Remex T100

User Manual

Portable X-ray System

20190826

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1 Introduction

The REMEX T100 Portable Dental X-Ray System should only be used by trained dentists/dental technicians, as an extra-oral x-ray source for producing diagnostic x-ray images that use intra-oral image receptors (digital sensors, phosphorus plates, or film). It is intended for use with adult and pediatric patients.

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS MANUAL and reviewed the accompanying materials.

Disclaimer: REMEX T100 Portable X-ray System is sold with the understanding that the user assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that Remedi Co., Ltd. agents or representatives, do not accept responsibility for:

- **injury or danger to personnel from X-ray exposure**
- **image over/under exposure due to poor operating techniques or procedures**
- **equipment not properly serviced/maintained in accordance with instructions contained in this publication**
- **equipment which has been damaged, modified, or tampered with in any way.**

It is the responsibility of the end-user/doctor/practice to give a comprehensive test to each operator to ensure the operator(s) fully understand how to use the product, and they must keep a record of the training and testing, per your states requirements. See Operator Training Test on page 44. This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

This User Manual may be revised for the improvement of the product, without prior notification. Images in this User Manual may differ from the actual product.

2 Regulatory Compliance

FDA Registered. This product complies with 21 CFR 1020.30-1020.31.

Complies with IEC 60601-1; IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6,

IEC 60601-2-65, IEC 62304, IEC 62366, ISO 14971 and CE 0068.

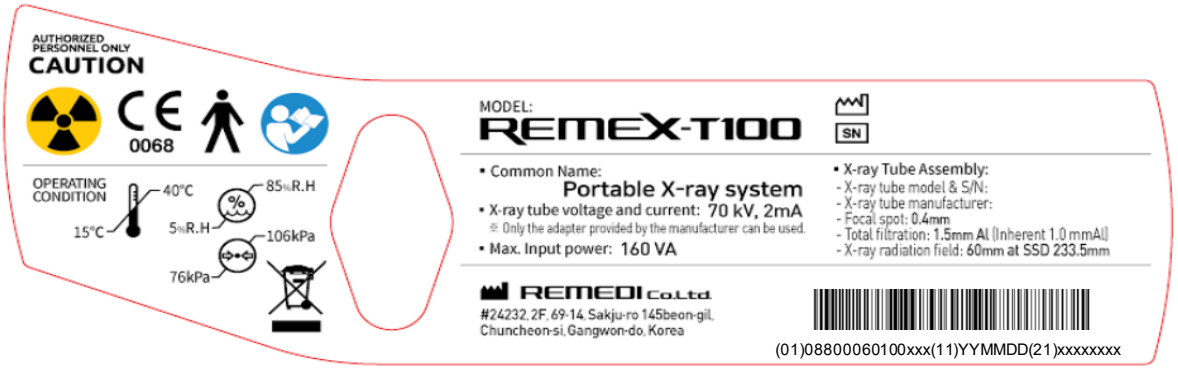
2.1 Indications for Use

The REMEX T100 Portable X-ray System is a diagnostic x-ray system which 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 intra-oral receptors. Its use is intended for both adults and pediatric subjects.

2.2 Intended Use

Intended as extraoral x-ray source to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.

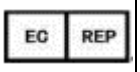
2.3 Device Label (located on the bottom of the device)

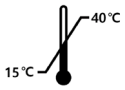
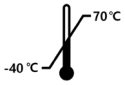
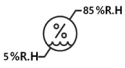
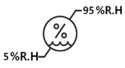
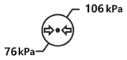
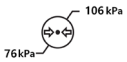


2.4 Symbols

The following are descriptions of the symbols located on the outside and packaging of the product. Please read carefully before using the product.

No	Symbol	Description	Location
1	SN	Serial Number of the Device	Product Label
2		Device Manufacturer	Product Label

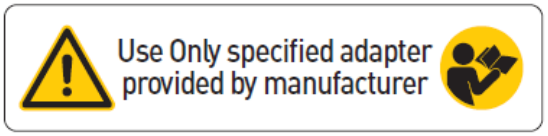
3		Date of manufacture	Product Label
4		TYPE B applied part	Product Label
5		Follow instructions for use	Product Label
6		X-ray Radiation Hazard	Product Label
7		Proper Disposal of Device—Product must be collected separately WEEE mark	Product Label
8		Warning: Electrical	Inside of equipment
9		General Caution, Warning (safety sign)	User Manual
10		General Prohibition (safety sign)	User manual
11		Keep dry	Package Label
12		Keep away from sunlight	Package Label
13		EC representative	Package Label
14		Manufacturer	Package Label

15		Operating temperature range	Product Label
16		Storage temperature range	Package Label
17		Operating humidity range	Package Label
18		Storage humidity range	Package Label
19		Operating Atmospheric pressure range	Package Label
20		Storage Atmospheric pressure range	Package Label
21	0068 CE	CE mark, Complies with European medical Devices directive	Product Label and Package Label

2.5 Additional Device Labels

Label of AC/DC adapter connector

Label location: Near the AC/DC adaptor connector



Label of Radiation hazard (Physiological effects)

Label location: on the Bottom center of back of device

Label of AC/DC adapter

Label location: On the adapter

POWER-TEKADAPTER

Model: YHY-1260201500

Input rate: 100-240VAC 50/60Hz 1.0A

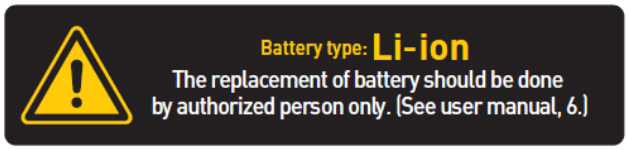
Output rate: 12.6V⎓ 1500mA

Manufacturer: SHENZHEN YINGHUIYUAN ELECTRONICS CO., LTD

Made in China

Label of re-chargeable battery

Label location: On the battery pack



High voltage tank

Label location: On the high voltage tank house (Inside the device)

3 Operator Caution

3.1 Radiation Safety

This X-ray device may be dangerous to the patient and operator unless safe exposure factors and operating instructions are observed.

1. **This X-ray tube assembly produces ionizing radiation when energized. Therefore, when used, it is better to have the patients wear X-ray protective devices such as apron, thyroid cover, etc.**
2. **It is imperative that the owner designates areas suitable for safe operation and service of the system and the operator ensures that it is used only in these designated areas.**
3. **It is the responsibility of the owner to ensure that all personnel wear radiating monitoring devices while using this system.**
4. **Operators must follow all applicable regulatory guidelines and in-house radiation protection program in regards to patients and operators who are pregnant or expect to become pregnant.**
5. **Do not attempt an exposure if anyone other than patient is in the direct beam. If others are assisting, then they must also wear protective covering.**
6. **When selecting and using position indicating devices (pids), preference should be given to models with backscatter shield and collimator cone that are permanently attached for maximum operator protection.**

1. **Do not apply any impact or vibration to the product while using or moving it.**
2. **Try not to move the device or incur vibration during exposure while using it as hand held. The image will not be clear if the device moves or there is a vibration during x-ray exposure.**
3. **Do not install or use the device in a dirty or unstable environment.**
4. **Do not pull the charger cords forcibly.**
5. **Do not allow a patient to touch the device and do not leave the device within the reach of a patient.**
6. **Do not misuse the device because it resembles a common photographic camera.**
7. **The internal construction of this device is designed to minimize the amount of X-ray leakage, but be aware that a minimum amount still may occur.**
8. **The remote control uses an infrared signal, please direct it toward the window of the**

receiver.

9. If you operate this device near a broadcasting station (a base station for radio telephone, a generator, or other X-ray devices) it may malfunction due to the effects of electrical energy or RF energy. Please refrain from using this device in such surroundings and use it in a stable environment.
10. Static electricity may affect this device at any time. Please use this device within the permissible range of humidity defined by the specifications. Please refrain from wearing a garment that may generate such static electricity.
11. Although this device has been designed and manufactured pursuant to the regulation of EMI (electromagnetic wave interference), it may still generate a low level of EMI that could affect other devices or a human body.
12. This device generates X-rays. You must install or use it pursuant to the international regulation or the regulation of the country and state where you intend to use this device.

3.2 General Cautions

Cautions

1.	This product is intended for use by a dentist or dental technician with appropriate license.
2.	Please read and understand the instructions carefully before using.
3.	No modification of this equipment is allowed. If the product is modified or used for any purpose other than those specified in this User Manual, the service Tech will not be responsible for the safe operation of the device.

Prohibited

1.	Do not use with unauthorized AC/DC adapter.
2.	Do not use it out of intended use. (For dental use only)
3.	Make sure the backscatter shield and cone are permanently attached.
4.	Do not disassemble the unit.
5.	Do not use the device outside of the significant zone of occupancy.

4 Getting Started

4.1 Unpack and Check the Device

Unwrap individual components from the protective case and check for any noticeable signs of damage. Make sure that the serial number on your invoice matches the serial number on the device label (Serial No.—located on the bottom of the device).

Check ✓	Package Items
	Remex T100 Handheld Device with cone and backscatter shield permanently attached
	Power Supply w/ cord
	Neck Strap, Hand Strap
	6 foot cord for remote control (If required by your State)
	User Manual on Memory Stick

4.2 Registration of the Device

This device must be registered with your State Health Dept. as an X-Ray Device by each dental office/practice. There is a requirement to complete FDA Form 2579 and submit this form to your State Health Dept. Certain States allow dealers/vendors to complete this submission, please verify that your state accepts this before allowing dealer/vendor to complete this registration for you. A fee may be charged for your State Registration. Please check your State's Health Dept. for rates and deadlines. ***Failure to comply with your States regulations may result in penalties/fines and REMEX T100 is sold with the understanding that the user assumes sole responsibility for any non-compliance with state regulations.***

Note: The REMEX T100 device is a portable x-ray unit that can be used as a handheld device. Device may only be used as a handheld in states permitting handheld x-ray units. If your state does not allow this function, use this device in accordance with your states rules and regulations.

4.3 Read Instructions

To start using your REMEX T100 Portable X-ray System, please read this User Manual for Operating the System instructions before using your device.

5 Warranty Information

COVERAGE: Remedi Co., Ltd. warrants its dental x-ray equipment and accessories to be free from any defects in material or workmanship for a period of two (2) year from the date of purchase.

The liability of Remedi Co., Ltd. is limited to repair or replacement of any parts that Remedi Co., Ltd. or its authorized resellers/dealers determine to be defective. Contact Remedi Co., Ltd. or Reseller/Dealer for a Return Authorization and shipping instructions. Parts proving defective shall be repaired or replaced. Equipment repaired or replaced under warranty shall continue to be warranted for the balance of the original warranty term. All warranty claims must be made no later than ten (10) business days following the expiration of the applicable warranty period.

LIMITATIONS OF COVERAGE: This warranty does not apply to equipment that is or has been abused, misused, or altered (including opening enclosure or tampering), improperly maintained, subjected to use beyond rated conditions, or damaged as a result of any carelessness or accidents. This warranty does not cover ordinary wear and tear or maintenance.

5.1 Quality Guarantee

- **We will provide you service for manufacturing defects that occur during the warranty period.**
- **Your limited warranty is void if the attached label is damaged.**
- **Service fees will be charged for damage caused by the customers' carelessness even though the warranty period has not expired.**
- **The limited warranty shall not be applied to a repair or service rendered by other repair shops other than those approved by Remedi Co., Ltd.**

The service period will not be extended when expired.

6 Product Description

The REMEX T100 Portable X-ray System is a diagnostic x-ray system, which is intended to be used by dentists and dental technicians as an alternate x-ray source to conventional x-ray units and it produces the same diagnostic x-ray images as wall-mounted units. By reducing loss with stable and effective DC High voltage, the REMEX T100 system enables you to take an X-ray with a smaller amount of radiation and thus, protects the patient, and operator.

Its use is intended for both adult and pediatric patients. This device includes a high frequency inverter that changes alternating current to direct current, a high-quality X-ray tube, electrical protective devices, and other elements. REMEX T100 provides sharp and clear images with an integral structure and internal battery. The cordless REMEX T100 system increases the user's convenience significantly.

Performance	Battery power source delivers dependable high voltage (70kV) and direct current (2mA).
Radiation Emission	**high-frequency, constant-potential X-ray generator provides high quality images, with a lower radiation dosage to the patient than standard AC X-ray systems.**
Radiation Protection	**Operator shielded from source and backscatter radiation**
Applications	**To be used only for diagnostic X-ray by dentist, veterinarians and orthopedic doctors**
Unit Design	**Provides complete flexibility and convenience, enabling exposures without moving the patients to the X-ray source**
Compatibility	**Works with both film and digital imaging systems**

6.1 Product Components

Figure 1 - Overview of REMEX T100

No.	Name	Description
1	System body	Case containing controls, display, battery and X-ray generator
2	Collimator cone	Limit the irradiation range of the beam during exposure
3	Backscatter shield	Limit reflection of radiation from metallic artifacts to the operator
4	Exposure button	Press and hold to trigger radiation exposure
5	Exposure indicator light	Glows red during exposure

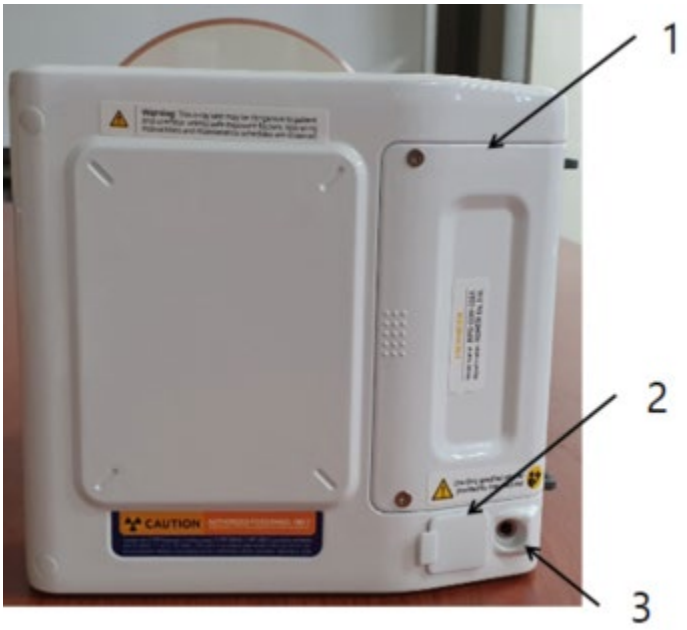


Figure 2 - Rear View

1	Battery cover	Remove this cover to replace a rechargeable battery.
2	Charging port	Connector for charging
3	Remote Control Port	Connector for remote control

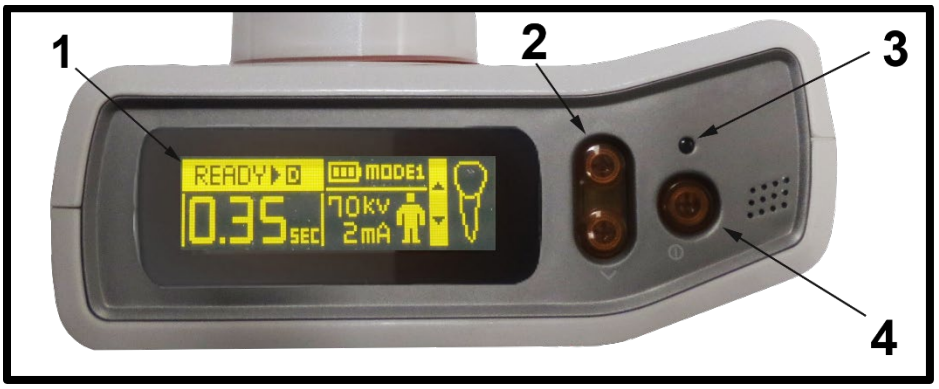


Figure 3 - Top View

1	LCD display window	Display the exposure conditions (kV, mA, exposure time, Mode, battery status).
2	Mode / Exposure Time	Set the X-ray exposure Mode or Time.

	control button	
3	Exposure status LED	When the X-ray is irradiated, the yellow LED is turned on.
4	Power button	Turn ON/OFF

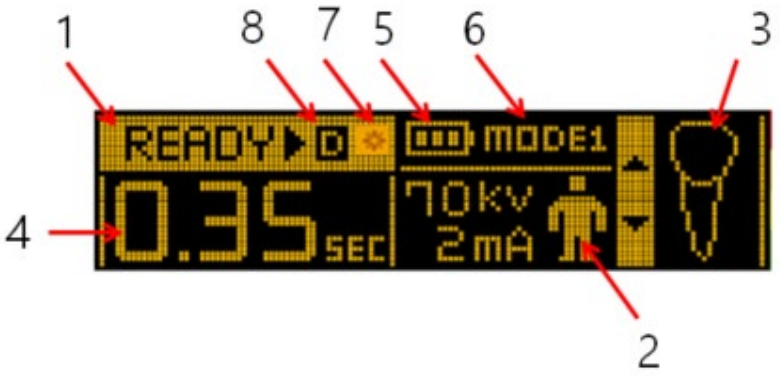


Figure 4 – Display Window

1	Status	Indicates the current status of the device. READY: "Ready" condition. READY ✲: "Exposure" condition. After exposure the X-ray, symbol ✲ is disappeared and "READY" is remained.
2	Mode select	[Adult, child] can be selected. Adult mode: exposure time – set to 0.65 s Child mode: exposure time – set to 0.30 s ⚠ Warning: Cone should not be placed in a direction other than face. Especially when the patient is child, the exposure time should be selected carefully. ⚠ The exposure time set in each mode is recommended by the manufacturer, and the time can be adjusted in each mode.
3	Tooth selection	Selecting three maxillary (front teeth, canines, molar teeth) and three mandibles (front teeth, canines, molar).

4	Exposure time select	Set the exposure time.
5	Battery condition	Displays the remaining battery level.
6	Time/Mode exchange	Display [Time] or [Mode].
7	Display Exposure( )	It is displayed on the display window during the time when X-rays are generated.
	X- ray irradiation prohibit display( )	The irradiation prohibition indication appears for 10 seconds after X-ray irradiation.
	Charger connection display( )	It is displayed when the charger is connected. (X-ray not irradiated during battery charging)
8	D/F select	Choice of tooth image acquisition device (D: Digital image, F: Film image)

7 Configuring Exposure Times

Operator choice of exposure time depends on clinical needs and type of x-ray receptor in use (film, PSP, digital sensor and imaging software).

Exposure times can be adjusted and saved by the operator for each combination of patient size and tooth type using the following procedure:

1. **While the power is off, press 'UP', 'DOWN', 'POWER' buttons simultaneously. The system will power on in configuration mode.**
2. **Press the UP/DOWN buttons to move the cursor to the numbered menu items for Mode and Tooth Type as listed below:**

MODE: ADULT MB (Mandible) **7 INCISOR = 0.35 SEC** **8 CANINE = 0.49 SEC** **9 MOLAR = 0.55 SEC**	**MODE: CHILD MB (Mandible)** **13 INCISOR = 0.22 SEC** **14 CANINE = 0.28 SEC** **15 MOLAR = 0.35 SEC**
MODE: ADULT MX (Maxilla) **10 INCISOR = 0.35 SEC** **11 CANINE = 0.49 SEC** **12 MOLAR = 0.55 SEC**	**MODE: CHILD MX (Maxilla)** **16 INCISOR = 0.28 SEC** **17 CANINE = 0.35 SEC** **18 MOLAR = 0.43 SEC**

Table 1 - Sample Exposure Times

The exposure time set in each mode is recommended by the manufacturer, and each time can be adjusted.

3. **Press the EXPOSURE button to select a menu item**
4. **Adjust the time by 0.01 by pressing the UP/DOWN buttons**
5. **Press the EXPOSURE button to save the time for the current tooth type**
6. **To change the time for another tooth, repeat steps 2-5 above.**
7. **Press the POWER button when you finish set-up to save your data and power off.**

Note: The system will <u>not</u> power off automatically while in configuration mode.

7.1 Configuring Audible Alerts

The system is configurable to play a series of short beeps when the exposure button is pressed.

These beeps can be disabled by the user:

1. **While the power is off, press 'UP', 'DOWN', 'POWER' buttons simultaneously. The system will power on in configuration mode.**
2. **Press the DOWN button to move the cursor to menu item 3 READY BUZ**
3. **Press the EXPOSURE button to select item**
4. **Press the DOWN button repeatedly to change the value to 0 to disable the beep**
5. **Press the EXPOSURE button to save the value**
6. **Press the POWER button when you finish set-up to save your data and power off**

Note: The system will <u>not</u> power off automatically while in configuration mode.

8 Dimensions of the Device

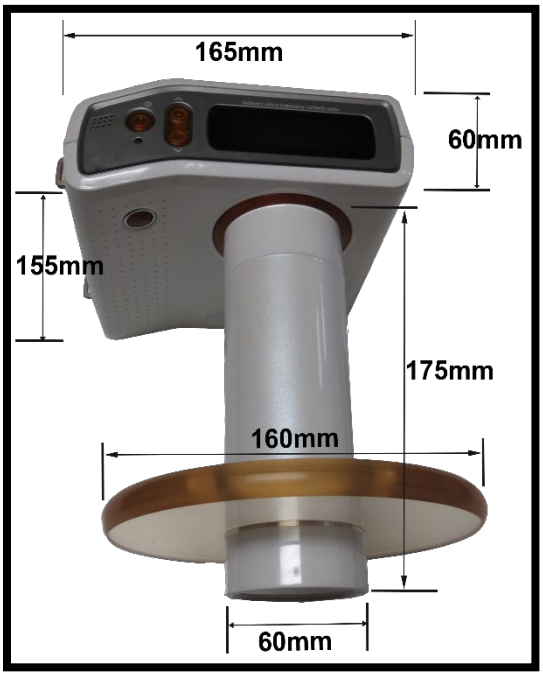


Figure 5 - Dimensions

- main body size: 165W ⨯ 155H ⨯ 60D mm

- cone size: 175L X 60W mm

- backscatter shield size: 160Φ X 12D mm

- weight: 2.2 kg (including cone 190 g, shield 300g)

- size: 90L ⨯ 45H ⨯ 30W mm

- weight: 150 g

Figure 6 - AC/DC adapter and power cord (Accessory)

8.1 Operating Conditions

- **Temperature: 15 ℃ ~ 40 ℃**
- **Related Humidity: 5 %R.H. ~ 85 %R.H. (Non-condensing)**
- **Atmospheric pressure: 76 kPa ~ 106 kPa**
- **Altitude: Less than 2,000 m**

8.2 Storage and Transportation Conditions

- **Temperature: -40 ℃ ~ 70 ℃**
- **Related Humidity: 5 %R.H. ~ 95 %R.H. (Non-condensing)**
- **Atmospheric pressure: 76 kPa ~ 106 kPa**

Optimal storage location is in a cool, dry location and out of direct sunlight with a 10-60% relative humidity. Recommended humidity conditions for use are 10-85% RH.

Do not store the REMEX T100 or its accessories in extreme conditions: below -10 °C (-14 °F) or above +40°C (+104°F), or beyond 90% relative humidity. Avoid using and storing the REMEX T100 in damp, dusty, and/or salty places or where the air is poorly circulated and where chemical substances or explosive gases are stored. Atmospheric pressure: 500hPa to 1060hPa

It is recommended that the REMEX T100 be allowed to acclimate before use when switching between temperature extremes (as such with all electronic equipment).

Take precaution to ensure that the REMEX T100 will not be knocked to the ground when not in use. Some battery charge may be lost during extended inactivity (leading to exposures between handset charging).

To maintain security, the storage case comes with a lock and keys. It is recommended that the REMEX T100 unit be placed in the storage case and locked when not in use.

Photo to the right shows the box the REMEX T100 comes in with a set of keys. It is recommended that the box be locked when not in use and the keys be placed in another

location, away from the box.

9 List of Frequently Used Functions

- Connecting Charging cable

- Checking Charging condition

- Mounting Cone

- Pushing ON/OFF button

- Setting Exposure time

- Setting Mode

- Checking Display LCD

- Pushing X-ray exposure button

10 Before Operating

The operator of REMEX T100 must be a dentist or dental technician with appropriate license.

- **Read and understand warnings, cautions and user manual.**
- **Check the Charging condition of battery before use. If the battery is not adequately charged, then charge the battery using AC/DC adapter.**
- **Note: REMEX T100 cannot be used while charging.**

- Use only the charging adapter provided by the manufacturer.

- The adapter plug is used as the means of isolation. Do not position the device so that it is difficult to disconnect from the charger.

10.1 Protection against Residual Radiation

Optimal operator radiation protection exists when:

8. **the operator remains within the Significant Zone of Occupancy immediately behind the device shield**
9. **the backscatter shield is positioned at the outer end of the collimator cone,**

10. the backscatter shield is parallel to the operator torso
11. the backscatter shield is close to the patient,
12. the patient tilts their head when needed to accommodate exposures.

Figure 10 - Significant Zone of Occupancy

11 Operating the System

1. **Position operator inside significant zone of occupancy as shown in Figure 10 - Significant Zone of Occupancy, and wear radiation safety apron. Collimator cone and backscatter shield are protective devices provided by manufacturer.**

   Warning: Cone should not be pointed in a direction other than patient's face.

2. **Press ON button for 2-3 seconds (No.4 button), and turn on the REMEX T100. Defaults are "Adult" mode and "0.65 s" exposure time.**

   Note: Refer to Figure 11 - Display and Controls.

3. **Review the exposure settings for intended use. Exposure time range is 0.01 s ~ 1.3 s**

4. **Set Mode (Adult, Child or Time entry) by pressing the Up and Down Arrows (No.2**

buttons) simultaneously to enter Mode selection state, then press Up or Down to choose Adult, Child, or Time Entry.

5. **To exit Mode selection state, Press the Up and Down Arrows (No.2 buttons) together.**

6. **Set exposure time using ↑(up) or ↓(down) button (No.2 button).**

Note: Tube voltage and current are fixed.

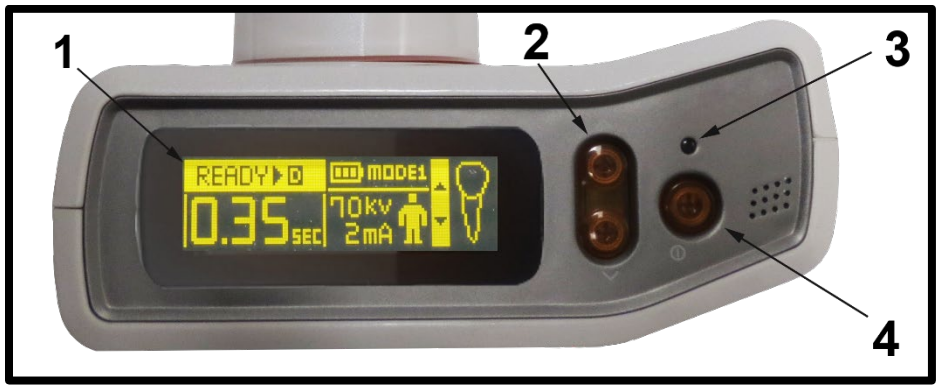


Figure 11 - Display and Controls

7. **Aim at the x-ray receptor (digital sensor, PSP, or film) intended for x-ray exposure. The X-ray beam dimension is Φ60mm (fixed), and the focal spot is aligned in the center of this beam area. The plane of the receptor should be perpendicular to the cone. Position the x-ray receptor in the patient's mouth (blue rectangle area of figure below).**

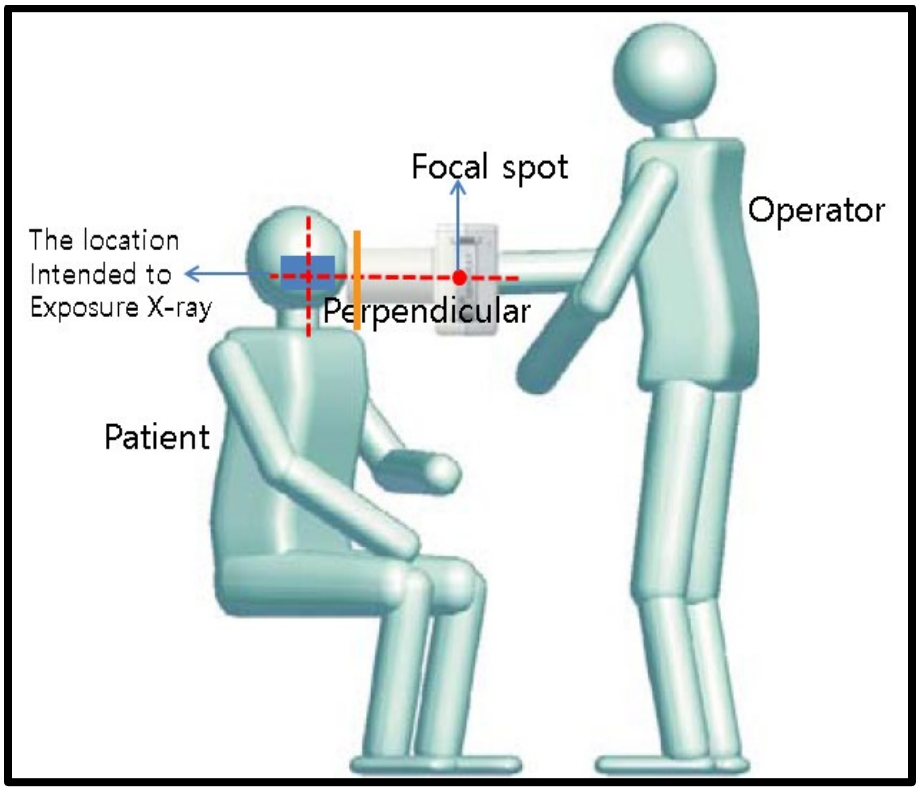


Figure 12 - Patient Positioning

8. **Press and hold the "Exposure" button (No.1 button in Figure 8 - Front View) until it stops beeping. Note: While the X-ray exposure is in progress, the red LED lamp turns on (No.3 LED in Figure 11 - Display and Controls).**

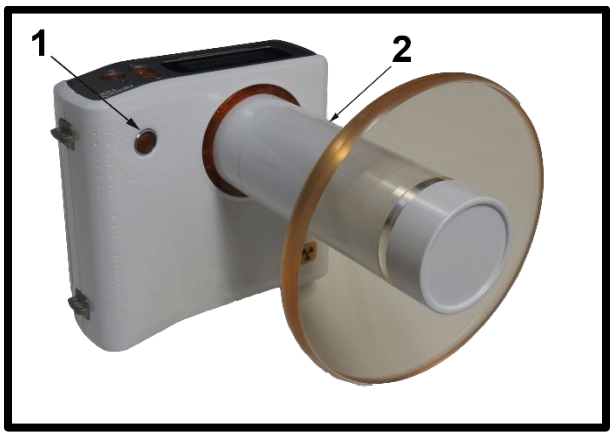


Figure 7 - Front View

If the image is not satisfactory because the dose of X-Ray is excessive or deficient, adjust the exposure. Refer to Chapter 7- Configuring Exposure Times on page 18.

Blurring of the X-ray image may occur due to movement of the patient or operator. To reduce image degradation, minimize the movement of patient and operator during X-ray exposure. The Max. exposure time is 1.3 s.

The most important thing for the X-ray is the distance of Source-to-Skin Distance (SSD). In order to get the best image from the equipment, X-rays should be irradiated at a close distance so that the cone does not touch the skin. REMEX T100 sets the suitable distance with the cone permanently attached.

12 After Operating

12.1 Storage and Cleaning after use

9. **Press “ON/OFF button” (No.4 button in Figure 11 - Display and Controls) to Turn off REMEX T100.**
10. **Check the Charging condition of battery after use. If the battery is not fully charged, then connect the supplied AC/DC adapter to charge the battery.**

> **Use only the charging adapter provided by the manufacturer. If you use another charging adapter, the battery may be damaged.**
>
> **- Disconnect the adapter cable from the device connector after charging fully.**

11. **Clean the exterior of REMEX T100 using a dry cloth.**

> **Do not use a damp cloth, and do not let water or liquid enter the unit.**

12. **Store the device in a designated safe place.**

> **Do not store in places where:**
>
> **- Water comes in contact**
>
> **- There is a risk of warping, vibration, or shock**
>
> **- Chemicals or gases are generated**
>
> **- Outside the specified storage environment**

12.2 Procedure for measurement of radiation quantity

- **Place the dosimeter (μGy) on the surface of the center of one side of the water equivalent phantom (The phantom should be filled with pure water free of bubbles.).**
- **Place the REMEX T100 on the surface of the center of the opposite side of the water equivalent phantom.**
- **The center should be aligned with the focal spot of REMEX T100.**
- **Set exposure time to 1.3 s**
- **Press the exposure button and measure the dose rate of the dosimeter.**
- **This measured radiation is reduced by low exposure time and increasing SSD, reducing the patient exposure dose.**

[Radiation Filled Area]

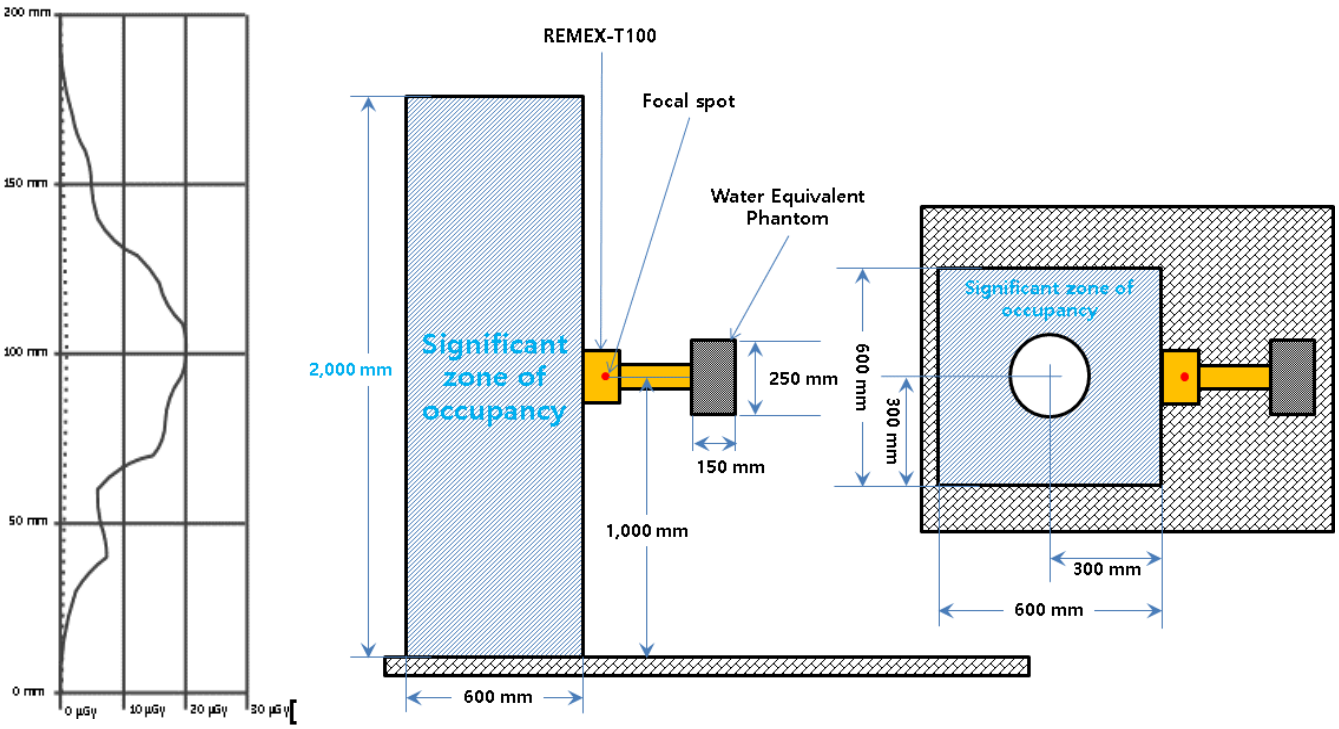


Figure 8 - Significant zone of occupancy

- **The case thickness of the water equivalent phantom is less than 10 mm. The phantom size is 250 × 250 × 150 mm^3. The phantom is made of PMMA material.**
- **Operator Dose rate in center of the significant zone of occupancy: 20 μGy**

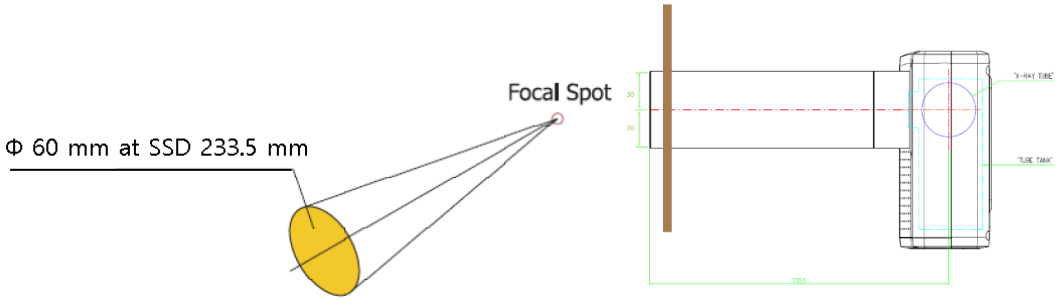


Figure 9 - Geometric position of focal spot

13 Troubleshooting Error Messages

Error code	Name	Detail	Description
ERROR 1	**Temperature error**	**Inner temperature of tube tank is over specified limit.**	**The device turned off after display "Error 1" on the LCD with the single buzzer sounds.**
ERROR 2	**Voltage error**	**Voltage of X-ray is over specified limit.**	**The device turned off after display "Error 2" on the LCD with the double buzzer sounds.**
ERROR 3	**Simultaneous error (Error 1 + Error 2)**	**Error 1 and error 2 occurred at the same time.**	**The device turned off after display "Error 3" on the LCD with the triple buzzer sounds.**
ERROR 4	Exposure button error	When user presses exposure button while turning on the device.	**The device turned off after display "Error 4" on the LCD with the single buzzer sounds.**
ERROR 5	Exposure button error	When user presses exposure button more than 10 seconds after X-ray exposure.	**The device turned off after display "Error 5" on the LCD with the single buzzer sounds.**

ERROR 6	Voltage, current feedback error	When the device doesn't get the feedback from tube and voltage while exposing X-ray.	**The device turned off after display "Error 6" on the LCD with the single buzzer sounds.**

- If the unit does not operate and does not display an error message, contact the manufacturer or a designated service provider.

14 Pediatric Guidelines

Children are more radiosensitive than adults. Adopting the Image Gently campaign guidelines and reducing dose for radiographic procedures while maintaining acceptable clinical image quality will benefit patients.

As a general rule, these recommendations shall be observed in pediatrics:

•If children are to be examined, they should always be accompanied by an adult. The adult should wear a lead apron.

•X-Ray Generator must have short exposure times.

•If possible, use high kVp techniques.

Positioning the pediatric patient: Pediatric patients are not as likely as adults to understand the need to remain still during the procedure. Therefore it makes sense to provide aids to maintain stable positioning. It is strongly recommended the use of immobilizing devices such as bean bags and restraint systems (foam wedges, adhesive tapes, etc.) to avoid the need of repeating exposures due to the movement of the pediatric patients. Whenever possible use techniques based on the lowest exposure times.

Shielding: We recommend you provide extra shielding of radiosensitive organs or tissues such gonads and thyroid glands.

The selection of the type of patient is at the discretion of professional dentist, however, we recommend using the "Child" function, for children up to 12 years old. For important information related with radiation safety in pediatric imaging please check the following links:

http://www.imagegently.org/

https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm

http://www.oeko.de/uploads/oeko/e-paper/ncl071v1.pdf

Summary:

- **Image only when there is a clear medical benefit.**
- **Image only the indicated area.**
- **Use the lowest amount of radiation for adequate imaging.**
- **Try to use always short exposure times, large source image distance values and immobilizing devices.**
- **Avoid multiple scans and use alternative diagnostic studies**

15 Technical Data

15.1 Specifications

- Electrical classification (Battery): Internally Power, Type B applied part

- Electrical classification (AC/DC Adaptor): Class II

- MDD (93/42/EEC) classification: Annex IX, rule 10, Class II b

- Mode of operation: Continuous operating

- Radiation quantity: Max entrance surface dose 216 mR at 70 kV / 2 mA / 1.3 s exposure time.

- For use in environments where no flammable anesthetics and/or flammable cleaning agents are present; non-alcohol based disinfectant only-wipes or cloth dampened with liquid/spray

15.2 X-ray exposure control

- Exposure time range: 0.01 s ~ 1.30 s (0.01 Step)

15.3 X-ray tube assembly (Toshiba)

Toshiba X-ray tube for REMEX T100

- Tube voltage range: 70 kV fixed

- Tube current range: Max. 9 mA

- Focal spot size: 0.4 mm

- Inherent filtration: Min. 1.0 mm Al

- Type: stationary

- Anode angle: 12.5°

- Anode material: Tungsten

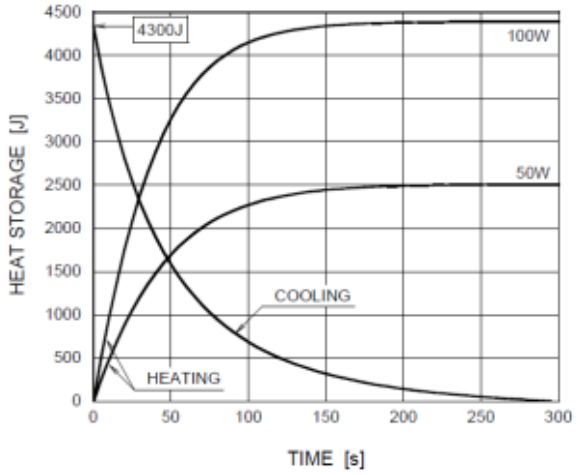
- Filament characteristic: 1.0 ~ 4.0 V, 2.2 ~ 3.0 A (max. filament current)

- Anode heat storage capacity: 4.3 kJ

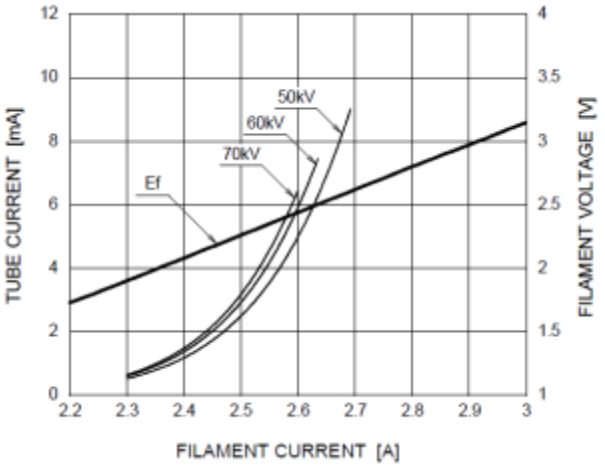
- Maximum Anode Heat Dissipation Rate: 430 W

- X-ray tube Characteristic curve

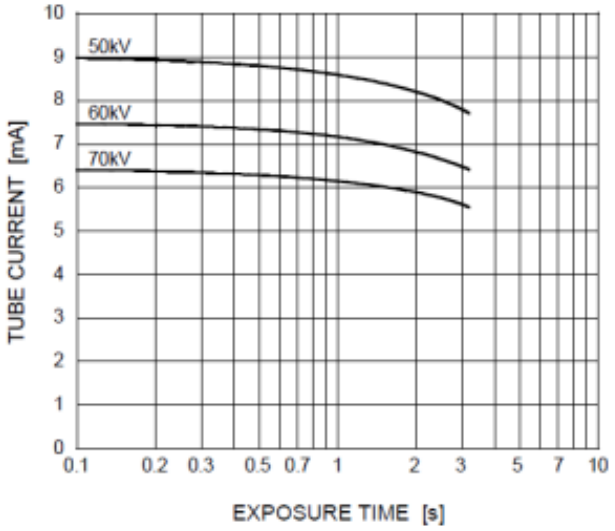
Anode Thermal Characteristics



Emission & Filament characteristics



Max. rating charts (Absolute Max. rating charts)



15.4 X-ray tube assembly (Kailong)

- Kailong X-ray tube for REMEX T100

- Tube voltage range: 70 kV fixed

- Tube current range: Max. 9 mA

- Focal spot size: 0.4 mm

- Inherent filtration: Min. 0.8 mmAl

- Type: stationary

- Anode angle: 12.0°

- Anode material: Tungsten

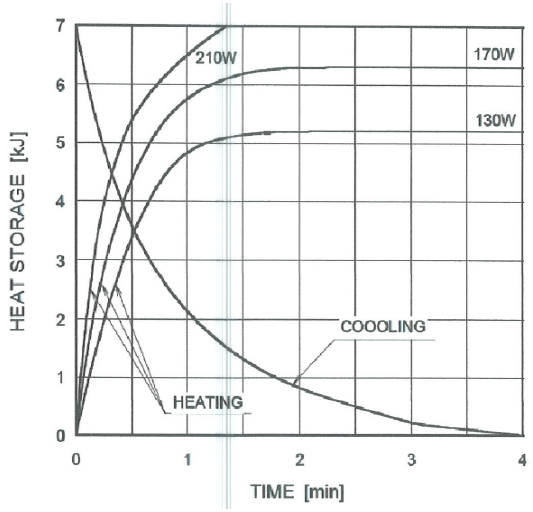
- Filament characteristic: 2.0 ~ 3.5 V, 2.2 ~ 3.0 A (max. filament current)

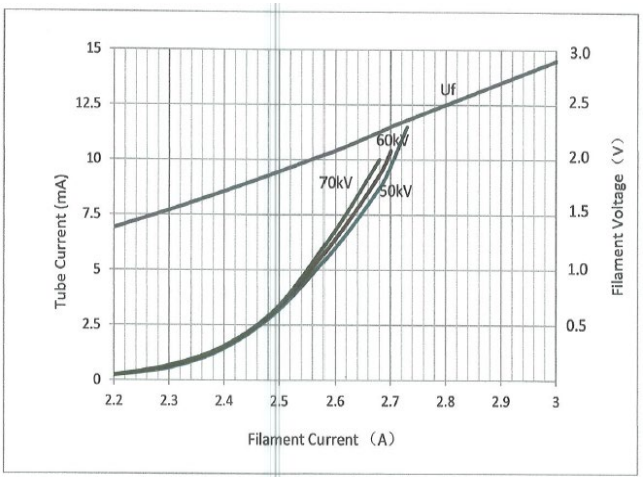
- Anode heat storage capacity: 7.0 kJ

- Maximum Anode Heat Dissipation Rate: 560 W

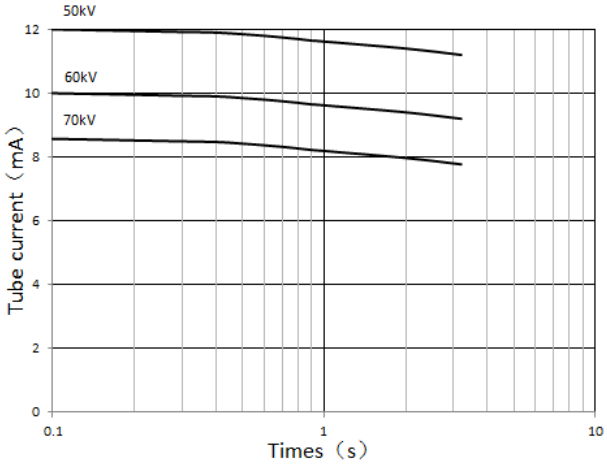
- X-ray tube Characteristic curve

Anode Thermal Characteristics **Emission & Filament characteristics**





Max. rating charts (Absolute Max. rating charts)



15.5 High voltage tank

- Type: 405 kHz, inverter type
- Tube voltage: 70 kV constant potential
- Tube current: Max. 2 mA direct current
- Additional filtration: Min. 0.5 mmAl
- Total filtration: Min. 1.5 mmAl
- **Rated power: 11.1 Vd.c. 14.4 A**

15.6 Beam limiting device (Collimator Cone)

- Type: round

- Source to Skin Distance (SSD): 233.5 mm

- X-ray field size: Φ60 mm

The beam limiting device (exit long cone) is lined with Pb because of leakage radiation.

15.7 Re-chargeable battery

- Model name: 3FB-683462XL-1500mAh-3S1P

- Manufacturer: Shenzhen Chuangxinjia Technology Co., Ltd

- Type: Li-Po Battery

- Output voltage: 11.1 Vd.c.

- Capacity: 1,500 mAh

- Size: 85 (Length) × 32 (Height) × 42 (Width) mm^3

15.8 AC/DC Charging Adapter

This power supply is specified as a part of ME equipment.

- Model name: YHY-1260201500

- Manufacturer: SHENZHEN YINGHUIYUAN ELECTRONICS CO., LTD

- Rated input: 100-240 Va.c. 50/60 Hz, 1.0 A

- Rated output: 12.6 Vd.c. 1.5 A

15.9 Software for Remex

- Type: Built-in

- S/W name: RPG-F-0702

- S/W version: 2.02

15.10 Minimum requirement for digital X-ray image receptor

- Min. resolution: 1000 line pairs

- Min. size: 40 mm × 40 mm

- Max. Pixel pitch: 40 μm

15.11 Metrics of x-ray performance

- The following parameters should be measured once each year by an authorized technician to assure imaging performance:

1) Tube voltage: measurement point 70 kV / Tolerance ± 10 %

2) Tube current: measurement point 0.2 mA, 2 mA / Tolerance ± 20 %

3) Exposure time: measurement point 0.01s, 0.1s, 0.3s, 0.65s, 1.3s / Tolerance ± 5 % + 50 ms

4) Leakage radiation

15.12 Characteristics of the X-ray tube voltage waveform

- The rising phase: increase to 70 kV within 15 ms, and kept it before push the exposure button.

- The falling phase: decrease to 0 kV within 7.8 ms after pushing the exposure button.

- The shape and amplitude of the X-ray tube voltage ripple: ripple is less than ± 10 % while 70 kV is maintained.

16 Maintenance

16.1 Replacement of Rechargeable battery

Figure 10 - Back View

1. **Remove screws on battery cover (No.1 in above figure).**
2. **Remove battery cover**
3. **Take the battery out of the main body.**
4. **Disconnect the battery connector and change the new battery.**
5. **Replace battery cover**
6. **Replace screws**

- Use only specified battery provided by manufacturer.

- The replacement should be performed by authorized person only.

- The battery should be periodically checked or replaced.

16.2 Periodic inspection

We recommend this Quality Control Procedure be performed annually.

- Only qualified technicians can check this equipment.

- Check items according to the local, state, and federal regulations.

- Inspection period: 1 time per 1 year

- If the result does not satisfy criteria, contact the manufacturer.

Inspection item	Method	Criteria
Tube voltage	Place the voltage measuring device at (25 ± 2) cm away from the focus point, set the device to 70 kV, and measure the value of irradiating the X-ray.	Within 70 kV ± 10 %
Tube current and exposure time	Open the battery cover. Connect the oscilloscope to current measurement terminal. (Yellow: signal, Black: reference) Set the device to 2 mA, and measure the value of irradiating the X-ray.	Within 2 mA ± 20 % Within (0.01~1.3) s ± 5 % + 50 ms
Battery voltage	Open the battery cover. Connect the oscilloscope to battery terminal and measure the value of battery DC voltage.	More than 10 Vd.c.

16.3 Disposal of the device

The device shall be disposed of in accordance with the country's specified procedures. Or It must be returned to the manufacturer for disposal. Please contact to Service center of Remedi Co., Ltd.

16.4 Circuit Diagram

The circuit diagrams, component part lists, etc., required to repair the device can be provided upon request. Please contact the Service Center of Remedi Co., Ltd. at +82-2-6968-2041**.**

16.5 Assessment of Leakage of Stray Radiation to the Operator

- The leakage and stray radiation value to the operator is described in Procedure for measurement of radiation quantity.

- This value is expressed as the value of "Significant zone of occupancy" because this device is hand-held type equipment and the operator should stay near the patient during X-ray exposure.

17 Check before Asking for Repair Service

If any errors or problems occur, stop using the equipment and re-check the relevant information stated in the user guide prior to contacting service technicians.

Check the error message, serial number (Lot No.) and purchase date of the equipment and then contact the designated service center.

18 Specifications of REMEX T100

Rated power of AC/DC adapter	**- Input: 100-240 Vac, 50/60 Hz, 1.0 A** **- Output: 12.6 Vdc, 1.5 A**
Rated power of re-chargeable battery	**11.1 Vdc, 1500 mAh**
Power input	**160 VA (At charging mode)**
Tube voltage	**70 kV (Fixed)**
Tube current	**2 mA (Fixed)**
Exposure time range	**0.01 s ~ 1.3 s**
Focal spot size	**0.4 mm (complied with IEC 60336:1993)**
Inherent filtration	**Min. 1.0 mmAl / 0.8 mmAl**
Filament characteristic	**1.0 ~ 4.0 V, 2.2 ~ 3.0 A (max. filament current)** **2.0 ~ 3.5 V, 2.2 ~ 3.0 A (max. filament current)**
Anode angle	**12.5° / 12.0°**
Thermal Characteristics	**4.3 kJ / 7.0 kJ**
Maximum Anode Heat Dissipation Rate	**430 W / 560 W**
Protection against ingress of water or particulate matter	**IPX0**
Mode of operation	**Continuous operation** **(Re-charging time of high voltage tank is 10 s.)**
Expected service life	**5 years**

Essential performance	**Accuracy of loading factors** **Tube voltage accuracy: less than 10 %** **Tube current accuracy: less than 20 %** **Irradiation time accuracy: less than 5 % + 50 ms** **Tube current time accuracy: ± (10 % +0.2 mAs)** **Reproducibility of the radiation output: The coefficient of variation of measured values of air kerma: less than 0.05**

19 Safety Standards of REMEX T100

IEC 60601-1:2012 **EN 60601-1:2013**	**Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**
IEC 60601-1-2:2014 **EN 60601-1-2:2010**	**Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests**
IEC 60601-1-3:2013 **EN 60601-1-3:2010**	**Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment**
IEC 60601-1-6:2013 **EN 60601-1-6:2010**	**Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard : usability**
IEC 60601-2-65:2012	**Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment**
IEC 62304:2006 **EN 62304:2008**	**Medical device – Software life cycle**

IEC 62366:2008 **EN 62366:2008**	**Medical devices - Application of usability engineering to medical devices**
ISO 14971:2012	**Medical device – Applications of Risk Management to medical devices**

20 Limited Warranty Form

Product Name	**Portable X-ray System**
Model name	**REMEX T100**
Serial number	
Purchased date	
Name of hospital or clinic	
Address	
Phone	
Distributor	**Remedi Co., Ltd.** **2F, 69-14, Sakju-ro 145beon-gil,** **Chuncheon-si, Gangwon-do,** **Republic of Korea** **+82-2-6968-2041** **www.remedihc.com**

21 Operator Training Test

Name: _____

Date: _____

Results: **Passed** **Failed**

1) A parent must wear a lead apron if they stay in the room when x-rays are taken of their child.

- **a. Yes**
- **b. No**

2) How is the unit locked and secured when not in use?

- **a. Sitting on the counter in the exam room**
- **b. Placed in a storage cabinet away from exam rooms**
- **c. Locked in the case and place the keys in another location**

3) When do you remove the backscatter shield?

- **a. Anytime it gets in the way**
- **b. Never. It must stay affixed to the end of the cone for operator safety**

4) What position should the backscatter shield be to the operator?

- **a. Perpendicular**
- **b. Angled**
- **c. Parallel**

5) What is the meaning of ALARA?

- **a. As Low As Reasonably Achievable**
- **b. As Little As Randomly Achievable**
- **c. As Long As Rationally Alerted**

6) What type of disinfectant should you use to clean the device?

- **a. Dry wipes**
- **b. Xylene**
- **c. Rubbing alcohol**

7) The correct way to hold the device is by the cone.

   a. **True**

   b. **False**

8) How would you change the radiology settings from adult to child?

   a.
   - **Press the Up and Down arrow buttons simultaneously to enter patient type selection mode.**
   - **System displays "MODE"**
   - **Press the Up or Down buttons to change patient type.**
   - **System will display current patient type.**
   - **Press the Up and Down arrow buttons simultaneously to exit patient type selection mode, and return to time selection.**
   - **System displays "TIME"**

   b. **Press the up arrow button, the down arrow button, then press OK**

   c. **Press the up arrow button, then press OK**

9) How would you change the exposure time?

   a. **Press the Up or Down arrow keys**

   b. **Choose another tooth type**

   c. **All of the above**

10) What is displayed after a full exposure?

   a. **" REMEX T100"**

   b. **"READY > Φ"**

11) **How do you resolve error codes?**

   a. **Ask another technician for advice**

   b. **Refer to the section Troubleshooting Error Messages in the User Manual**

12) **What color is the LED during exposure?**

   a. **Green**

   b. **Red**

   c. **Purple**

13) **Required exposure times typically differ from film to sensor.**

   a. **True**

   b. **False**

14) REMEX T100 should be inspected at least once per year by a qualified technician.

a. True

b. False

15) What is the source to skin distance in accordance with FDA regulations?

a. A limit SSD to not less than 18 centimeters

b. A limit SSD to not less than 20 centimeters

16) The pistol grip is an accessory that is approved in my state for use.

a. True

b. False

17) This device is FDA approved and therefore we can ignore our state requirements.

a. True

b. False

18) Does your state department have any restrictions for a handheld x-ray device?

a. Yes

b. No

19) How do you register the REMEX T100 with the state department?

a. Call the state department and let them know you have the REMEX T100.

b. Send a letter to the state health department on our letterhead and state that you have the REMEX T100.

c. Fill out an application from your state health department and send it in to them.

20) If your state department has restrictions for REMEX T100, please list the restrictions.

NOTE: Answers to Questions 16-20 will vary from state to state. The purchaser should go over their specific state requirements with their staff/employees.

22 Operator Training Test Answers

1. **A**
2. **C**
3. **B**
4. **C**
5. **A**
6. **A**
7. **B**
8. **A**
9. **C**
10. **B**
11. **B**
12. **B**
13. **A**
14. **A**
15. **A**
16. **A or B – depends on each state's regulation**
17. **B**
18. **A or B – depends on each state's regulation**
19. **C**
20. **List the information.**

23 INDEX