list of Invitium computer and monitor specifications, please refer to *Section 5: Technical Specifications* in this manual.

This photo shows location of the connectors and ports in the computer connector bay.

This photo shows the connectors on the bottom of the monitor enclosure.

1.2 — About the Invitium™ system power adapter

The Invitium Medical Workstation has an external power adapter rated to work from 90 to 240Vac at 50 to 60Hz. This external, double-insulated power supply is equipped with an IEC320 appliance coupler.

The power adapter includes an attached power cable that terminates in the required monitor power connector. An LED indicates when power is applied. Adapter power is supplied via a medical grade 3m power cable. The adapter input voltage ranges between U.S. and European standards and comes equipped with either European or US standard medical-grade power cables.

Please refer to *Section 5: Technical Specifications* of this manual for complete power adapter specifications.

1.3 — About the Invitium™ optional battery pack

The Invitium Battery Pack is a system option that supplies a regulated +12 VDC to the Invitium Medical Workstation.

The battery pack contains a sealed lead acid (SLA) battery, medically certified universal input power supply, charging and monitoring electronics, and output voltage regulator. It is contained within a plastic enclosure with all components mounted to an internal sheet metal frame to provide mechanical strength as well as EMI/EMC protection and shielding.

The battery pack provides up to eight hours of system operation at a nominal load of 60 watts. Recharge time is less than four hours. The charging and monitoring electronics control the charge rate of the battery as well as the maximum discharge level. This is to ensure safe operation of the battery and to prevent damage from high charge rates and low discharge levels.

The Invitium system's battery pack is certified by Underwriters Laboratories to medical standard UL2601-1 and C22.2 No. 601.1 M1990 for sale in the U.S. and Canada. The system is also CE marked for use in the Europe.

For a full list of battery pack specifications, please refer to *Section 5: Technical Specifications* in this manual.

⚠ **The Invitium Medical Workstation is a Class I system under the MDD, intended for near-patient proximity use. It is not intended for direct connection to the patient.**

1.4 — Safety Instructions

The Invitium Medical Workstation is designed to ensure both the highest level of product quality and safety for the user. To maintain both quality and safety, follow the instructions in this manual and these safety guidelines.

1. Read the safety and installation guidelines carefully.
2. Keep this manual handy for future reference.
3. Install and use the Invitium system only on a sturdy surface and in stable surroundings.
4. Do not place the Invitium workstation near a window. Exposing the system to rain, water, moisture or constant direct sunlight can severely damage it.
5. Do not place anything on top of the monitor-to-computer signal cord. Make sure the cord is placed where it will not be stepped on.
6. Do not apply excessive pressure to the monitor screen. Excessive pressure may cause permanent damage to the display.
7. The Invitium workstation has no internal user-serviceable parts. Refer all servicing to qualified personnel to maintain your warranty.
8. Do not cover or obstruct any venting holes on the computer or the monitor.
9. Store the Invitium system within –20 to +65 degrees Celsius. Storing the system outside that temperature range could result in permanent damage.
10. If any cord or cable is frayed or damaged, immediately replace it with another of the same type and rating as supplies by Planar. The safety and regulatory listing and certifications are based on cables supplied by Planar.

11. If the Invitium system has been exposed to liquid, has been dropped, or if its casing has been damaged, it may pose a shock or fire hazard. Immediately unplug it and contact customer service for assistance.
12. Use only the power adapter that has been tested and approved for use with this product.
13. Use and maintain the safety ground plug set (power cord) included with the unit.
14. After you have installed the Invitium system, secure all electrical cords to prevent the unit from being pulled off the table or other accidental damage.
15. The Invitium computer system, its power supply and its optional battery pack meet the UL 2601 standard for cleaning in a hospital environment. Please see the upcoming section on Cleaning for details.
16. Before cleaning, or if the unit becomes wet for any reason, it is best to disconnect the unit from its power source.
17. Practice caution when moving the Invitium system to a different location. Use original packaging whenever possible.

⚠ **The Invitium system must be plugged into a GROUNDED power outlet.**

1.5 — Cleaning

The Invitium Medical Workstation continues to operate normally while being cleaned in a fashion normal for a hospital environment. This includes cleaning with a damp, mildly soapy cloth. Drip protection is provided in accordance with IPX1 rating defined in the IEC/EN60529 standard.

The Invitium system can withstand cleaning solutions used in hospitals for similar equipment. This is typically warm water and mild detergent for all surfaces, or 70 percent IPA for the touchscreen surface. Possible chemicals include:

- 70% isopropyl alcohol
- 1.6% aqueous ammonia
- Cidex, (2.4% glutaraldehyde solution)
- Sodium Hypochlorite (bleach) 10%
- "Green soap" USP
- 0.5% Chlorhexidine in 70% isopropyl alcohol
- Ovation®
- Formula 409®
- Fantastic®
- WexCide®

To clean the Invitium monitor screen, do not spray liquid cleaners directly onto it. Stand away from the monitor and spray the cleaning solution onto a nonabrasive cloth. Clean the screen with the slightly dampened cloth, without applying excessive pressure.

1.6 — Service support

The Invitium Medical Workstation requires no routine maintenance. There are no user-serviceable components inside it. If repair is required, please return the unit to Planar Systems for servicing to maintain the product warranty. See details in the *Warranty* section in the opening pages of this manual.

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