

Portable X-ray system



# **User Manual**

UM-206

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## **About the Manual**

The following manual for the ZEN-PX4 covers all operational instructions and pertinent information.

Please read through this manual for proper and safe use of the equipment.

GENORAY Co., Ltd. is continuously developing the equipment, so it's manual and configuration may change without the user's prior consent. If you have any questions about the equipment or manual, please contact our service center.

The manufacturer and importer are responsible for ensuring the safety and reliability of the equipment along with its installation, calibration and repair by qualified personnel.



#### Used Symbols

| Symbol             | Description   | Location        |
|--------------------|---|-----------------|
| $\sim$             | AC (Current)  |                 |
|                    | Protective earth (Ground)   | Boards          |
|                    | "ON" (Power)  | ON/OFF Switch   |
| $\bigcirc$         | "OFF" (Power)   | ON/OFF Switch   |
|                    | X-Ray generator, X-Ray inspection   | Label           |
| <u>A</u>           | Warning, electricity  | Generator       |
| X                  | WEEE Mark   | Label           |
| *                  | Type-B Applied Part   | Label           |
|                    | Name of Manufacturer and Address  | Label           |
| $\sim$             | Manufactured Date   | Label           |
| SN                 | Equipment Serial Number   | Label           |
| <b>(</b>           | Refer to the User Manual  | Label           |
| <b>C E</b><br>2460 | The CE symbol indicates that this product complies with<br>the European Directive for Medical Devices 93/42/ EEC as<br>amended by 2007/47/EC as a class IIb device. | Label<br>Manual |
| EC REP             | Authorized Representative in the European community   | Label<br>Manual |



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## 1. Equipment Introduction and Safety Information

### 1.1 Equipment Introduction

The ZEN-PX4 Portable X-ray system is intended to be used by trained dentists and dental technicians as an extra oral x-ray source for producing diagnostic x-ray images using an intraoral image receptor. This device is intended for both adult and children.

The multiple name of the ZEN-PX4 is PORT-X IV.

The applied part where the patient and the ZEN-PX4 are in contact is the cone and sensor part.

- Features of the ZEN-PX4
  - Convenient User Interface
  - Exposure time settings for each tooth
  - Using IPS LCD well-equipped for viewing angles
  - Reduced overall weight to improve portability
  - When connected with a Genoray sensor, it is possible to view the images obtained by equipment on the back LCD



This equipment conforms to Class II according to the Rule 10 of Classification Criteria, Annex IX of Council Directive 93/42/EEC.

- Firmware version
  - Version 1.0.6.9



The Firmware is constantly updated so the manual version and actual equipment may differ in versions.

To set automatic firmware updates, please refer to "2.6.1 Settings – Menu."



Equipment Warranty

All equipment of GENORAY Co., Ltd. receives warranty repairs free of charge for breakdowns and defects occurring during warranty period after purchase.

In the following cases, a service fee will be charged after the repair:

- The warranty period has expired.
- Breakdown was caused by a natural disaster such as earthquake, fire, lightning, etc.
- Breakdown due to improper transportation of equipment or careless use.
- Breakdown was caused by repair or modification by someone other than Genoray Co., Ltd. or designated service personnel.



Federal law restricts this device to sale by or on the order of a physician, dentist and veterinarian.



We will make available on request circuit diagrams, component part lists or other information that will assist service personnel to repair those parts of ZEN-PX4.



#### **1.2** Precautions before use

Users are responsible for equipment operation and maintenance. For your safety, please be familiar with the following precautions and perform regular inspections.

- There is always potential risk present with the use of medical devices that use X-rays and electricity.
- Please read the safety related information provided in the manual such as the method of use and methods for handling emergency situations, etc.
- Please read this manual thoroughly before using this equipment.
- This equipment may only be used by legally qualified doctors, dentists and radiologists.
- Please check condition of contact, polarity and confirm the equipment is operating correctly.
- Please check that all cord connections are correct and complete.
- Since a rechargeable battery is used, please check the charge before use and if the charge is insufficient, use the dedicated adapter to charge it.
- If any abnormality is found or if the battery needs to be replaced, consult the distributor or manufacturer.
- Only use the adaptor supplied by Genoray Co., Ltd.
- In case of malfunction, do not attempt to operate the system until it has been inspected by a qualified service technician.
- Instruct the patient to remove any kind of accessories and metals, such as glasses, hearing
  aids, dentures, or hairpins before the imaging. There may be shadows and reflections when
  you take an image with the above-mentioned objects. For safety reasons, it is
  recommended that any attire that goes around the neck, such as scarfs, mufflers, and
  neckties, be removed.
- Do not change this equipment without the permission of the manufacturer.



Do not modify this device without the permission of the manufacturer.



### 1.3 Suitability

The user of this equipment is responsible for verifying the X-ray exposure, leakage dose, valid beam center and accuracy of kV and mAs.

- This equipment may be used only by legally qualified doctors and radiologists.
- Only authorized persons may enter the X-ray room.

#### **1.4** Precautions During Use

- Use it by following user's age, gender, body conditions and be aware to not exceed the time required for diagnosis and treatment.
- Use as directed by a specialist. It is to be used only by authorized personnel.
- Continue to monitor the device as a whole and the patient for any abnormalities.
- If abnormalities are found in the device as a whole or in the patient, take appropriate measures, such as keeping the patient in a safe condition and stopping the operation of the device, etc.
- In the event of a malfunction of the device, do not touch the device but check the power supply and for the appearance of abnormality based on the judgment of the person in charge. Make a request to the manufacturer's or seller's specialist for repair after marking it appropriately.
- The Micro SD card should be examined on a regular basis, and if it is unreadable, you must purchase a new SD card.
- We recommend only using SD cards that the manufacturer has authorized or provided.
- When removing the SD card from the equipment, make sure to turn the power off.
- If you attempt to remove the Micro SD card while the power is on, it may cause data loss or damage to the Micro SD card and cause errors in the card.
- Do not disassemble or modify the Micro SD card.



#### **1.5** Precautions when using a wireless USB Dongle

- Wireless Lan USB Dongle is provided as an option for the ZEN-PX4.
- We recommend that you only use products that have been provided by CE/FCC certified by Genoray.
- The router uses WPA-PSK or a higher form of security, preventing external devices from connecting. (ZEN-PX4 cannot connect to routers without a password).
- Regularly change passwords.
- If the password is exposed externally, immediately change the password.
- Block any external devices connecting to the router that is being used.
- Have the PC OS system updated at all times.
- Use antivirus programs for your PC and keep the antivirus programs updated at all times.
- Have ZEN-PX4 updated to the newest Firmware.
- Periodically change the ID and password when ZEN-PX4 is connected to the PC.
- If the ID and password used when the ZEN-PX4 is connected to the PC are exposed externally, change both immediately.
- Do not connect ZEN-PX4 with the PC if the PC is infected with a malicious virus.
- If the PC is infected by a malicious virus, immediately sever the network connection and seek security advice.



### **1.6 Storage Precautions**

- Please store it at a place away from water.
- Store in a place where adverse effects are not caused by atmospheric pressure, temperature, humidity, ventilation, consistency, dust, salt, ions, etc.
- Pay attention to safety conditions such as slope, vibration, shock, etc.
- Do not store in chemical storage or gas generating locations.
- When using the device, do not use any device that can generate external electromagnetic fields, such as a cell phone.
- Regularly check the performance of the device and components.
- When using a device that has not been used for a long time, check with the manufacturer to make sure that it is operating completely normally.
- Use a neutral detergent to clean regularly and ensure that liquid does not go into the equipment.
- Use a disinfectant solution such as 2% ammonia water to disinfect the areas patients have touched.
- Do not use corrosive detergents or disinfectants.



### 1.7 Electrical Safety and Fire

Please check the following before using this equipment.

- This equipment is powered by a battery.
- While charging the battery, please check if the plug supplying power is appropriate.
- The same should be checked for the power input of all peripheral devices (signal input/output including peripheral devices).



To avoid electrical interference when charging the power supply of this equipment, keep it away from power generators, other X-ray equipment, and broadcasting stations. If this equipment shares power with other electrical or electronic equipment, abnormal images may occur.



ZEN-PX4 is a Class 1 device and Type B device with respect to its rated safety type and grade.

This equipment is not protected against liquid.



To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



Make sure that the grounding is connected properly to avoid electric shock.



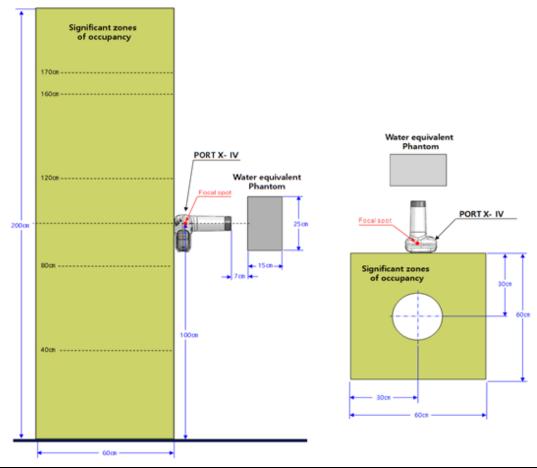
The electrical circuits in this equipment utilize voltages that can cause serious injury or death from electric shock. To avoid such risks, users should never remove the cover from any part of the unit.



To charge the battery, use the provided charger. If it is used for any purpose other than charging this equipment, it may cause damage or breakdown of the equipment.



## **1.8 Significant zones of occupancy**



| Height(cm) | Highest permissible Air<br>kerma | Measured stray radiation<br>in one hour |
|------------|----------------------------------|---|
|            | In one year, mGy                 | mGy                                     |
| 0          | 1.5                              | 0.101                                   |
| 20         | 0.7                              | 0.309                                   |
| 40         | 0.7                              | 0.334                                   |
| 60         | 0.7                              | 0.140                                   |
| 80         | 0.7                              | 0.081                                   |
| 100        | 0.7                              | 0.149                                   |
| 120        | 0.7                              | 0.242                                   |
| 140        | 0.7                              | 0.221                                   |
| 160        | 0.7                              | 0.208                                   |
| 170        | 0.7                              | 0.108                                   |
| 180        | 0.7                              | 0.198                                   |
| 200        | 0.7                              | 0.129                                   |



### 1.9 Radiation Safety

Must comply with all radiation laws and regulations with the local jurisdiction.

- When taking exposures, the x-ray room of the floor, wall material and radiation protection must be strengthened.
- When taking exposures, operators and service personnel must protect themselves from radiation.
- Protect the patient from scattered radiation by placing a protective lead apron over the patient.
- When taking an X-ray exposure of a child or pregnant woman, consult a doctor.
- Before exposing the X-ray, ask any female patient of childbearing age whether she might be pregnant.
- All patients must be provided with a shielded apron for gonad protection.
- We recommend you use Backscatter shield to prevent unnecessary exposure.
- Please refer to the following for radiation safety information for pediatric.
  - Always comply with recommended X-ray dose when exposing the X-ray of a pediatric.
  - Avoid additional exposures by unnecessary movement of a pediatric, must be accompanied by a parents.
  - Always use thyroid collars.
  - Use special care when imaging patients outside the typical adult size range.
- For more information, please visit: <u>http://www.fda.gov/Radiation-</u> <u>EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.ht</u> <u>m</u>



Cautions when using Implantable pacemaker, Implantable AED. In case of using continual exposure, the minimum output of x-ray is required to prevent direct exposure to Implantable pacemaker or AED and malfunction.



The unit may be dangerous to the user and the patient, if the safety regulations and standard procedures in this manual are ignored.



The unit can be used at all age that requires X-ray diagnosis, but consult a doctor if the system is used for using children and pregnant women.



This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.



### 1.10 Equipment Overheating

| Temperature                    | Color                 | X-Ray Exposure Status   |
|--------------------------------|-----------------------|---|
| Room temperature 5°⊂ or below  | နှင့်<br>Grey         | X-ray exposure impossible   |
| Room temperature 6°⊂ to 13°⊂   | <b>B</b> lue          | X-ray exposure possible (recommended<br>to use after warming up)          |
| Room temperature 14°C to 40°C  | <b>e</b><br>Green     | X-Ray exposure possible   |
| Room temperature 41°C to 44℃   | <b>}</b><br>Yellow    | X-ray exposure possible (recommended to use after cooling)                |
| Room temperature 45°C or above | <mark>}</mark><br>Red | X-ray exposure impossible (overheating of high voltage generating device) |

The below warning is displayed when the high voltage generating device is overheated.

 In case of overheating of high voltage generating device, turn off the power and wait for 2 to 3 hours for cooling time. After that, turn on the power and check if exposure is possible.



If you use the equipment continuously without cooling time, the X-ray tube may be damaged. Therefore, use it after allowing it to have the post-exposure cooling time.



#### **1.11 Usage Environment**

- Allowable Environment
  - Temperature: 6 °C to 35 °C (42.8 °F to 95 °F)
  - Relative Humidity: 10% to 80%
  - Atmospheric pressure: 800 to 1060 hPa (80 to 106 kPa)
- Optimal temperature and humidity
  - Temperature: 19 °C to 25 °C (66.2 °F to 77 °F)
  - Relative Humidity: 40% to 60%
- Move & Storage Environment
  - Temperature: -10 ~ 60°C (14 °F to 140 °F)
  - Relative Humidity: 10 ~ 80%
  - Atmospheric pressure: 500~1060 hPa
- Avoid the following conditions when using and storing the equipment.
  - Exposure to direct sunlight
  - Exposure to dusty conditions
  - Exposure to high humidity
  - · Environments that may cause problems with the ventilation of the equipment
  - Exposure to a salt-containing atmosphere
  - Exposure to chemical or hazardous gases

#### 1.12 Waste Treatment Methods

Disposal of worn out equipment and accessory wastes is as follows.

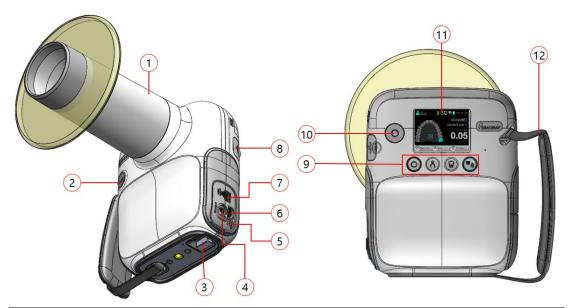
| No. | Component                                     | Disposal Method                     |
|-----|---|-------------------------------------|
| 1   | X-ray Tube                                    | Industrial Waste Treatment Facility |
| 2   | Plastic                                       | Recycled                            |
| 3   | PCB & Harness or Other Processing<br>Material | Industrial Waste Treatment Facility |





## 2. Composition of ZEN-PX4

## 2.1 Structure and Naming



| No. | Naming                         | No. | Naming                               |
|-----|--------------------------------|-----|--------------------------------------|
| 1   | Exposure Restriction Mechanism | 7   | Hand switch connector                |
| 2   | X-ray exposure button          | 8   | Oral sensor USB connector            |
| 3   | Wireless USB dongle connector  | 9   | Power button/Status indicator<br>LED |
| 4   | Charging connector             | 10  | Trackball                            |
| 5   | Reset button                   | 11  | Display                              |
| 6   | Micro SD card connector        | 12  | Strap Handle                         |



#### **Component**

| Image             | Description                    |
|-------------------|--------------------------------|
| 420               | Battery                        |
| B                 | Charger                        |
| The second second | Hand switch                    |
|                   | Back Scatter Shield            |
|                   | FFC jig                        |
|                   | Wireless USB dongle (optional) |
|                   | Intra Oral Sensor (Option)     |
|                   | Tripod (optional)              |



## 2.2 Buttons for Equipment Operation

Optimal images can be obtained by subdividing the patient's size and tooth position selection as well as equipment ON/OFF control.



| Button | Description  |  |
|--------|--|--|
| Ċ      | <ul> <li>[Equipment ON]</li> <li>If you press the power button for at least 0.5 seconds, the status indicator button turns on blue with a start sound and the unit turns on.</li> <li>[Equipment OFF]</li> <li>If you press the power button for at least 2 seconds, the equipment turns of with a shutdown sound.</li> <li>The equipment is set to use power saving mode by default.</li> <li>Power Saving Mode: If the device is not used for a set period of time, it will change to the power saving mode.<br/>In power saving mode, a white LED lights up on the trackball.</li> <li>Shut down: While in power saving mode, if you do not use the device for a specified period of time,</li> <li>It will shut down automatically.</li> <li>If the battery has less than 10% remaining, the device will shut down with a shut down sound.</li> <li>Press one of the buttons to cancel the power saving mode.</li> <li>Power saving time and auto shutdown time can be changed from "Menu → Settings → Set Time."</li> </ul> |  |
| ho     | <ul> <li>[Changing Patient Size]</li> <li>If you press the patient size button, the patient size changes.</li> <li>The x-ray exposure time changes depending on the size of the patient.</li> <li>Patient size is categorized as "large, medium and small."</li> </ul>   |  |



| Button      | Description   |  |
|-------------|---|--|
|             | [Tooth Selection]   |  |
| $\cap$      | <ul> <li>Select the tooth position.</li> </ul>  |  |
| W           | <ul> <li>Use the trackball to select the maxillary/mandibular and the tooth to be<br/>imaged.</li> </ul>                            |  |
|             | <ul> <li>Depending on the tooth, the x-ray exposure time will vary.</li> </ul>  |  |
|             | [Menu]  |  |
| $\equiv$    | <ul> <li>The menu window appears or disappears.</li> </ul>  |  |
| ∕₽          | [X-ray LOCK]  |  |
| 0           | <ul> <li>When pressed for 2 seconds or longer, red indicator will appear and the<br/>device enter an X-ray locked state.</li> </ul> |  |
| [Trackball] |   |  |
| ( )         | <ul> <li>You can set the X-ray imaging time.</li> </ul>   |  |
| $\bigcirc$  | <ul> <li>You can move up, down, left, and right in menus, keyboards, etc.</li> </ul>  |  |
|             | [X-ray Exposure]  |  |
|             | <ul> <li>Used for X-ray exposure.</li> </ul>  |  |
| (3407)      | <ul> <li>Press the button until the beep sound stops and it will exposure 1 time as per<br/>set exposure time.</li> </ul>           |  |
|             | Releasing the button during exposure immediately stops X-<br>ray exposure and movement of the instrument.                           |  |
| 9           | <ul><li>[Reset]</li><li>Used for forced shut down and updating the equipment.</li></ul>   |  |



The buttons are basically used as above, but can be used differently for each menu.

Menu-specific button functions are shown at the bottom of the "Display."

The underlined function in the display is activated when the button is pressed for at least 2 seconds.



## 2.3 Exposure Restriction Mechanism

Exposure Restriction Mechanism

| Image | Description  |
|-------|--|
|       | This is a device to prevent X-rays from being exposed.<br>The inside is shielded with lead and equipped with an<br>aluminum filter to minimize radiation exposure for patients<br>and users. |



### 2.4 Connector

| Image | Description   |  |  |  |
|-------|---|--|--|--|
|       | [Micro SD Card connector]   |  |  |  |
|       | <ul> <li>A connector that inserts the Micro SD Card.</li> </ul>   |  |  |  |
|       | It is encouraged to have important clips be backed<br>up elsewhere other than the Micro SD card, as our<br>company does not have any responsibility for any<br>form of loss or damage of recorded data on the<br>Micro SD card. |  |  |  |
|       | Our company does not provide warranty for any errors with Micro SD cards other than the ones we provide.  |  |  |  |
|       | [Hand switch connector & mA measurement connector]  |  |  |  |
|       | <ul> <li>A connector that connects the hand switch.</li> </ul>  |  |  |  |
|       | <ul> <li>It is usable when measuring mA from the outside.</li> </ul>  |  |  |  |
|       | You can only use the hand switch connector provided by the company.   |  |  |  |
|       | [Charger connector]   |  |  |  |
|       | <ul> <li>A connector that is used to charge the battery.</li> </ul>   |  |  |  |
|       | <ul> <li>If you are charging from 0% battery, allow up to 4 hours and<br/>30 minutes to fully charge.</li> </ul>  |  |  |  |
|       | The charging time may vary based on the battery percentage.   |  |  |  |
|       | You can only use the charging adaptor provided by the company.  |  |  |  |
|       | [Oral sensor USB connector]   |  |  |  |
|       | <ul> <li>A USB connector that connects the oral sensor.</li> </ul>  |  |  |  |
|       | You can only use the oral sensor provided by our company.   |  |  |  |
|       | Furthermore, the oral sensor needs to be permitted with 5 V.d.c provided by our company.  |  |  |  |



| Image | Description   |  |
|-------|---|--|
|       | <ul> <li>[Holder string]</li> <li>In order to use the equipment securely, hold the equipment firmly with your hand.</li> <li>The string length can be adjusted for the user's convenience.</li> </ul>   |  |
|       | <ul> <li>[Wireless USB dongle connector]</li> <li>A USB connector to insert a wireless USB Dongle.</li> <li>The company encourages the usage of a wireless USB dongle (optional) provided by us.</li> <li>The company does not provide warranty for any errors caused from using a wireless USB dongle that is not provided by us.</li> <li>The wireless environment and network status determines the speed of the transfer of data.</li> <li>The device will not function properly if there is a</li> </ul> |  |



#### 2.5 Battery

Repeated charging shortens the available time for use.

As an approximate standard, after the battery has been charged about 500 times, the possible time it can be used is around 70-80% of what was possible at the time it was first purchased.

It is recommended to make sure to charge it once every months.

Due to the nature of lithium-polymer batteries, the remaining battery capacity reduces even when not in use.

- Please note that if the equipment is not used for a long time, there may be cases where charging does not take place even when the charger is connected.
- The charging time and usage time may differ depending on the usage environment.
- If the remaining battery power is insufficient, the amount of X-ray radiation may be insufficient during shooting, so you should always maintain the remaining power.
- When the battery reaches the lowest limit due to insufficient battery power, the remaining battery indicator flashes on the LCD screen, and after a certain period of time, the power of the device is automatically turned off.



The charging time of a battery is approx. 3 hours 30 min from the lowest level to 90%. The expected fully charging time is approx. 10 hours



While charging the battery, X-ray exposure is disabled. The message "Warning 00" displayed.



Use the battery supplied by GENORAY only.

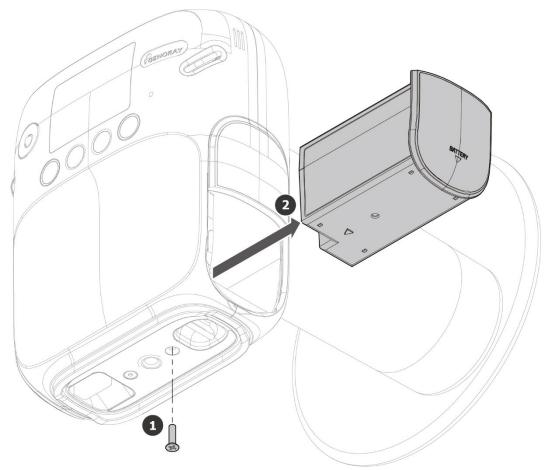
The operator is responsible for any malfunction from use with non-approved battery.



Battery maintenance may vary depending on the device.



#### How to replace the battery



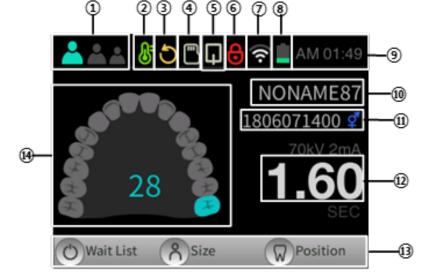
- **1.** Use a (+) screwdriver to remove the battery fixing bolts (1 pcs) from the bottom of the equipment.
- 2. Remove the battery.
- 3. Replace the battery and assemble the battery in the reverse order of disassembly.



- Please dispose used battery as general waste.
- Dispose of used batteries according to the laws and regulations of each country or region.



## 2.6 Display



You can check the device status and filming condition on the display.

| No. | Feature                           | No. | Feature                     |
|-----|-----------------------------------|-----|-----------------------------|
| 1   | Patient size selection            | *8  | Battery check               |
| 2   | X-ray tube temperature check      | 9   | Current time                |
| 3   | Firmware update notification      | 10  | Patient name                |
| 4   | Micro SD card insert check        | 11  | Patient number, Patient sex |
| 5   | Oral sensor connection check      | 12  | X-ray exposure time         |
| 6   | X-ray exposure lock notification  | 13  | Button feature description  |
| 7   | Wireless (Wi-Fi) connection check | 14  | Tooth placement selection   |



#### \*8 Battery Check

| Equipment in use |                   | Charging |                        |
|------------------|-------------------|----------|------------------------|
|                  | Low battery level | ۶        | Battery charging (10%) |
|                  | Battery 50% left  | ۶        | Battery charging (50%) |
|                  | Battery 100% left | ۶        | Battery fully charged  |



It is recommended to maintain the remaining battery level at 50% or more for smooth use of the equipment.



When the main system is connected to the charger, an alarm occurs on the bar above the display for a second, as below:

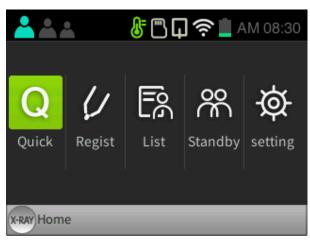
- When connected: remaining time to be fully charged.

- When disconnected: available use time (standby time)

# GENORAY

#### 2.6.1 Menu

- **1.** When the menu button (  $\bigcirc$  ) is pressed, the following screen will be displayed.
- **2.** If you want to return to the main screen from the menu screen, click the X-ray exposure button.



| Menu   | Description  |  |
|--------|--|--|
| Quick  | <ul> <li>[Quick]</li> <li>Click on Quick button to automatically register patients.</li> <li>Patient number: It is registered as "Registration Time", "Patient Name: NONAME", "Sex: Neutral."</li> </ul>   |  |
| Regist | <ul> <li>[Regist]</li> <li>The patient registration window will pop up when you click Regist button.</li> <li>After inputting patient information, click the power button (<sup>(U)</sup>) to register.</li> <li>Image: Image: Im</li></ul> |  |



| Menu               | Description   |  |  |
|--------------------|---|--|--|
| <b>E</b> 중<br>List | [List] <ul> <li>The patient list will pop up when you click on List button.</li> <li>If you click patient information using the trackball, an image thumbnait view will pop up.</li> </ul> <b>ID ID ID ID ID ID ID ID</b>   |  |  |
|                    | Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server PC to be set.         Image: Send" feature requires wireless settings and a server pc to 200 patients and save 100 images per patient.         Image: Send" feature requires wireless settings and a server pc to approximately 3400 films with a 16 GB Micro SD card.  |  |  |
| <u>ش</u>           | [Standby] • When you click Standby button, the list of patients who requested for image will pop up on PORTVIEW.          Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image: Image will pop up on PORTVIEW.         Image will pop up on PORTVIEW. |  |  |
| Standby            | <ul> <li>The "Standby" feature</li> <li>Can only be linked with a PORTVIEW version higher than 2.2.5.0.</li> <li>Wireless network settings and a server PC need to be set.</li> </ul>   |  |  |
|                    | If multiple devices are using a server PC at the same time<br>and you are trying to select patients, you will not be able<br>to select multiple patients.   |  |  |



| Menu             | Description  |  |  |
|------------------|--|--|--|
|                  | <ul> <li>[Setting]</li> <li>The settings window will pop up when you click on Setting.</li> <li>The settings window is divided into "when using the oral sensor" and<br/>"when not using the oral sensor." You can set the usage environment of<br/>ZEN-PX4.</li> </ul>  |  |  |
| र्ट्ट<br>setting | Image: System       Image: System<   | Setting<br>Wireless Language System<br>Time Init Update  |  |
|                  | [using the oral sensor]  | [not using the oral sensor]  |  |
| Wireless         | [Wireless]<br>• The wireless connection method is a<br>① Settings -> Select Wireless   | <ul> <li>as follows.</li> <li>Check the wireless AP list and select the wireless AP to use.<br/>When linking with PortView, connect to the same wireless AP with the server PC</li> <li>Wireless 40:A5:EF:DB:E8:91</li> <li>genoray_dev1 Connected</li> <li>genoray-3F-1</li> <li>genoray-3F-5</li> <li>Manual set Refresh KRW Home</li> </ul> |  |
|                  | 3 Enter the password for the selected wireless AP.          Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the selected wireless AP.         Image: Constraint of the password for the password for the selected wireless AP.         Image: Constraint of the password for the password for the password for the selected wireless AP.         Image: Constraint of the password for the password | Connect to the wireless connection.     AM 10:53 genoray5     Connect Cancel Delete     Next   |  |



| Menu   | Description  |  |  |
|--------|--|--|--|
|        | If the connection is not stable, you can set the settings to manual if you click on the register patient button.   |  |  |
|        | You can only use networks with passwords.  |  |  |
|        | This does not work if there is a jammer.   |  |  |
| Server | <ul> <li>[Server]</li> <li>You can select Server PC to connect to a server PC.</li> <li>Basic ID: PORTXIV PW: 12345678</li> <li>The IP address has to be the same as the server PC.</li> <li>Setting&gt;Server</li> <li>PORTXIV</li> <li>PW</li> <li>PORTXIV</li> <li>PW</li> <li>PORTXIV</li> <li>PW</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>Setting&gt;Server</li> <li>PORTXIV</li> <li>PW</li> <li>Setting&gt;Server</li> <li>PORTXV</li> <li>PW</li> <li>Setting&gt;Server</li> <li>Seting&gt;Se</li></ul> |  |  |
|        | See Appendix for the server PC ID, PW change, and server IP address. [Tooth]   |  |  |
| Tooth  | <ul> <li>You can set the tooth numbers.</li> <li>You can set the tooth numbers.</li> <li>AM 08:31</li> <li>Setting&gt;Tooth</li> <li>FDI World Dental Federation notation</li> <li>Palmer notation method</li> <li>Universal numbering system</li> </ul>   |  |  |



| Menu    | Descr   | iption                               |
|---------|---|--------------------------------------|
|         | [Auto FFC]  |                                      |
| AutoFFC | If the message that there is no FFC click the Create FFC button again to      FFC JIG      FFC JIG |                                      |
|         | I/O SENSOR  | are automatically generated when     |
|         | [HostAP]  |                                      |
|         | <ul> <li>You can connect the mobile app and</li> </ul>  | equipment to each other.             |
|         | <ul><li>Basic Name: PORTXIV</li><li>Basic PW: 12345678</li></ul>  |                                      |
|         | <ul> <li>The wireless icon changes color whe</li> </ul>   | en it is properly connected.         |
|         | AM 08:32  | ▲ ▲                                  |
| HostAP  | NAME PORTX4<br>PW<br>a b c d e f g h i<br>j k l m n o p q r<br>s t u v w x y z<br>AP ON Pol Wkey/Next x-RAY Home  | 70kV 2mA<br>28 0.05<br>SEC           |
|         | [not connected]   | [connected]                          |
|         | Supported devices: An   | droid, Android tablet, iPhone, iPad. |



| Menu              | Description  |
|-------------------|--|
|                   | [Language]   |
|                   | <ul> <li>You can set the language of the equipment.</li> </ul>                                   |
|                   | Settable languages: Korean, English, Japanese  |
| Language          | Setting>Language Korean  |
|                   | Japanese   |
|                   | Set X-RAY Home   |
|                   | [System]   |
|                   | Automatic transfer   |
|                   | When you check automatic transfer, the data is transferred automatically and sent to the server. |
|                   | Twain use Mount  |
|                   | Exposure without tooth number when using Twain   |
|                   | Format SD card   |
|                   | When you check Format SD card, all of the patient information and films will be deleted.         |
|                   | Lisa Server  |
|                   | If you check Lisa Server, all the patient information is sent to the Lisa Server.                |
|                   | Power saving mode  |
| ±Q <sup>2</sup> 4 | Set the power saving time and equipment OFF time.  |
| System            | Brightness adjustment  |
|                   | Adjust the brightness of the LCD.  |
|                   | Setting>System   |
|                   | Auto Trx     Twain Use Mount     SD card Format  |
|                   | Lisa Server<br>Sleep Mode  |
|                   | Rrightness<br>RRAY Home  |
|                   | When formatting the Micro SD card, all patient information and films are deleted.                |



| Menu | Description   |  |  |
|------|---|--|--|
| Time | [Time] <ul> <li>You can set the time.</li> <li>Manual setting Select Settings, and control the time using the trackball. Select Settings, and control the time using the trackball. Setting&gt;Time&gt;Manual Setting Set Reverse and the time using the trackball. Automatic setting If you select a country when connected to the Internet, the time is automatically set to the time of the selected country. Setting&gt;Time&gt;Auto Setting Setting&gt;Time&gt;Auto Setting Setting&gt;Time&gt;Auto Setting Setting&gt;Time&gt;Auto Setting Setting&gt;Time&gt;Auto Setting Setting&gt;Time&gt;Auto Setting Set Reverse Auto Setting</li></ul> |  |  |
| Init | <ul> <li>[Init]</li> <li>Film time reset<br/>Initialize the X-ray imaging time.</li> <li>Wi-Fi reset<br/>The Wi-Fi network settings are reset.</li> <li>Overall reset<br/>All of the settings are reset.</li> </ul>   |  |  |



| Menu   | Description   |  |  |
|--------|---|--|--|
|        | <ul> <li>[Update]</li> <li>You can check current version of the firmware and also update it to the latest version.</li> <li>Check firmware version You can check the version of the firmware by clicking on the tooth select button.</li> <li>How to Update Firmware <ol> <li>Check the version.</li> <li>Click the power button O</li> <li>to proceed updating.</li> </ol> </li> <li>3 After update is completed, click on the reset button to reboot the douise.</li> </ul> |  |  |
| Update | <ul> <li>device.</li> <li>The update environment is as follows.</li> <li>Wireless network connection</li> <li>Insert the Micro SD card</li> <li>Micro SD capacity: at least 50 Mb</li> <li>Battery must be higher than 50% or has to be charging.</li> </ul>  |  |  |
|        | Do not use any other firmware updates that are not provided by the manufacturer.<br>It can damage the device.<br>Any damage caused by using firmware updates that are not provided by the manufacturer are not covered by warranty.   |  |  |
|        | If you disconnect the battery or use an unstable charging port, the device may be damaged.  |  |  |





# 3. Directions

### 3.1 Preparation before use

- Get well-acquainted with the user manual.
- Check the voltage specified by the manufacturer.
- Check the charging level before use.



X-ray exposure is not possible while the device is charging.



Before imaging, you must ask the patient to remove other jewelry and metallic items worn by them.

Performing imaging which such objects are present may cause shadows and reflections in the image.



The operator should do the imaging from a location safely protected from X-rays and while wearing protective equipment.



Be careful not to release the exposure button during imaging.

Releasing the exposure button will stop X-ray exposure and you will receive a message about an abnormal shutdown of the equipment.



Pay attention to the condition of the patient and the equipment during the imaging.

In the case of an unexpected problem, immediately release the exposure button.



### 3.2 Image Acquisition

The X-ray exposure time can be set depending on whether or not the intraoral sensor is used. Please refer to the following method for each operation.

Using the Sensor

The preset radiation setting value of each tooth will be exposed when you select tooth number.

Not Using the Sensor

The radiation setting value can be selected into 3 methods as Incisor, Canine, and Molar mode.

If, after the end of X-ray exposure, the image is not satisfactory due to an insufficient or excessive X-ray dose,

You can adjust the X-ray exposure time by moving the trackball up or down.



- ↑: Increase X-ray exposure time (Large/Medium/Small: 30 Step)
- ↓ : Reduce X-ray exposure time (Large/Medium/Small: 30 Step)

After changing the exposure time set as above, the changed X-ray exposure time is saved simultaneously at the end of exposure.



## **3.2.1** Filming Method - Not Using the Sensor

| Sequence                             | Description   | Notes                        |  |
|--------------------------------------|---|------------------------------|--|
|                                      | <ol> <li>Click the patient size button to set the size of the patient.</li> <li>Patient size button ( )</li> </ol>  | <mark>▲ ≛ ±</mark>           |  |
|                                      | <ul> <li>② After clicking the tooth selection button, set the location for imaging using the trackball</li> <li>Tooth selection button ( W)</li> <li>Trackball( )</li> <li>Maxilla/Mandible (↑, ↓)</li> <li>Move to the right, Move to the left (←, →)</li> </ul> |                              |  |
| 1. Setting X-ray<br>exposure<br>time | <ul> <li>When selecting patient size and tooth, the pre-stored X-ray exposure time is set</li> </ul>  |                              |  |
|                                      | If, after the end of X-ray exposure, the image<br>is not satisfactory due to an insufficient or<br>excessive X-ray dose,  |                              |  |
|                                      | You can adjust the X-ray exposure time by moving the trackball up or down.  |                              |  |
|                                      | <ul> <li></li></ul>   | 0.22                         |  |
|                                      | (Large/Medium/Small: 30 Step)   | $0$ . $\mathbf{Z}\mathbf{Z}$ |  |
|                                      | ↓ : Reduce X-ray exposure time  |                              |  |
|                                      | (Large/Medium/Small: 30 Step)   |                              |  |
|                                      | After changing the exposure time set as<br>above, the changed X-ray exposure time is<br>saved simultaneously at the end of exposure.  |                              |  |
| <b>2.</b> Equipment Alignment        | ① Accurately place the exposure restriction equipment at the site to be photographed  |                              |  |



| Sequence   | Description   | Notes        |
|------------|---|--------------|
|            | ① Press the X-ray exposure button.  |              |
|            | <ul> <li>2 A "Ready" message appears in the LCD window for about 2 seconds.</li> </ul>                                      | $\bigotimes$ |
|            | ③ When the exposure begins, an "X-ray exposure"<br>notification window is displayed on the LCD, and a beep<br>sound occurs. |              |
| 3. Imaging | You have to press the X-ray exposure<br>button for the set X-ray exposure time.   |              |
|            | ④ When the exposure is completed, the beep sound ends<br>and the X-ray exposure notification window disappears.             | <u>≁</u>     |
|            | <ul> <li>Duty Cycle of Exposure Interval time</li> </ul>  |              |
|            | • X-ray exposure time is limited for about 30 times the exposure time.  |              |
|            | • Ex) Maximum exposure time (1.6 seconds) X-ray exposure is limited for approximately 50 seconds.                           |              |



## 3.2.2 Filming Method - Using the Sensor

| Sequence  | Description  | Notes            |
|---|--|------------------|
| 1. Register patients  | ① Register or select the patient getting imaged.<br>Menu $\rightarrow$ "Quick", "Regist", "List"   | Refer to "2.6.1" |
| <ul> <li>(1) Set the size of the patient by clicking on the patient button</li> <li>Patient size button ( <sup>∧</sup>)</li> <li>(2) After clicking on the teeth size button, use the trackle select the place you wish to photograph.</li> <li>Tooth selection button ( <sup>√</sup>)</li> <li>Trackball( <sup>(○)</sup>)<br/>Maxilla/Mandible (↑, ↓)</li> </ul> |  | 27               |
| 2. Set X-ray<br>exposure<br>time  | <ul> <li>Move to the right, Move to the left (←, →)</li> <li>③ When selecting patient size and teeth, the previously saved x-ray exposure time will be set.</li> </ul> |                  |
|   | If, after the end of X-ray exposure, the image<br>is not satisfactory due to an insufficient or<br>excessive X-ray dose,   |                  |
|   | You can adjust the X-ray exposure time by moving the trackball up or down.   |                  |
|   | <ul> <li></li></ul>  | 0 22             |
|   | (Large/Medium/Small: 30 Step)  |                  |
|   | <ul> <li>         ↓: Reduce X-ray exposure time     </li> </ul>  |                  |
|   | (Large/Medium/Small: 30 Step)  |                  |
|   | After changing the exposure time set as<br>above, the changed X-ray exposure time is<br>saved simultaneously at the end of exposure.                                   |                  |
| 3. Device alignment   | ① Place the device exactly where you wish to locate.   |                  |

### ZEN-PX4 Filming Technique



| Sequence                  | Description  | Notes        |
|---------------------------|--|--------------|
|                           | ① Click on the x-ray exposure button   | (SRAY)       |
|                           | ② On the LCD screen, "Ready" pop-up window will appear<br>for about 2 seconds.   | $\bigotimes$ |
|                           | ③ Once the exposure starts, the "X-ray exposure" pop-up will show up on the LCD screen and the beeping will begin.   |              |
| <b>4.</b> Take the image  | You are required to press on the X-ray button for the amount of time set to perform the X-ray.   |              |
|                           | ④ Once the exposure is over, the beeping will stop and X-ray exposure pop up screen will disappear.  | <u>♦</u>     |
|                           | <ul> <li>Duty Cycle of Exposure Interval time</li> <li>X-ray exposure time is limited for about 30 times the exposure time.</li> <li>Ex) Maximum exposure time (1.6 seconds) X-ray exposure is limited for approximately 50 seconds.</li> </ul>  |              |
|                           | <ol> <li>Check the image once imaging is completed.</li> <li>The captured image is automatically saved to the</li> </ol>   |              |
|                           | <ul> <li>The captured image is automatically saved to the<br/>Micro SD card.</li> <li>When automatic transmission is selected, the image is<br/>automatically sent to the server.</li> </ul>   |              |
| <b>5.</b> Check the image | 171117<br>GENORAY<br>GENORAY<br>GENORAY<br>SEND FILE<br>Sending FFC file (1/1)<br>Sending FFC file (1/1)<br>Sending FFC file (1/2)<br>Sending FFC file (1/2) |              |



| Server | Linked | Imaging | Method |
|--------|--------|---------|--------|
|        |        |         |        |

| Sequence                                    | Description   | Notes          |
|---|---|----------------|
| 1. Select<br>Standby<br>Patients            | <ol> <li>Select the standby patient that has been registered on<br/>the server.</li> <li>Menu → "Standby"</li> <li>Click the power button on the main screen.</li> </ol>  | Refer to 2.6.1 |
| <b>2.</b> X-ray<br>exposure<br>time setting | <ul> <li>1 The size of the patient and placement of teeth are automatically set to the site designated by PC.</li> <li>2 When selecting patient size, the previously saved X-ray exposure time will be set.</li> <li>If, after the end of X-ray exposure, the image is not satisfactory due to an insufficient or excessive X-ray dose, You can adjust the X-ray exposure time by moving the trackball up or down.</li> <li>              1 : Increase X-ray exposure time             (Large/Medium/Small: 30 Step)          </li> <li>             1 : Reduce X-ray exposure time             (Large/Medium/Small: 30 Step)               After changing the exposure time set as above, the changed X-ray exposure time is saved simultaneously at the end of exposure.      </li> </ul> | 0.22           |
| <b>3.</b> Device alignment                  | ① Place the device exactly where you are going to image.  |                |



| Sequence                           | Description   | Notes                         |
|------------------------------------|---|-------------------------------|
|                                    | ① Click on the x-ray exposure button  |                               |
|                                    | ② On the LCD screen, "Ready" pop-up window will appear<br>for about 2 seconds.  | ${\color{black}{\bigotimes}}$ |
|                                    | ③ Once the exposure starts, the "X-ray exposure" pop-up will show up on the LCD screen and the beeping will begin.  |                               |
| <b>4.</b> Take the image           | You are required to press on the X-ray button for the amount of time set to perform the X-ray.  |                               |
|                                    | ④ Once the exposure is over, the beeping will stop and X-ray exposure pop up screen will disappear.   | <u>~</u>                      |
|                                    | <ul> <li>Duty Cycle of Exposure Interval time</li> <li>X-ray exposure time is limited for about 30 times the exposure time.</li> <li>Ex) Maximum exposure time (1.6 seconds) X-ray exposure is limited for approximately 50 seconds.</li> </ul> |                               |
|                                    | <ol> <li>Check the image once imaging is completed.</li> <li>The captured image is automatically saved to the Micro<br/>SD card.</li> </ol>   |                               |
|                                    | <ul><li>② Send the file to the server.</li></ul>  |                               |
| <b>5.</b> Check the image and send | Click on the Select Teeth button ( ) to begin transfer.   |                               |



## 3.3 Image Transfer

Send images from ZEN-PX4 to the server PC.



Based on the distance of the router and connection stability, the transfer time may differ.



When you are transferring the file for the first time, the FFC file will be transferred, which may require additional time.



There are two types of transfers: automatic and manual. These settings can be changed in Menu  $\rightarrow$  System. (Refer to 2.6.1)

#### 3.3.1 Automatic Transfer

| Logistics                      | Description  | Notes  |
|--------------------------------|--|--|
| 1. Complete<br>imaging         | <ol> <li>After exposure, the image and the progress<br/>bar will appear.</li> </ol>  | Resolution of the second secon |
| <b>2.</b> Complete<br>transfer | <ol> <li>Once the transfer is completed, move on to<br/>the next image.</li> <li>For multiple images for one patient, go to<br/>the main screen.</li> <li>Once imaging is completed, go to<br/>Standby Patient List.</li> <li>For re-imaging, go to PortView and<br/>request imaging.</li> </ol> | Notification<br>Image transfer completed   |



### 3.3.2 Manual Transfer

| Logistics                     | Description  | Notes  |
|-------------------------------|--|--|
| <b>1.</b> Complete<br>imaging | <ol> <li>Once imaging is completed, the captured<br/>image will be printed.</li> <li>For re-imaging, press X-ray exposure button<br/>to conduct re-imaging.</li> </ol>   | A80512<br>GENORAY                                      |
| <b>2.</b> Complete transfer   | <ol> <li>Click on Select Teeth button to transfer the<br/>image.</li> <li>For multiple images for one patient, go to<br/>the main screen.</li> <li>Once imaging is completed, go to<br/>Standby Patient List.</li> </ol> | SEND FILE<br>Sending image file (1/1)<br>16%<br>Cancel |



## 3.4 Image Transfer

| Menu                 | Description   |  |
|----------------------|---|--|
| Transfer image       | <ul> <li>[Transfer]</li> <li>Click on Select Imaging Location button () to transfer the images to the server PC.</li> <li>1711231329</li> <li>NONAME6</li> </ul>  |  |
| Zoom-in the<br>image | Com       Com       Com       Com         Image       Image       Image       Image         Image       Image       Image       Image       Image |  |

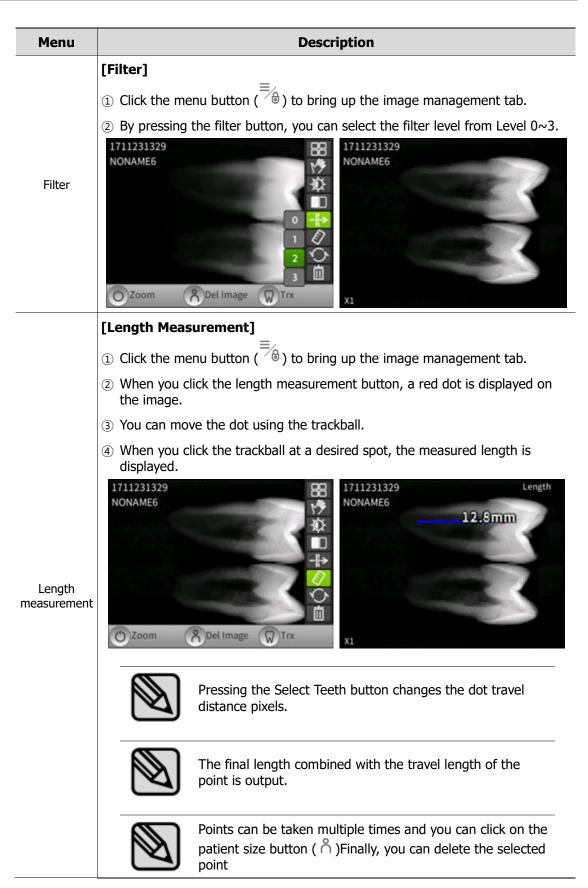


| Menu         | Description   |  |
|--------------|---|--|
| Image list   | <ul> <li>[List]</li> <li>① Click the menu button ( → ) to bring up the image management tab.</li> <li>② Click the list button to go to the thumbnail screen.</li> <li>1711231329<br/>NONAME6</li> <li>NONAME6</li> </ul> |  |
| Moving image | <ul> <li>[Moving]</li> <li>① Click the menu button ( ) to bring up the image management tab.</li> <li>② After clicking the move button, you can move the image using the trackball.</li> </ul>  |  |



| Menu                     | Description  |  |
|--------------------------|--|--|
|                          | [Brightness Adjustment]  |  |
|                          | ① Click the menu button ( $\overline{\mathbb{A}}$ ) to bring up the image management tab.  |  |
|                          | ② After clicking the brightness control button, you can adjust the brightness<br>using the trackball.  |  |
| Brightness<br>adjustment | 1711231329         NONAME6         Image         Image |  |
|                          | [Color Inversion]  |  |
|                          | (1) Press the menu button ( $\equiv 6$ ) to bring up the image management tab.   |  |
|                          | <ol> <li>Press the menu button ( ) to bring up the image management tab.</li> <li>Click the color inversion button to invert the color of the image.</li> </ol>  |  |
| Color inversion          | Chick the color inversion button to inter the color of the indect.   |  |
|                          | [Pre- inversion] [Post- inversion]   |  |







| Menu           | Description  |
|----------------|--|
|                | [Initialization]   |
|                | ① Click the menu button ( $$ ) to bring up the image management tab.                                     |
|                | ② Changed image can be initialized to original image.  |
| Initialization | 171117<br>GENORAY  |
|                | Zoom, movement, and brightness will be all reset to the original image.                                  |
|                | [Delete Image]   |
|                | (1) Click the menu button ( $\overline{\mathbb{F}}_{\mathbb{B}}$ ) to bring up the image management tab. |
|                | ② Click the patient size button ( $\red{o}$ ) to delete the image  |
| Delete image   | 1711231329<br>NONAME6  |



## 4. Precautions after Use

## 4.1 Regular Inspection

- It is recommended that this equipment is inspected by the service center at least once a year.
- This equipment is subject to equipment inspection and defense inspections once every three years by the inspection agency of the Ministry of Food and Drug Safety in accordance with the regulations on radiation safety control.

## 4.2 Care and Cleaning

- The performance of the device and its components must be checked regularly. See "Appendix 5. Maintenance."
- If the equipment has not been used for a long time, inspect the unit to make sure that it is operating normally. Please call the service center for inspection.
- If the equipment requires cleaning, turn off the power and then use a soft cloth or gauze to wipe it without using force avoid damages to the equipment.



# 5. Equipment Specifications

## 5.1 Main Component Specifications

#### X-ray generator

| Item                                       | Specification |
|--|---------------|
| Tube Voltage                               | 70 kV ±7%     |
| Tube Current                               | 2 mA ±10%     |
| Maximum specified energy input in one hour | 232 mAs       |

#### X-ray control

| Item          | Specification  |
|---------------|----------------|
| Power Output  | 22 Vdc         |
| Exposure Time | 0.05 ~ 1.6 sec |
| SSD           | 200 mm         |

#### Beam Limiting Device

| Item                   | Specification |
|------------------------|---------------|
| Туре                   | Round type    |
| Output Radiation Field | 60 mm         |

#### **Battery**

| Item     | Specification |
|----------|---------------|
| Туре     | Li Polymer    |
| Voltage  | 22.2 Vdc      |
| Capacity | 1000 mAh      |

#### **Adapter**

| Item              | Specification               |
|-------------------|-----------------------------|
| Rated power input | 100~240 V~, 50/60 Hz, 1.0 A |
| Output Voltage    | 28 V.d.c                    |
| Output current    | 1.42 A                      |



#### **Dimensions and weight**

| Item   | Specification            |
|--------|--------------------------|
| Size   | 140(W) X 173(H) X 254(D) |
| Weight | 1.5 kg                   |

#### Sensor (Option)

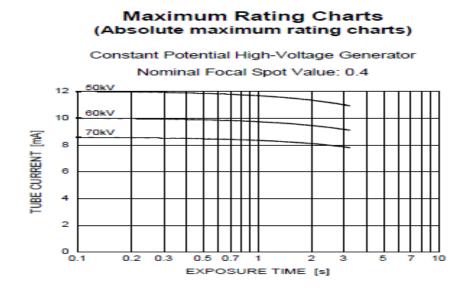
| Item                              | Specification             |
|-----------------------------------|---------------------------|
| Scintillator type                 | CsI(TI)                   |
| Pixel size(µm)                    | 20 x 20                   |
| Pixel pitch (HxV) (µm)            | 20                        |
| Number of effective pixels(pixels | 1000 x 1500 / 1300 x 1700 |
| High resolution                   | 20 Lp/mm typ              |
| Dynamic Range                     | 57 dB                     |
| Interface                         | USB 2.0                   |

#### X-ray tube

| Item                                | Specification    |  |
|-------------------------------------|------------------|--|
| Model                               | D-045S (Canon)   |  |
| Туре                                | Stationary Anode |  |
| Focal spot                          | 0.4 mm           |  |
| Target Angle                        | 12.5°            |  |
| Target material                     | Tungsten         |  |
| Cooling Method                      | Oil cooling      |  |
| Maximum Tube Voltage                | 70 kV            |  |
| Minimum Tube Voltage                | 50 kV            |  |
| Maximum Tube Current                | 12 mA            |  |
| Thermal Characteristics             |                  |  |
| Anode Heat Storage Capacity         | 4.3 kJ           |  |
| Maximum Anode Heat Dissipation rate | 100 W            |  |

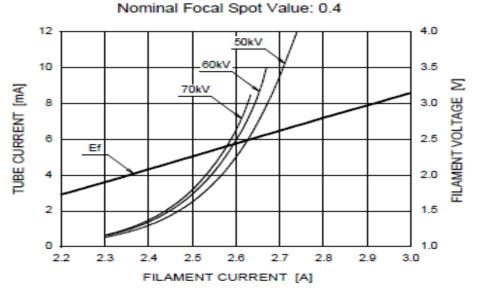


#### Maximum Rating Charts (Absolute Maximum Rating Charts)



#### **Emission Characteristics**

#### **Emission & Filament Characteristics**

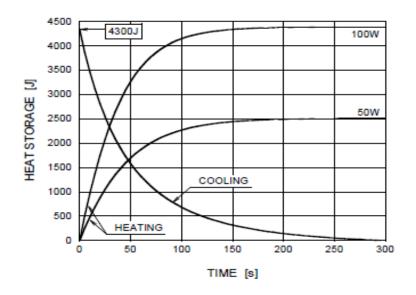


Constant Potential High-Voltage Generator



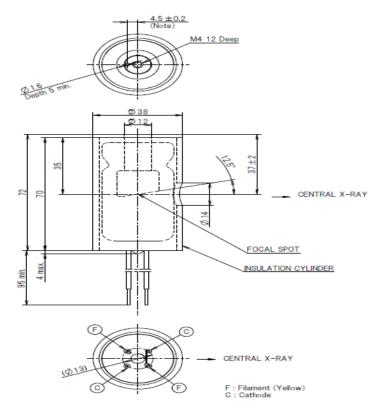


#### **Anode Thermal Characteristics**



#### Anode Heating / Cooling Curve

#### D-045S Dimensions (Unit: mm)



Note : Dimensions from an anode shank to a mounting hole.



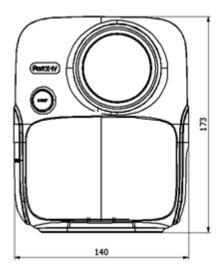
| Item                | Specification  |
|---------------------|--|
| Chipset             | Realtek 8188 EUS   |
| Standard            | IEEE 802.11g, IEEE 802.11b, CSMA/CA with<br>ACK used with IEEE 802.11n (draft 2.0) |
|                     | wireless technology  |
| Interface           | USB 2.0  |
| Frequency           | 2.4 ~ 2.4835 GHz   |
|                     | 11n: the highest data rate can reach 150<br>Mbps                                   |
| Wireless Speed      | 11g: 6/9/12/18/24/36/48/54 Mbps (Dynamic)  |
|                     | 11b: 1/2/5.5/11 Mbps (Dynamic)   |
| Working channel     | 1~13   |
|                     | 11b: CCK, DQPSK, DBPSK   |
| Data Modulation     | 11g: OFDM  |
|                     | 11n: OFDM with PSK, BPSK, 16-QAM, 64-<br>QAM                                       |
| RF power            | 20 dBm (Maximum)   |
| Antenna gain        | 2 dBi internal smart antenna   |
| Encryption          | 64/128/152 digit WEP encryption, WPA/WPA-<br>PSK, WPA2/WPA2-PSK Encryption         |
|                     | Working temperature: 0 °C to 40 °C   |
| Mouling, on income  | Storage temperature: -40 °C to 70 °C   |
| Working environment | Working Humidity: 10% to 90% RH  |
|                     | Storage Humidity: 5% to 90% RH   |
| Dance               | Indoors: 50-100 m (Theoretical Value)  |
| Range               | Outdoors: 100-200 m (Theoretical Value)  |

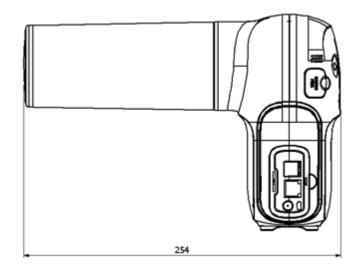
### Wireless USB Dongle Specification (Optional)



#### **Dimensions and weight**

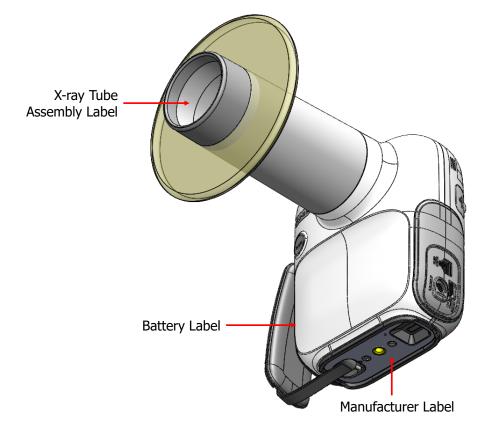
- Equipment weight: 1.5 kg ± 5%
- Equipment dimensions: 140 x 173 x 254 (Unit: mm)







## 5.2 Equipment Labeling



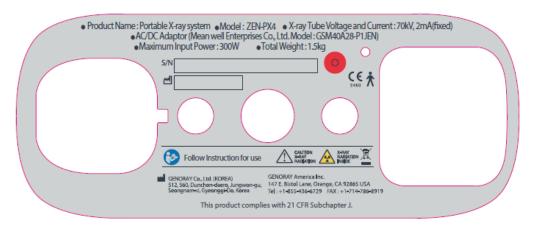
Be sure to check the label and manual before turning on the power.

Picture: X-ray Tube Assembly label / ID label (maker Label) /Warning Label

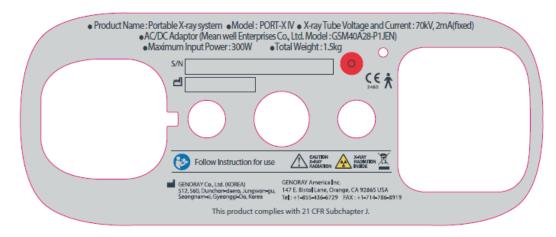


#### Manufacturer display items

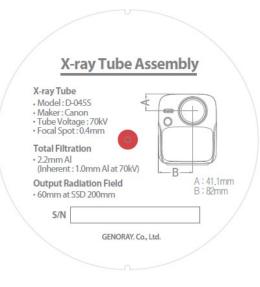
ZEN-PX4



Multiple name



Tube label





### **Battery**

| GENORAY  | 🗥 SAFETY WARNING 🛛 🕱  |
|--|---|
| Product : Rechargeable Li-ion Battery Pack<br>Type of battery : 6ICP6/35/62<br>Model : GPB-1100<br>Rating(s) : 22.2 VDC   1000mAh<br>Distributor : GENORAY Co., Ltd.<br>Manufacturer : GENORAY Co., Ltd. (Made in Korea)<br>S/N  | <ol> <li>Use only the charger desginated for this battery pack.</li> <li>Store this product at room temperature and avoid crush,<br/>high temperature and humidity.</li> <li>Disassemble, open, or misuse may present a risk of fire<br/>or explosion.</li> </ol> |
| GENORAY  | GENORAY   |
| Product : Rechargeable Li-ion Battery Pack<br>ype of battery : 6ICP6/35/62<br>Model : P4-6ICP6/35/60_Pc<br>Rating(s) : 22.2 VDC   1000mAh<br>Distributor : GENORAY Co., Ltd.<br>Manufacturer : BN TECH Co., Ltd. (Made in Korea) | Product : Rechargeable Li-ion Battery Pack<br>Type of battery : 6lCP6/35/62<br>Model : HS603560H25-061PBH<br>Rating(s) : 22.2 VDC   1000mAh<br>Distributor : GENORAY Co., Ltd.<br>Manufacturer : Han Sung A-Tech (Made in Korea)                                  |
|  |   |





## Appendix1. Error Messages and Interim Measures

If a problem occurs while using the equipment and/or is not functioning properly, an error message is displayed on the X-ray control unit.

After checking the message, take appropriate action.

If the same issue is repeated even after taking the temporary measures, contact the service center.

### A.1.1 Error message

| 1 | Code number   | Error 1   |
|---|---------------|---|
|   | Error message | OCP ERROR   |
|   | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Error 2   |
| 2 | Error message | The kV is high.   |
| 2 | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Error 3   |
| 3 | Error message | The kV is low.  |
| 3 | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Error 4   |
| 4 | Error message | The mA is high.   |
| + | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Error 5   |
| 5 | Error message | The mA is low.  |
| 5 | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Error 6   |
| 6 | Error message | The mA is high.   |
|   | Measures      | <ul><li>After rebooting the device, check to see if the issue has been resolved.</li><li>If the same issue continues, contact the service center.</li></ul> |



| 7  | Code number   | Error 7   |
|----|---------------|---|
|    | Error message | The tank temperature is high.   |
|    | Measures      | <ul> <li>Please use the device after keeping the power OFF for 30 minutes or more.</li> <li>If the same issue continues, contact the service center.</li> </ul> |
| 8  | Code number   | Error 8   |
|    | Error message | The tank temperature is low.  |
|    | Measures      | <ul><li>Use after leaving it in a warm place for 30 minutes or more.</li><li>If the same issue continues, contact the service center.</li></ul>                 |
| 9  | Code number   | Error 9   |
|    | Error message | One of the kV/mA output is high.  |
|    | Measures      | <ul><li>After rebooting the device, check the symptoms.</li><li>If the same issue continues, contact the service center.</li></ul>                              |
|    | Code number   | Error 10  |
| 10 | Error message | The shot switch is broken or depressed.   |
| 10 | Measures      | <ul><li>Release the Hand switch or Shot switch after the shot.</li><li>If the same issue continues, contact the service center.</li></ul>                       |
|    | Code number   | Error 11  |
| 11 | Error message | Image creation failure.   |
| 11 | Measures      | <ul><li>After reconnecting the oral sensor, take the image again.</li><li>If the same issue continues, contact the service center.</li></ul>                    |
|    | Code number   | Error 12  |
| 12 | Error message | Temp sensor malfunction.  |
|    | Measures      | <ul><li>Apply for service.</li><li>If the same issue continues, contact the service center.</li></ul>   |



## A.1.2 Warning Message

|   | Code number   | Warning 00  |
|---|---------------|---|
| 1 | Error message | X-ray exposure is limited while the battery is charging.  |
|   | Measures      | <ul><li>Use after charging is completed.</li><li>If the same issue continues, contact the service center.</li></ul>                       |
| 2 | Code number   | Warning 01  |
|   | Error message | Low battery level   |
|   | Measures      | <ul><li>Use after charging the battery.</li><li>If the same issue continues, contact the service center.</li></ul>                        |
|   | Code number   | Warning 02  |
| 3 | Error message | FFC file is missing.  |
|   | Measures      | Please create a FFC file.   |
|   | Code number   | Warning 03  |
| 4 | Error message | Low backup battery level.   |
| • | Measures      | <ul><li>Replace the backup battery.</li><li>If the same issue continues, contact the service center.</li></ul>                            |
|   | Code number   | Warning 04  |
| 5 | Error message | Time synchronization failed.  |
| 5 | Measures      | <ul><li>Please retry time synchronization.</li><li>If the same issue continues, contact the service center.</li></ul>                     |
|   | Code number   | Warning 05  |
| 6 | Error message | Wireless dongle connection failed.  |
| Ū | Measures      | <ul><li>Please reconnect the wireless dongle.</li><li>If the same issue continues, contact the service center.</li></ul>                  |
|   | Code number   | Warning 06  |
| 7 | Error message | Server PC connection failure.   |
|   | Measures      | <ul><li>Check the Wi-Fi connection and the server PC settings.</li><li>If the same issue continues, contact the service center.</li></ul> |
|   | Code number   | Warning 07  |
| 8 | Error message | Image transmission failed.  |
|   | Measures      | <ul><li>Try sending the image again.</li><li>If the same issue continues, contact the service center.</li></ul>                           |



| 9  | Code number   | Warning 08   |
|----|---------------|--|
|    | Error message | Micro SD card connection failure.  |
|    | Measures      | <ul><li>Check the micro SD card connection.</li><li>If the same issue continues, contact the service center.</li></ul> |
|    | Code number   | Warning 09   |
| 10 | Error message | Oral sensor connection failure.  |
| 10 | Measures      | <ul><li>Reconnect the oral sensor.</li><li>If the same issue continues, contact the service center.</li></ul>          |



## **Appendix2. X-ray Exposure settings**



X-ray Exposure conditions are recommended irradiation conditions when using digital sensors and chemical films. The Exposure conditions may vary depending on the specifications and performance of the digital sensor and chemical film used by the user.

## A.2.1 Initial setting

#### **Digital Sensor**

| Digital Sensor |          |         | Exposure time(sec) |  |  |  |  |
|----------------|----------|---------|--------------------|--|--|--|--|
|                |          | Incisor | 0.22               |  |  |  |  |
|                | Maxilla  | Canine  | 0.25               |  |  |  |  |
| Pig            |          | Molar   | 0.28               |  |  |  |  |
| Big            |          | Incisor | 0.16               |  |  |  |  |
|                | Mandible | Canine  | 0.18               |  |  |  |  |
|                |          | Molar   | 0.22               |  |  |  |  |
|                |          | Incisor | 0.2                |  |  |  |  |
|                | Maxilla  | Canine  | 0.22               |  |  |  |  |
| Middle         |          | Molar   | 0.25               |  |  |  |  |
| Midule         | Mandible | Incisor | 0.14               |  |  |  |  |
|                |          | Canine  | 0.16               |  |  |  |  |
|                |          | Molar   | 0.2                |  |  |  |  |
|                |          | Incisor | 0.16               |  |  |  |  |
|                | Maxilla  | Canine  | 0.18               |  |  |  |  |
| Child          |          | Molar   | 0.22               |  |  |  |  |
| Crillu         |          | Incisor | 0.1                |  |  |  |  |
|                | Mandible | Canine  | 0.14               |  |  |  |  |
|                |          | Molar   | 0.18               |  |  |  |  |



#### **Chemical Film**

| Digital Sensor |          |         | Exposure time(sec) |  |  |  |  |
|----------------|----------|---------|--------------------|--|--|--|--|
|                |          | Incisor | 0.9                |  |  |  |  |
|                | Maxilla  | Canine  | 1                  |  |  |  |  |
| Dia            |          | Molar   | 1.12               |  |  |  |  |
| Big            |          | Incisor | 0.63               |  |  |  |  |
|                | Mandible | Canine  | 0.71               |  |  |  |  |
|                |          | Molar   | 0.9                |  |  |  |  |
|                |          | Incisor | 0.8                |  |  |  |  |
|                | Maxilla  | Canine  | 0.9                |  |  |  |  |
| Middle         |          | Molar   | 1                  |  |  |  |  |
| Midule         | Mandible | Incisor | 0.56               |  |  |  |  |
|                |          | Canine  | 0.63               |  |  |  |  |
|                |          | Molar   | 0.8                |  |  |  |  |
|                |          | Incisor | 0.63               |  |  |  |  |
|                | Maxilla  | Canine  | 0.71               |  |  |  |  |
| Child          |          | Molar   | 0.9                |  |  |  |  |
| Crilla         |          | Incisor | 0.4                |  |  |  |  |
|                | Mandible | Canine  | 0.56               |  |  |  |  |
|                |          | Molar   | 0.71               |  |  |  |  |

# Appendix3. Air-kerma & Dose Information

| Step | Sec  | Air-kerma<br>(mGy) | DAP<br>(mGy*cm²) | Step | sec  | Air-kerma<br>(mGy) | DAP<br>(mGy*cm²) |
|------|------|--------------------|------------------|------|------|--------------------|------------------|
| 5    | 0.05 | 0.13               | 3.65             | 20   | 0.32 | 0.83               | 23.34            |
| 6    | 0.06 | 0.15               | 4.38             | 21   | 0.36 | 0.93               | 26.26            |
| 7    | 0.07 | 0.18               | 5.11             | 22   | 0.40 | 1.03               | 29.18            |
| 8    | 0.08 | 0.21               | 5.84             | 23   | 0.45 | 1.16               | 32.82            |
| 9    | 0.09 | 0.23               | 6.56             | 24   | 0.50 | 1.29               | 36.47            |
| 10   | 0.10 | 0.26               | 7.29             | 25   | 0.56 | 1.44               | 40.85            |
| 11   | 0.11 | 0.28               | 8.02             | 26   | 0.63 | 1.63               | 45.95            |
| 12   | 0.13 | 0.34               | 9.48             | 27   | 0.71 | 1.83               | 51.79            |
| 13   | 0.14 | 0.36               | 10.21            | 28   | 0.80 | 2.06               | 58.36            |
| 14   | 0.16 | 0.41               | 11.67            | 29   | 0.90 | 2.32               | 65.65            |
| 15   | 0.18 | 0.46               | 13.13            | 30   | 1.00 | 2.58               | 72.94            |
| 16   | 0.20 | 0.52               | 14.59            | 31   | 1.12 | 2.89               | 81.70            |
| 17   | 0.22 | 0.57               | 16.05            | 32   | 1.25 | 3.22               | 91.18            |
| 18   | 0.25 | 0.64               | 18.24            | 33   | 1.40 | 3.61               | 102.12           |
| 19   | 0.28 | 0.72               | 20.42            | 34   | 1.60 | 4.13               | 116.71           |

- DAP value was calculated considering the EXIT FIELD SIZE (Φ60 mm) with the estimated air kerma value. (Formula for DAP = Air-kerma \* Φ60 mm)
- D.A.P (Dose Area Product ) Model : Kerma X plus DDP "single"



The error range for the measured dose value is within  $\pm 10\%$  on average.





# Appendix4. Resetting the FileZilla Shared Folder

| Logistics | Contents   |  |  |  |  |  |  |
|-----------|--|--|--|--|--|--|--|
| 1         | After running the FileZilla program, select Menu $\rightarrow$ Edit $\rightarrow$ Users. |  |  |  |  |  |  |
| 2         | Select Shared folders tab.   |  |  |  |  |  |  |
| 3         | Click [Remove] button to remove an existing shared folder.                               |  |  |  |  |  |  |



| Logistics | Contents  |
|-----------|---|
|           | <ul> <li>Click [Add] button to add a shared folder.</li> <li>Shared folder will be located in the PortView setting location.</li> <li>After adding a shared folder, be sure to click the [Set as home dir] button to set it to Home directory.</li> <li>Once you set the Home directory, H is displayed in front of the folder.</li> <li>File permissions should be set as shown below.</li> </ul>  |
| 4         | Users       X         Page:       Shared folders       Isers         Speed limits       Directories       Isers         IP Filter       Append       Directories         Add       Remove       Rename         Add       Remove       Rename         Add       Remove       Rename         Add       Remove       Rename         Advectory allas will also appear at the specified location. Allases must contain the full vitual path. Separate multiple allases for one directory with the pipe character (1)       If using allases, please avoid cyclic directory structures, it will only confuse FTP clients. |



## **Appendix5.** Maintenance

Experienced users are responsible for the proper operation and maintenance of the system.

Check regularly for the safety of the patient and the operator as per the following information.

### A.5.1 Cleaning

• Use a disinfectant (less than 17% alcohol) with a cloth to clean the ZEN-PX4.

Always keep the tip of the cone clean. This portion of the unit is in frequent contact with the patients.

 Be careful not to let the cleaning spray solution or disinfectant, etc. enter into the equipment.

This may cause electric failure.

Do not use cleaners meant for hard surfaces.

Certain chemical combinations can degrade plastics.

Do not use cleaning agents containing solvents that can dissolve plastics.



Before cleaning the equipment, be sure to turn off the power and disconnect the power plug from the outlet.



### A.5.2 Dose Confirm

The ZEN-PX4's X-ray generating is factory calibrated and tested.

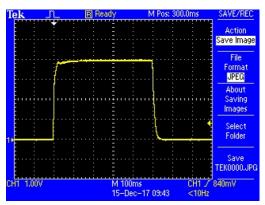
The following checks are to be performed by a qualified technician.

The test items measure the X-ray tube voltage/current, radiation time and dose and can diagnose the condition of the equipment with the measured results.

For measurement instruments, we recommend that you use certified instruments from a specialist supplier.

#### **Measurement Method**

- Tube current measurements are performed using an oscilloscope.
- Connect the oscilloscope to no. 6 and no. 8 of the RJ45 external output terminal on the equipment.
- Exposure time from RJ45 No. 6 (mA\_OUT) to RJ45 No. 8 (GND) is set at 0.5 sec and then the X-ray is exposed.
  - Reference value: 2 mA -> 4 V ± 10% (3.6 to 4.4 V)



mA: 0.5 mA per 1 V

- If the oscilloscope's waveform is not displayed correctly then take another x-ray exposure.
- If the output waveform does not match the reference value, contact the manufacturer.
- Tube voltage, dose value and exposure time measurements are carried out using a dosimeter.

Set the exposure time (refer to Appendix. 2) as follows and exposure X-rays.

| Item                  | Reference                   | Timer setting and its allowable range |        |         |          |           |  |  |
|-----------------------|-----------------------------|---------------------------------------|--------|---------|----------|-----------|--|--|
|                       | value                       | 50 ms                                 | 100 ms | 500 ms  | 1000 ms  | 1600 ms   |  |  |
| kVp (eff)<br>Accuracy | 70 kV ±7%                   | 66-75                                 | 66-75  | 66-75   | 66-75    | 66-75     |  |  |
| Timer<br>Accuracy     | Setpoint<br>±10%, ±20<br>ms | 45-55                                 | 90-110 | 450-550 | 900-1100 | 1440-1760 |  |  |



- If it is out of the above error range then take another x-ray exposure.
  - If it is continuously out of the error range, contact the manufacturer.
- Details regarding the measuring equipments used are as follows.

We recommend using the following equipment or equivalent certified products.

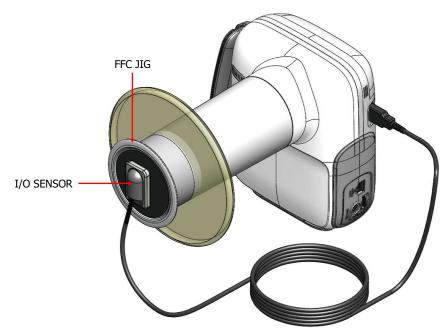
| Model                      | Manufacturer | Photo          |
|----------------------------|--------------|----------------|
| Oscilloscope<br>(TDS2022C) | Tektronix    |                |
| Dose Meter<br>(255)        | Piranha      | Piranha<br>Mar |



#### A.5.3 Check image

Please refer to "Dose Confirm" item to check whether the X-ray output is normal.

#### **Make Flat Field Correction**



In order to obtain a low-noise image, execute the FFC (flat filed correction) function by using the FFC JIG provided for the first connection with the ZEN-PX4 and Intra Oral sensor



Select Setting-AutoFFC to execute the FFC function automatically.



#### **Resolution**

Check the image quality by measuring the clarity of the image via resolution.

Please see instructions below:

| Logistics  | Photo  |
|--|--|
| ① Attach the I/O Sensor to the phantom.  | I IIIE   |
| ② Exposure X-ray for 0.2 seconds.  |  |
| <ul> <li>③ The lines of the resolution chart should appear as shown in the image.</li> <li>More than 14 Line Pairs should appear.</li> <li>If the line pair is not visible, proceed to FFC and take another exposure.<br/>If the line pair is still not visible, please contact our service center.</li> </ul> | 18<br>12<br>14<br>16<br>18<br>12<br>14<br>14<br>14<br>14 |

• Additional information on the phantom:

| Model                           | Manufacturer | Photo |
|---------------------------------|--------------|-------|
| QUART<br>dent/digitest<br>M2/M1 | QUART        |       |



#### A.5.4 Service

- Only technicians certified by Genoray Co. can perform inspection and service of equipment.
- For technical support, please contact our service center.

### A.5.5 Returns and repairs

- If the equipment is found to be defective and needs repair, please contact our service center.
- Genoray Co. will not be responsible if the product is disassembled or modified arbitrarily.



## A.5.6 Maintenance table

| Inspection                 |  | _            |   | Result |   |   |   |         |  |
|----------------------------|--|--------------|---|--------|---|---|---|---------|--|
| period                     | Inspection items   | Inspector    | 1 | 2      | 3 | 4 | 5 | Remarks |  |
|                            | Power plug connection status                                 |              |   |        |   |   |   |         |  |
|                            | Grounding connection status                                  |              |   |        |   |   |   |         |  |
|                            | Power off after using the<br>equipment                       |              |   |        |   |   |   |         |  |
|                            | Cleanliness of the equipment                                 |              |   |        |   |   |   |         |  |
| Everyday                   | Disinfecting sections that come<br>into contact with patient |              |   |        |   |   |   |         |  |
|                            | On/off switch  | User         |   |        |   |   |   |         |  |
|                            | Up/down, right/left buttons                                  |              |   |        |   |   |   |         |  |
|                            | Exposure Switch  |              |   |        |   |   |   |         |  |
|                            | Patient registration   |              |   |        |   |   |   |         |  |
|                            | Saving and loading images                                    |              |   |        |   |   |   |         |  |
| Even week                  | Temperature and humidity                                     |              |   |        |   |   |   |         |  |
| Every week                 | Emergency switch   |              |   |        |   |   |   |         |  |
|                            | Tube voltage accuracy test                                   |              |   |        |   |   |   |         |  |
| 6 months or<br>more Unused | Tube current accuracy test                                   | Manufacturer |   |        |   |   |   |         |  |
| equipment                  | Exposure dose to the patient                                 | manufacturer |   |        |   |   |   |         |  |
|                            | Detector calibration   |              |   |        |   |   |   |         |  |



Carry out periodic inspections and tests to maintain great equipment and image quality.



For a longer life expectancy of the unit, regular inspections must be made every 3 years after the date of purchase.





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