Apex Digital Dental X-Ray System

Apex Dental Sensor Size #1

Apex Dental Sensor Size #2

User Manual

Before attempting to connect or operate this product, please read these instructions completely!

Version：1.00

Contents

1. Notice

1.1 Indication of Use

The Digital dental X-ray imaging system is intended to generate intraoral x-ray image require to working with x-ray source and imaging software in dental clinic for dentist and orthodontists.

1.2 Brief Introduction of this Manual

This manual consist of the safety issue, Apex Dental Sensor brief introduction, how to use sensor and the warranty policy.

1.3 Manufacturer

Manual Name: Apex Digital Dental X-Ray System Manual
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The system shall be in accordance with IEC60601-1-1. The person connect the product to the host computer shall insure its compliance.

Manufacturer

HAMAMATSU PHOTONICS K.K.
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1.4 Packing List

1: Sensor
2: Dental Sensor Holders
3: Sensor Covers

3. X-Ray Sensor and Control Box 1pcs
4. Holder 1pcs
5. Sleeves 1 bag

1.5 Symbols

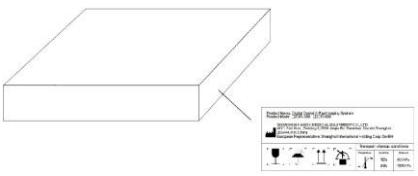
Marking and Labeling Symbols

Symbol	Description
	Caution , refer to accompanying documentation
	Class-Ⅱ Device
	Type BF applied part
SN	Manufacture’s serial number
	MANUFACTURE Manufacture’s name and address
	FRAGILE Contents of the transport package are fragile therefore it shall be handled with care
	THIS WAY UP Indicates correct upright position of the transport package.
	KEEP AWAY FROM RAIN Transport package shall be kept away from rain.
	Antiroll
	Max and Min. temperature
	Indicates that in the European Union, at the end of product life this device must be disposed of in accordance with the requirements of the Waste Electrical and Electronic Equipment (WEEE) directive 2002/96/EC

Label Location

The following Figure indicates the label locations of The Apex Dental Sensor Systems.

Figure 1 The Apex Dental Sensor Label Locations



2. Safety issue

2.1 Check Sensor and controller before using them

Before each usage, check the outer surface of the Sensor and controller for any signs of physical damage or defect. Sensor and controller surfaces should have a smooth finish, with no evidence of chipping or damage. If detected, contact your local distributor of this product for further instructions.

2.2 Protect Sensor from Potential ESD Damage

Like other electronic devices, Sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low humidity environments. During cable replacement, when Sensor contacts are exposed, it is especially important to protect the device from potential ESD damage. Touching a metal surface prior to replacing the cable will reduce the risk of damaging Sensor components by accidental static discharge. The use of anti-static floor mats or floor treatments (for example Staticide 2005/2002) will also help eliminate static build-up in your office.

2.3 Do Not Touch Exposed Connectors on Non-Medical Equipment and the Patient at the Same Time

When the Sensor and controller are in use, avoid touching exposed connectors on non-medical electrical equipment and the patient at the same time. The human body is capable of conducting electrical current and may cause a shock hazard to patients if appropriate safety practices are not observed.

2.4 Ensure Proper System and PC Workstation Installation and Operation

The Sensor and controller have been determined to be in accordance with international safety standards and are deemed suitable for use within the patient area, which extends from the patient for a distance of 5 ft (1.5m). To comply with these standards, do not operate non-medical equipment (such as a PC workstation) inside the patient area. Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / IEC 60950-1 certified Information Technology Equipment (ITE) computer equipment is acceptable. The host computer (PC

workstation) should be CE-approved and conform to the Low
Voltage [73/23/EC] and EMC Directive [89/336/ERC]. The system shall be in accordance with IEC60601-1-1. The person connect the product
to the host computer shall insure its compliance. Also, to help ensure optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not impact imaging applications after installation. Any questions please contact your local distributor

2.5 Safety Classifications

Safety Type: Class-Ⅱ BF
Power: DC5V
Degree of protection against ingress of water: IP67
Non AP equipment, non APG equipment
Mode of operation: Continuous operation

2.6 Conditions required in operation, transportation, and storage

2.6.1 Operating conditions

Environment Temperature : 0℃～+35℃
Environment relative humidity : ≤70%；
Air pressure : 700hPa～1060hPa；

2.6.2 Transport and Storage conditions

Environment Temperature: -40℃~+70℃;
Environment relative humidity : 10%~70%;
Air pressure : 700hPa~1060hPa;

3. Waste Electrical and Electronic Equipment

3.1 Background

The European Union's Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC) has been implemented in member states as of August 13, 2005. This directive, which seeks to reduce the waste of electrical and electronic equipment through re-use, recycling, and recovery, imposes several requirements on producers. HAMAMATSU PHOTONICS K.K. and its Dealers are committed to complying with the Directive.

3.2 WEEE Marking

All HAMAMATSU products subject to the WEEE Directive and shipped after August 13, 2005 will be compliant with the WEEE marking requirements. These products will be identified with the "crossed-out wheeled bin" WEEE symbol shown below, as defined in European Standard EN 50419, and in accordance with WEEE Directive 2002/96/EC.

This "crossed-out wheeled bin" symbol on the product or on its packaging indicates that this product must not be disposed of with other unsorted municipal waste. Instead, it is user's responsibility to dispose of EE waste equipment by handing it over to a designated collection point for the reuse or recycling of waste electrical and electronic equipment. The separate collection and reuse or recycling of Electrical & Electronic waste equipment will help to conserve natural resources and ensure that it is recycled in a manner that protects the environment and human health. For more information about where you can drop off your waste equipment for recycling, please contact your local officials.

3.3 Reporting

According to the WEEE Directive, HAMAMATSU PHOTONICS K.K. or its Dealers will ensure that information needed to calculate the financial obligations with respect to EEE products will be provided as required.

3.4 WEEE from Users other than Private Households

According to the WEEE Directive, HAMAMATSU PHOTONICS K.K. or its Dealers will fulfill its obligations for the management of WEEE from users other than private households. Furthermore, as required by the WEEE Directive, in order to enable the date upon which the equipment was put on the market to be determined unequivocally, a mark on the equipment will be placed to specify that the equipment was put on the market after August 13, 2005.

3.5 Information for Reuse Centers, Treatment and Recycling Facilities

After August 13, 2005, and as required by the WEEE Directive, HAMAMATSU PHOTONICS K.K. or its Dealers will provide reuse, treatment, and recycling information for each type of new EEE put on the market within one year of the date in which the equipment is put on the market.
Information will include the different EEE components and materials as well as the location of substances in these items. The information will be provided as a printed document or in electronic media (on CD-ROM or by web download, for example)

3.6 Warning and Safety Instructions

For Device:

- Read and comprehend this Safety Instruction before using the Apex Dental Sensor Systems.
- The operation and maintenance of this device must be taken charge by you. This device only can be operated by the legally qualified persons. If necessary, have an authorized qualified technician carry out inspection and maintenance operations.
- This device must be installed in an X-ray room that complies with current installation standards. From this location, any visual or audio communication with the patient must be maintained by you and the Acquisition interface module during exposure.
- X-ray equipment is hazardous to patients and the operator if you do not comply with the exposure safety factors and operating instructions.
- This device must not be allowed to be operated if there is the threat of an earthquake. After an earthquake, ensure that the device is operating satisfactorily before using it again. Failure to observe patients to hazards.
- DO NOT place any objects within the field of operation of the device.
- Connect this equipment ONLY to a mains power supply with protective ground to avoid any risk of electric shock.
- Disposing of the device or its components must be executed by a qualified service technician.
- Never be allowed to modify the device.
- This device is never allowed to be applied in conjunction with oxygen-rich environments.

Nor intended for apply with flammable anesthetics or flammable agents. Using accessories other than those specified in this document with the exception of those sold by Masterlink may result in a lower level of security for the entire system.

For Computer:

- DO NOT place the computer and the peripheral equipment connected to it in the immediate vicinity of the patient in the unit. Leave at least 1.5m distance between the patient and the unit. The computer and the peripheral equipment must conform to the IEC60950 standard.
- Read your computer installation guide for details of the data processing system and screen. Ensure the proper ventilation with leaving a sufficient amount of clear space around the CPU.
- In order to acquire maximum image quality and visual comfort, direct light reflections from internal or external lighting should be avoided when position the screen.

3.7 Hygiene and Disinfection Instruction

- DO NOT place the sensor in an autoclave environment as which could cause serious damage to the sensor.
- The sensor head should be disinfected after each patient.
- Do not apply chemical autoclave for the toothbrush holders and avoid direct contact with the metallic part of the autoclave.
- To prevent from cross-contamination, apply a new hygienic barrier for each new patient

4. Masterlink – Apex Sensor
General Introduction

Dental digital x-ray imaging system is consisted of sensor, image controller, image capture system and connection cable (USB port), connected with PC or notebook via USB cable. The power of controller and sensor is supplied by USB port, require no battery or power charge system. The whole equipment need to work together with imaging software.

4.1 Functional Components

4.11 Apex sensor

The sensor active surface is flat including the size 1 and size 2.

- Size1, universal sensor---Use for regular procedures, both for children and adult.
- Size2 sensor---Use for bitewings procedures.

The sensor non-reactive to X-Rays surface, contains the cable attachment.
Figure 2 Apex Sensor

1 Sensor non-reactive to X-Rays surface
2 Sensor active surface

4.2 Technical Specifications

Sensor: APS CMOS sensor
External dimension (mm): 25mmx39mm(size1) ;
30.4mmx41.9mm(size 2)
Sensor Active Area: 20mmx30mm(size1) ;
26mmx34mm(size2)
Sensor Thickness : 5.3mm
Power : USB2.0 (5V, 4.25min)
Image Transfer Time :< 3sec
Cable Length :.> 2m

4.3 Sharing the Sensor Between Rooms

You can share the sensor between several rooms to provide access for several dentist based on Apteryx XrayVision software. The computer must have the Apteryx XrayVision dental imaging software installed on each computer.

To share the sensor between several computers, move it from room to room. When you connect the sensor to a USB 2.0 port on the computer, the sensor is recognized automatically and is operational.

To share data between rooms, you can connect them to remote data--- Apteryx XrayVision Server database. The Apteryx XrayVision dental imaging software needs only to access a shared database on the same computer or on a remote computer, which means Apteryx XrayVision database.

4.4 Using the different Positioning Systems

There are two ways to position the sensor in the patient mouth to get a classic radiograph. You may spend some time to adapt due to the rigidity of the sensor.

One method is angular bisector technique, the other method is paralleling technique. It is just the way to position sensor, which can be chosen by practitioner's experience.

4.5 X-Ray Generator Compatibility

Normally, the sensor is compatible with all generators which meets the present standard of intraoral radiology. You can use a high frequency or conventional generator. To achieve gaining better images, the generator must operate with a voltage of **65** to **70kV.**

5. Imaging Software General Introduction

5.1 Computer System Requirements

Processor: Intel 1.2GHz chip or above;
Memory: Above 1G ;
Hard disk: Above 40G;
Interface: USB 2.0;
Display: Resolution 1024 × 758 (15") or above
Operating System: Windows XP
The computer connected to system shall be in accordance with IEC 60950-1:2005.

5.2 Imaging Software

The Apex Dental Sensor imaging system operates with the following software:

- Apteryx XrayVision
- Apteryx XrayVision Server for sharing information between workstations.

Apteryx XrayVision Software is a user-friendly working interface that was designed and developed specifically for radiological diagnosis. It is the common imaging platform for all our digital systems for dentistry.

6. Troubleshooting Images

Troubleshooting images using the troubleshooting table below. If the problem persists, or if it is not outlined below, contact your representative.

⚠**Notice:** If the malfunction persist or more serious conditions occur, contact your representative.

Table 1

Malfunction	Possible Cause & Action
No images is displayed after triggering the x-rays.	Make sure the capture window is open, Check the connection of the sensor on the USB2.0 port.
The image is pale, too light	● The exposure time is too short; increase it. ● The generator voltage is too low; have the generator checked. ● The generator is too far from the patient with respect to the selected dose. ● Check the monitor setting (contrast and brightness) and ensure there are no reflections on the screen.
The image is too dark.	● The exposure time is too high; lower it. ● Check the monitor setting (contrast and brightness) and ensure there are no reflections on the screen.
The image is blurred.	● Patient moved during exposure. ● Generator head was not stable ● Use an image filter.
The image is white.	● Active face of sensor was not exposed to x-rays. ● X-Ray dose is insufficient. ● Sensor is not connected, or is improperly connected. ● Ensure the generator is producing x-rays; have it checked by a certified technician.
There is white lines on the image	● Make sure install the calibration files.

7. Maintenance

7.1 Visual Inspection

Like all electrical equipment, the product requires not only correct use, but also visual inspection prior to operation, and routine checks at regular intervals. These precautions will help ensure that the product operates accurately, safely, and efficiently.

Before operating the system, users shall check it for any signs of physical damage or defect. If detected, contact your local distributor of this product for further instructions.

7.2 Periodic Maintenance

Periodic maintenance is performed as needed, but at least once a month. It consists of various checks performed by the operator or by a qualified service technician.

- Check that the labels are intact, readable, and adhere well to the surfaces on which they are positioned
- Check that all of the cables are undamaged
- Check that there is no external damage to the product which could compromise its ability to operate safely
- Check the installation, then do the step 1, 2 and 5 of operation and check that the indicator lights and indicator area in software are in normal.

7.3 Cable Care

Improper coiling of a sensor's cable is the most common cause of the sensor failure.

The following instruction is important to be followed for preventing cable damage.

- Grasp the connector not the sensor cable when disconnecting the sensor from USB control box. Pull it gently.
- Once unpacked, never coil the sensor cable, repeated coiling may cause kinks and irreversible damage.
- Store the sensor in its holder when it's not in use.
- Don't let the cable hang on or near the floor where can become tangled.
- Don't tangle the cable during use.

Note: The length is actual only when it was calibrated. If not, the value is just for reference.

7.4 Damaged or Non-Functioning Sensor

In the event of obvious physical damage to the Sensor or in the event that the sensor can’t work properly, customers shall discontinue use of the Sensor, and contact their local distributor of the products to substitute another Sensor if available.

7.5 Image Quality Assurance

Image quality of the Apex sensor depends on several factors:

•The quality of the X-ray source (kV, focal spot size, distance)

•The alignment of the X-ray source to the anatomic region

•The applied X-ray dose / exposure time

•The settings of the computer monitor

It is recommended that you establish a procedure for periodic review of the image quality.

If image quality is not satisfactory, or degrading images, check your manufacturer guidelines of your generator to make sure it not a software problem. Then contact customer support at (800) 869-0915.

Display Image: Refer to the software manual for guidance on how to ensure good display settings and image display properties.

8. Warranty

The warranty covers manufacturing defects from the original purchase date.

The warranty service you can be offered as below
2 Year Warranty Basis

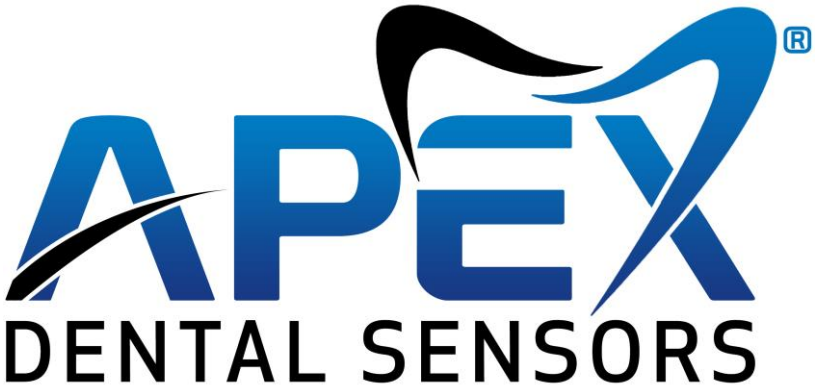
Warranty Conditions End User
Thank you for purchase the Masterlink products, we hope you enjoy with it and satisfied with the security of our warranty service.

All the products developed and supplied by Masterlink are well tested to ensure that they meet strict standards. In that case, if a problem occurs and the problem is caused by a defect in material and /or workmanship during manufacture, Masterlink will in its duty for either fix or replace the products.

The period of the basic warranty shall be 2 year from the date of the purchase time. The product must be registered within 30 days of the date of installation.

This warranty covers only manufacturing defects and is applicable only when the product is correctly operated and maintained according to the manual instruction. If the product is proven to be defective or faulty in materials or manufacture, we will take the responsible to repair the product or replace spare parts. Regardless of the solution chosen by Masterlink, the customer must return the faulty product at the customer's cost and we shall examine any alleged defective product. Please contact your dealer in order to handle any warranty claim. Please note that you are not entitled to withhold payment of invoices or make deduction on account of products claimed to be defective.

This warranty does not cover any damage by misapply, neglect, accidents, abrasion, exposure to extreme temperatures, solvent, acids, water, or normal wear and tear. We cannot therefore be held responsible for any consequences resulting from the non-application of the operating instructions contained in the installation, including (but not limited to) bodily harm, profit loss, loss of production, data loss, financial loss or and other incidental and consequential damages are expressly disclaimed. Labor charges and damages attributable to work performed by anyone other than a Masterlink representative or certified service provider are not covered by this warranty. The warranty provided is limited to the value of the product. Manufacturing specifications are subject to change without notice.



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