REMEDI

User Manual

REMEX-T(K)100

Portable X-ray Equipment

Document Version 08

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■ EN □ ES □ CS □ DA □ DE □ ET □ EL □ CZ □ RO □ MT □ RO □ PT

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.

CE 0068

Table of Content

1. About User Manual

This User Manual is provided to the user along with the REMEX-T(K)100.

This User Manual only pertains to the REMEX-T(K)100 and does not serve for any other products of the company. In the event of loss of or damage to this User Manual, please contact to service center of REMEDI Co., Ltd.

This User Manual describes the precautions and possible risks that the user should be aware of and give attention to prior to use the REMEX-T(K)100. Please read carefully all the precautions before you start using the device.

Please refer to the Table of Contents to easily find the information that you need.

If you have any inquiries or need detailed information on the product, please refer to the contact information or call our customer service center.

1.1 Cautions

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Under copyright law, this document cannot be reproduced, modified or otherwise amended without prior approval.

1.2 Quality Assurance

The contents of this document may be revised without notification.
The company will not be responsible for any consequential problems, loss or damage arising from the use of any performance specification or information that differs from the information contained in this User Manual.

1.3 Revision History

The part numbers and revision number indicated in this document represent the current version.
The revision number will not be changed even if any sub-documents are revised.
The revision number may be changed when there is a major change in part numbers or technical information in the document.

1.4 Symbols

Symbols are indicated on the exterior, packaging of the product and in this User Manual.
The symbols represent important cautions and advice to the user. Please read the following symbols carefully and be well informed of them for the use and storage of the product.

⚠	WARNING	This symbol represents “WARNING.” It is associated with possible matters that may harm or cause irreversible damage to the product or the patient.
⚠	CAUTION	This symbol represents “CAUTION.” It is associated with possible matters that may damage the product or harm the patient.

* This User Manual may differ from the actual product in terms of functionality.
* If deemed necessary, the company may make any improvement to the product to enhance its performance, without prior notification, and the company has no obligation to apply the same specification change to the products already sold.

2. Precautions

2.1 General Cautions

CAUTIONS	
1.	This product is intended for use by a dentist or dental technician having received appropriate license.
2.	Please read and understand the instructions carefully and then use your device.
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, REMEDI Co., Ltd. will not be responsible for the safe operation of the REMEX-T(K)100.

2.2 General Prohibitions

PROHIBITIONS	
1.	Do not use with unauthorized AC/DC adapter.
2.	Do not use it out of intended use. (For dental use only)
3.	Do not use without mounting the cone.
4.	Do not disassemble the unit.
5.	Do not use the device outside of the significant zone of occupancy.

2.3 General warnings

WARNINGS	
1.	Electrical circuits inside the equipment use voltages which are capable of causing serious injury or death from electric shock. To avoid this hazard, operators should never remove any of the cabinet covers.
2.	This system is not waterproof. Water, soap, or other liquids, if allowed to drip into the equipment, can cause electrical short circuits leading to electric shock and fire hazards. If liquids should accidentally spill into the system electronics, do not connect the power cord to a supply connection or turn the system on until the liquids have dried or evaporated completely.
3.	This x-ray unit may be dangerous to patient and operator unless safe exposure values are used and correct operating procedures are observed.

⚠ WARNINGS	
4.	The other equipment may malfunction due to the electromagnetic waves generated by this device. This device may malfunction due to electromagnetic interference generated by other equipment. Do not use it adjacent to other equipment or load other equipment do.
5.	Only use the AC/DC adapter supplied by the manufacturer to charge. There is a risk of fire or explosion if unspecified AC/DC adapters are used. If LED light on the adaptor changes to green from red, the charge is complete. Disconnect the adapter from the device after the charge is complete. Do not charge after the charge is complete. It may cause fire or explosion.
6.	Do not connect the power cord to supply mains with wet hands.
7.	Do not use this device if the cone(Beam limiting device) is broken or damaged. Using damaged or damaged cones may be exposed to unwanted X-radiation.
8.	Always use the cone(Beam limiting device) when using the device. If used without a cone, it may be exposed to unwanted X-radiation.
9.	This device must be used by the intended user. Patients and users may be at risk from a variety of hazards when using the device by someone other than the intended user.
10.	If intentionally ignore the cautions, warnings, and safety signs specified in this manual, patient and user may be at risk from various hazards..
11.	To prevent the device from falling down, it is necessary to hold the unit with both hands and to use the wrist strap together. Using a damaged device due to falling may expose the patient or user to unwanted X-radiation.

3. Appearance and Specifications

3.1 Intended Use

REMEX-T(K)100 Portable X-ray Equipment 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 image receptors. Its use is intended for adult and child.

The owner/operator is responsible for verifying continued compliance exposure rates, leakage radiation, alignment of the useful beam, and the calibration of kVp and mAs. Annual verification by a qualified service technician may be required by federal law. Compliance with applicable statutory and regulatory requirements is the responsibility of the owner/operator. Consult local, state, and/or federal agencies regarding specific requirements and regulations applicable to the use of this type of medical electronic equipment.

Ensure the adaptor is unplugged before attempting to clean. To make sure that power is off for REMEX-T(K)100 while cleaning. Use a non-alcohol based disinfectant only - wipes or a cloth dampened with liquid or spray. REMEX-T(K)100 and the accompanying adaptor are not designed to be subjected to any kind of sterilization procedure. REMEX-T(K)100 is not designed to be used to sterilize anything else.

3.2 Specification

Classification	Class IIb (Annex IX, Rule 10, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)
Model	REMEX-T100, REMEX-K100 (Model name is different according to the X-ray tube.)
Protection type from electrical shock	- Class Ⅱ equipment (Charging mode) - Internal power source equipment (Exposure mode) - B type Applied part
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
Representative configurations for test	□ Charging mode - Charge with the battery fully discharged □ Exposure mode - Tube voltage: 70 kV - Tube current: 2 mA - Exposure time: 1.3 s
Deosimetric indications	See table below

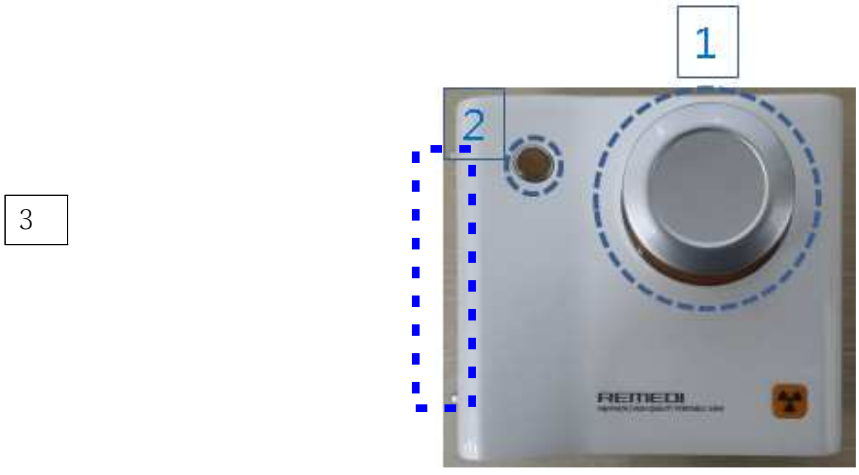
Tube Voltage	Tube current	Exposure time	Air Kerma (± 20%)
70 kV	2mA	0.01s	0.000134mGy
		1.30s	0.016920mGy

3.3 Safety Standards

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

3.4 Appearance

3.4.1 Front view of Main body

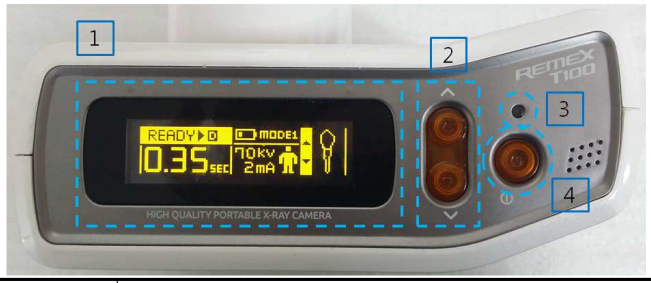


No.	Name	Description
1	Beam limiting device	When irradiating X-rays, limit the irradiation range of the beam.
2	X-ray exposure button	Press this button to exposure the X-ray.
3	Eyelet for strap	Eyelet for strap

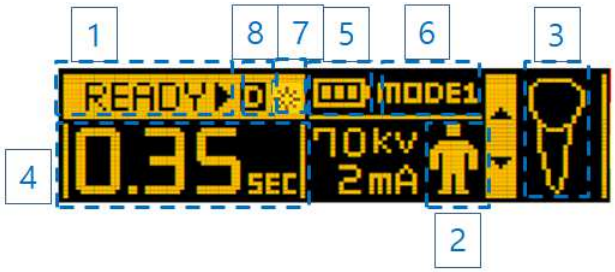
3.4.2 Rear view of Main body

No.	Name	Description
1	Battery cover	Remove this cover to replace a rechargeable battery.
2	Charging port	Connector for charging

3.4.3 Top view of Main body



No.	Name	Description
1	LCD display window	Display the exposure conditions (kV, mA, exposure time, Mode, battery status).
2	Mode control button	Set the X-ray exposure mode.
3	Exposure status LED	When the X-ray is irradiated, the yellow LED is turned on.
4	Power button	Turn ON/OFF



No.	Name	Description
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)

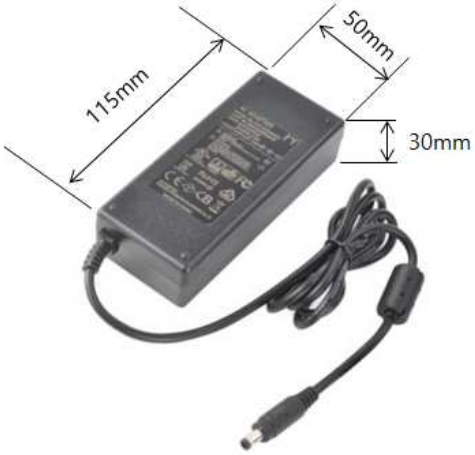
3.5 Dimension

3.5.1 Main body

- size: 165(Length) × 155(Height) × 60(Width) mm^3
- weight: 1.9 kg (including cone 190 g)

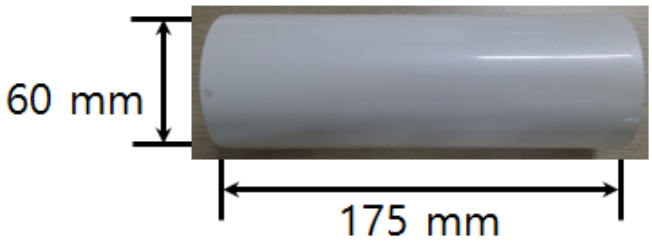
3.5.2 AC/DC adapter and power cord (Accessory)

- size: 115(Length) × 30(Height) × 50(Width) mm^3
- weight: 280 g



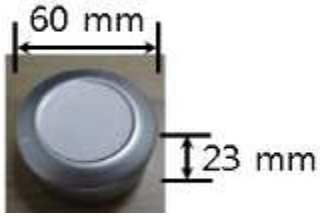
3.5.3 Cone (Accessory)

- size: 175(Length) × 60(Diameter) mm^2
- weight: 190 g



3.5.4 X-ray exposure cover (Accessory)

- size: 23(Length) mm × 60(Diameter) mm
- weight: 20 g



3.6 Hand strap

- size: 130(Length) mm × 43(Width) mm, strap length 333 mm
- weight: 20 g

3.7 Operating condition

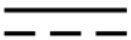
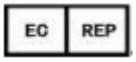
- Temperature: 15 ℃ ~ 40 ℃
- Related Humidity: 5 %R.H. ~ 85 %R.H. (Non-condensing)
- Atmospheric pressure: 76 kPa ~ 106 kPa
- Altitude: Less than 2,000 m

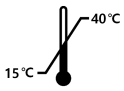
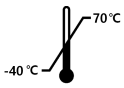
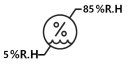
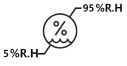
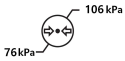
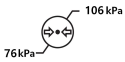
3.8 Storage and transportation condition

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

3.9 Symbols

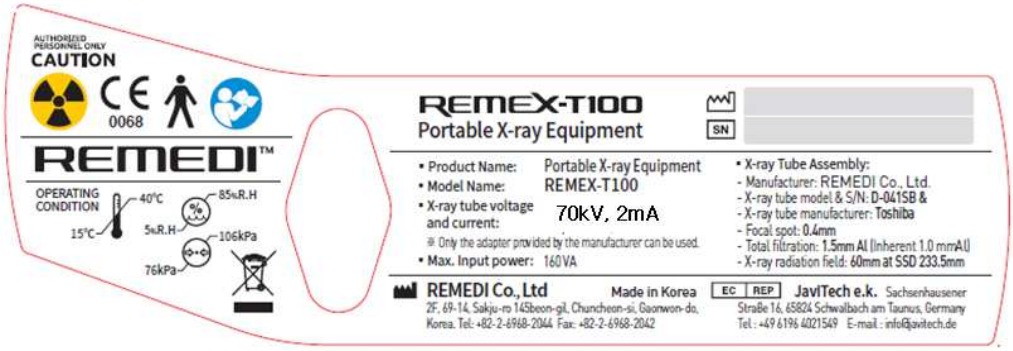
The following are descriptions of the symbols located on the outside and packaging of the product. Please read carefully before using the product.

No	Symbol	Description	Location
1		batch code	Product Label
2		Date of manufacture	Product Label
3		TYPE B applied part	Product Label Cone connector
4		Follow instructions for use	Product Label
5		Note	User manual
6		General Caution, Warning (safety sign)	User manual
7		Warning: Electrical	Inside of equipment
8		General Prohibition (safety sign)	User manual
9		Alternating current	Product Label
10		Direct current	Product Label
11		Keep dry	Package
12		Keep away from sunlight	Package
13		EC representative	Package Product Label

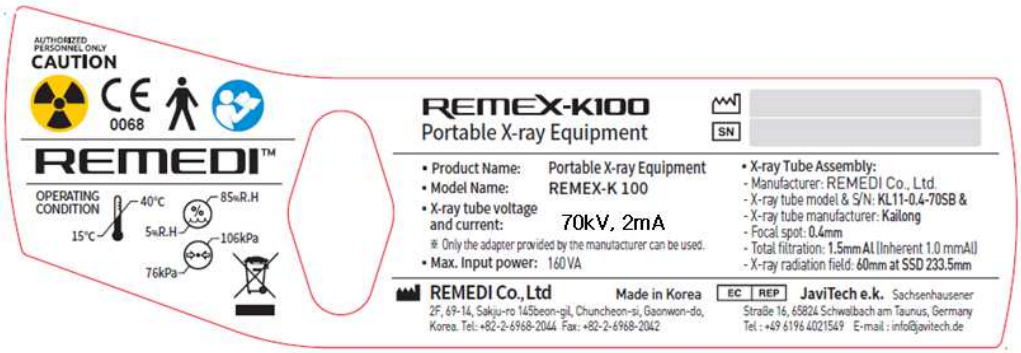
14		Manufacturer	Package Product Label
15		Operating temperature range	Product Label
16		Storage temperature range	Package
17		Operating humidity range	Product Label
18		Storage humidity range	Package
19		Operating Atmospheric pressure range	Product Label
20		Storage Atmospheric pressure range	Package
21		CE marking, Complies with european medical devices directive	Package Product Label
22		WEEE Mark	Package Product Label
23		Warning: Hight voltage	Inside the device
24		Radiation hazard	Product Label Product enclosure

3.10 Labels of Main body

Label location: on the Bottom of equipment / REMEX-T100

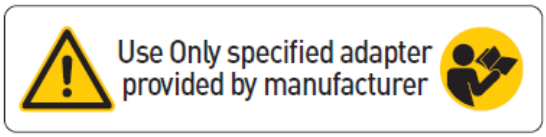


Label location: on the Bottom of equipment / REMEX-K100



3.11 Label of AC/DC adapter connector

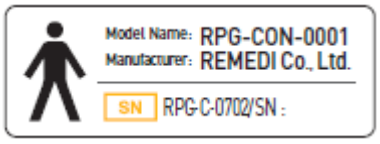
Label location: Near the AC/DC adaptor connector



3.12 Label of Cone

Label location(Applied part): near the connector of the cone

Label location(Applied part): On the cone



3.13 Label of Radiation hazard (Physiological effects)

Label location: On the bottom right of front of the device

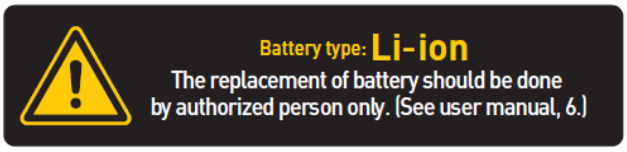
3.14 Label of AC/DC adapter

Label location: On the adapter

AC/DC ADAPTER
Model: YHY-12601500
Input rate: 100-240VAC 50/60Hz 1.0A
Output rate: 12.6V⎓ 1500mA
Manufacturer: SHENZHEN YINGHUI YUAN ELECTRONICS CO., LTD
Made in china

3.15 Label of re-chargeable battery

Label location: On the battery pack



3.16 Label of protective cover

Label location: On the cover

3.17 High voltage tank

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

4. How to use (Start-up and Shutdown procedure)

4.1 Frequently used functions

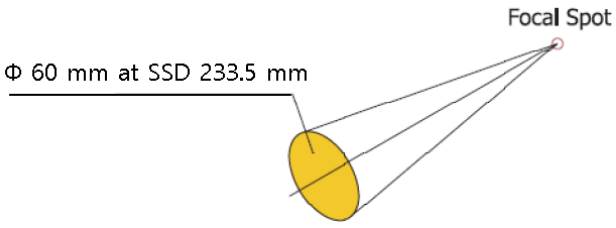
- Connecting “Charging cable”
- Checking “Charging condition”
- Mounting “Cone”
- Pushing “ON/OFF button”
- Setting “Exposure time”
- Setting “Mode”
- Checking “Display LCD”
- Pushing “X-ray exposure button”

4.2 Pre-procedure

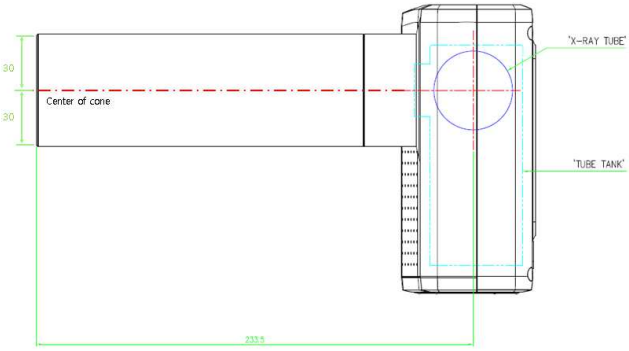
1. The operator of REMEX-T(K)100 must be a dentist or dental technician having received appropriate license.
2. Understand warnings, cautions and user manual.
3. Check the Charging condition of battery before use. If the battery is not charged enough, charge the battery using AC/DC adapter. (While charging mode, REMEX-T(K)100 could not be used.)

> - Only the adapter provided by the manufacturer can be used.
> - The plug of adapter is used as the isolation means. Do not position the device so that it is difficult to operate the disconnection device.

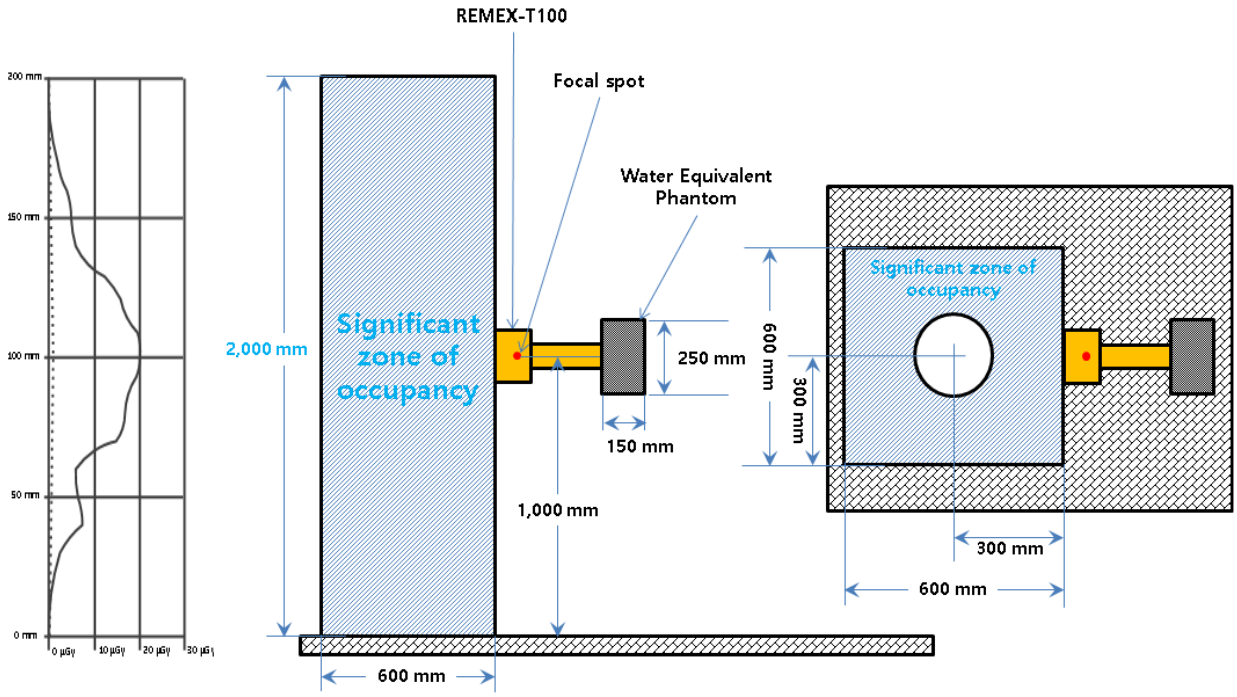
4. Please establish significant zone of occupancy as following and puts individual defense tool such as apron(protective device provided by manufacturer is beam limiting device(cone)) in this area and face in radiography.



[Radiation filed Area]



[Geometric position of focal spot]



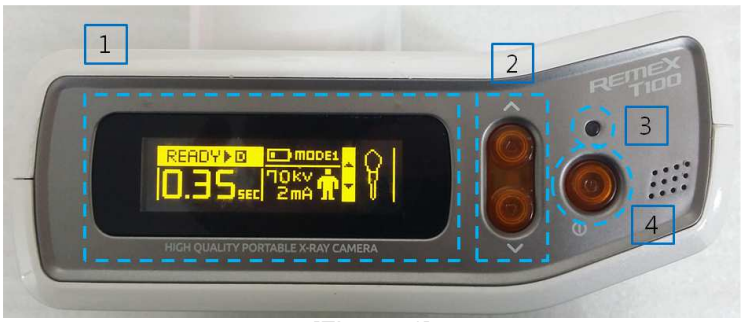
〔Dose〕 [Significant zone of occupancy]

- The case thickness of water equivalent phantom is less than 10 mm, the material of it is PMMA. The size of it is 250 × 250 × 150 mm^3.
- In this area, the all performance of REMEX-T(K)100 can be used.
- Operator Dose rate in center of the significant zone of occupancy: 20 μGy

4.3 Operation procedure

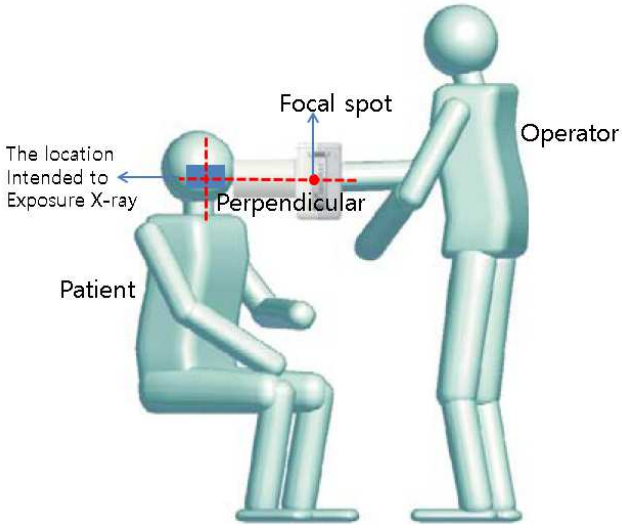
> ⚠ Always use the device with the cone(Beam limiting device) attached. The cone should be turned clockwise and tightened until there is no gap between the cone and the device.

1. Turn on the REMEX-T(K) 100 by pressing the “On Button” (Figure 1 button number 4) for 2 seconds. To turn off, press again the “On Button” for 2 seconds.
2. The mode setting can be set by pressing the Up and Down buttons (∧, ∨) together simultaneously. When Turned on, the mode will be set to previously used mode. By pressing Up and Down buttons simultaneously, the mode can be changed in the order of Adult Mode ▶ Child Mode ▶ Time Mode ▶ Adult Mode(Figure 1)



[Figure 1]

3. For Adult Mode (Mode 1.), Adult image will be displayed
   For Child Mode (Mode 2.), Child image will be displayed
   For Time Mode, “TIME” will be displayed.
4. In the adult mode (MODE1) and the child mode (MODE2), you can select three Maxillary and three Mandible by pressing the Up and Down buttons(∧, ∨)
5. To adjust the irradiation time in Adult Mode and Child Mode (Mode 1 & Mode 2), press down the Up and Down buttons(∧, ∨) for more than half a second and the irradiation time can be controlled by 0.01 seconds.
6. To adjust the irradiation time, first set the mode to “Time Mode” and control the irradiation time by using the Up and Down buttons(∧, ∨)
7. D/F Settings can only be set by manufacturer or seller. (Users are prohibited from setting)
8. Set the location intended to exposure X-ray. The X-ray beam dimension is Φ60(fixed), and the focal spot is aligned in the center of this beam area. The plane of the intended location should be perpendicular to the cone. And the image receptor is positioned in the patient’s mouth(blue rectangle area of [Figure 2].). See the below [Figure 2].



[Figure 2]

9. When all settings are completed, press the “Exposure” button (No.2 Button in [Figure 3]) for few seconds (about 2 seconds). While the X-ray is irradiated, the red LED lamp (No.3 LED in [Figure 1]) is turned on and is displayed on the LCD (as shown in the Figure).
10. If you press the “Exposure” button shorter than the set time, the message “WARNING: Early X-ray Button OFF“ appears. See the below [Figure 4].

[Figure 4]

If the image is not satisfactory because the dose of X-Ray is excessive or deficient, adjust the exposure time pushing the key right side of main display.

Blurring of the X-ray image may occur due to movement of the patient or operator. To reduce the image degradation, minimize the movement of patient and operator when X-ray is irradiated. (The Max. exposure time is just 1.3 s, care should be taken not to move the patient for a while, and the operator should be careful not to move.)

[Figure 3]

4.4 Storage and Cleaning after use

1. Press “ON/OFF button”(No.4 button in [Figure 1]) to Turn off REMEX-T(K)100.
2. Check the Charging condition of battery after use. If the battery is not charged enough, charge the battery using the specific AC/DC adapter.

- When you use ordinary adapter, the battery can be damaged. Only the adapter provided by the manufacturer should be used.
- Disconnect the adapter cable from the device connector after charging fully.

3. Clean the exterior of REMEX-T(K)100 using dry cloth.

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

4. Store the device in a designated safe place. Do not store in the places mentioned below.

- Where water comes in contact
- Where there is a risk of warping, vibration, or shock
- Where chemicals or gases are generated
- Outside the specified storage environment

4.5 Procedure allowing measurement of the radiation quantity

- Refer to the figure [Significant zone of occupancy]
- Place the dosimeter(μGy) on the surface of the center of the one side of the water equivalent phantom(The phantom should be filled with pure water free of bubbles.).
- Place the REMEX-T(K)100 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-T(K)100.
- Setting of REMEX-T(K)100: exposure time 1.3 s
- Press the exposure button and measure the dose rate of the dosimeter.
- This measured RADIATION QUANTITY is reduced by low setting of exposure time and increment of SSD. And it can reduce the patient exposure dose.

4.6 Error message

- Please refer to the error message described below to keep the unit usable.
- If the unit does not operate without displaying an error message, contact the manufacturer or a designated service provider.

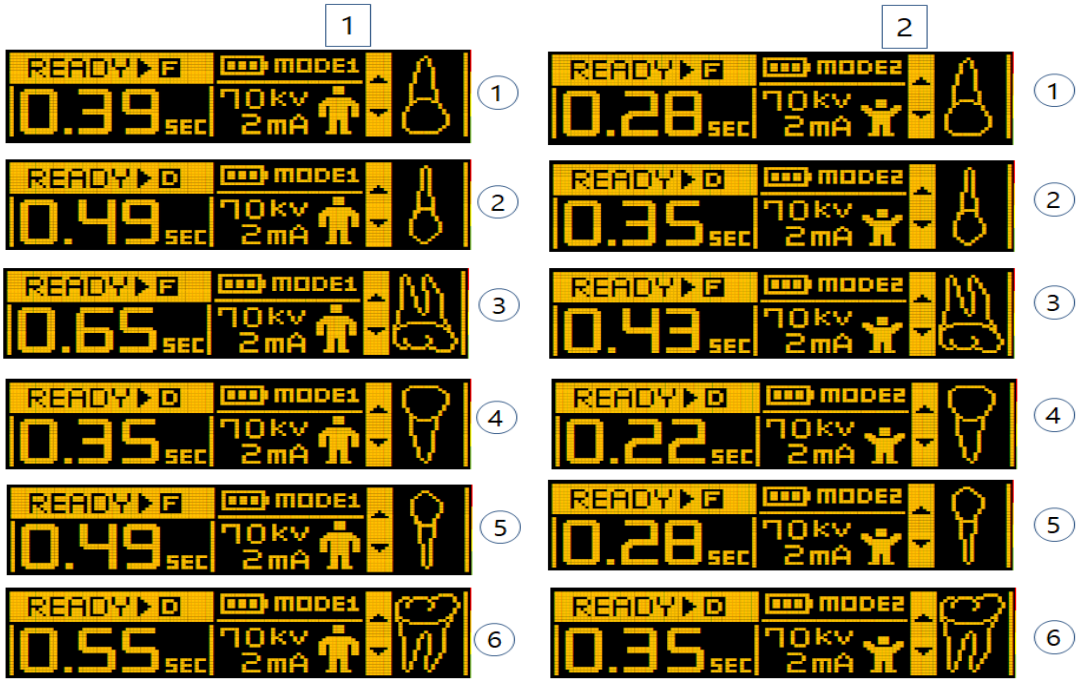
Error code	Name	Detail	Description
ERROR 1	Temperature error	When tube tank temperature reach to the limit.	The device turned off after display “Error 1” on the LCD with the single buzzer sounds.
ERROR 2	Voltage error	When voltage reach to the limit.	The device turned off after display “Error 2” on the LCD with the double buzzer sounds.
ERROR 3	Simultaneous error (Error 1 + Error 2)	When Error 1 and Error 2 occurs at once.	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.

4.7 Exposure time setting

The exposure time table below is only for the reference. If the X-ray image is vague or dark, adjust exposure time.
When using the device in pregnant women and children, you should consult a doctor

Type of receptor	Exposure part		Recommended exposure time
Analog film	Upper	Incisor	0.7 sec ~ 0.8 sec
		Canine	0.9 sec ~ 1.0 sec
		Molar	1.1 sec ~ 1.2 sec
	Lower	Incisor	0.5 sec ~ 0.6 sec
		Canine	0.6 sec ~ 0.7 sec
		Molar	0.7 sec ~ 0.8 sec
Digital sensor	Upper	Incisor	0.31 sec ~ 0.47 sec
		Canine	0.39 sec ~ 0.59 sec
		Molar	0.52 sec ~ 0.78 sec
	Lower	Incisor	0.28 sec ~ 0.42 sec
		Canine	0.39 sec ~ 0.59 sec
		Molar	0.44 sec ~ 0.66 sec

4.8 Mode select



No.	Name	Description
1 - Adult mode	① Maxillary incisor	Set up exposure time: 0.39 s
	② Maxillary canine	Set up exposure time: 0.49 s
	③ Maxillary molars	Set up exposure time: 0.65 s
	④ Mandibular incisors	Set up exposure time: 0.35 s
	⑤ Mandible canine	Set up exposure time: 0.49 s
	⑥ Mandibular molar	Set up exposure time: 0.55 s
2 - Child mode	① Maxillary incisor	Set up exposure time: 0.28 s
	② Maxillary canine	Set up exposure time: 0.35 s
	③ Maxillary molars	Set up exposure time: 0.43 s
	④ Mandibular incisors	Set up exposure time: 0.22 s
	⑤ Mandible canine	Set up exposure time: 0.28 s
	⑥ Mandibular molar	Set up exposure time: 0.35 s

5. Technical Data

5.1 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 IIb
- 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

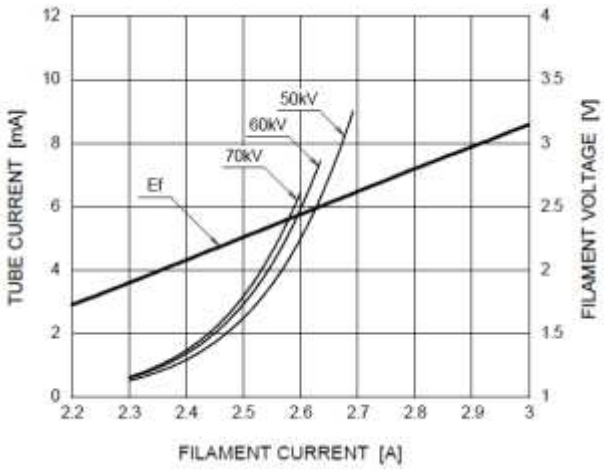
5.2 X-ray exposure control

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

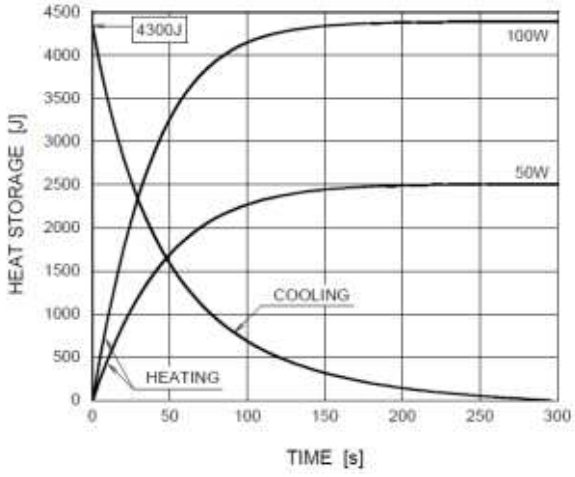
5.3 X-ray tube assembly

1) Toshiba X-ray tube for REMEX-T100

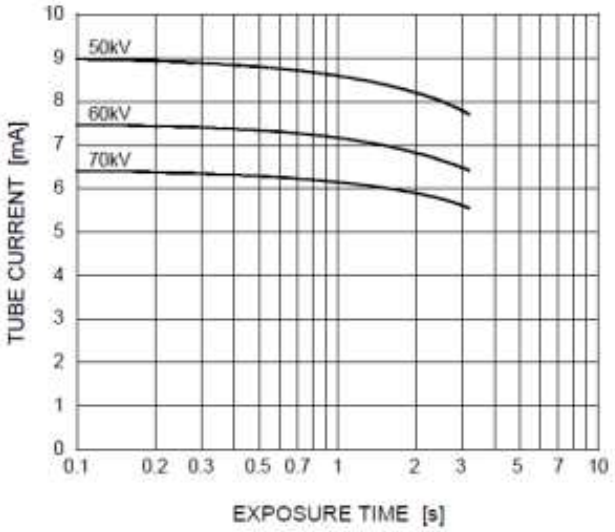
- Tube voltage range: 70 kV fixed
- Tube current range: Max. 9 mA
- Focal spot size: 0.4 mm
- Inherent filtration: Min. 1.0 mmAl
- Type: stationary
- Anode angle: 12.5°
- Anode material: Tungsten
- Filament characteristic: 1.0 ~ 4.0 V, 2.2 ~ 3.0 A (max. filament current)
- Anode heat storage capacity: 4.3 kJ
- Maximum Anode Heat Dissipation Rate: 430 W
- X-ray tube Characteristic curve



Emission & Filament characteristics



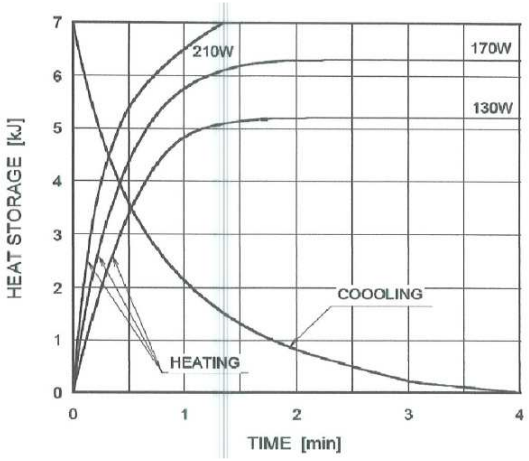
Anode Thermal characteristics



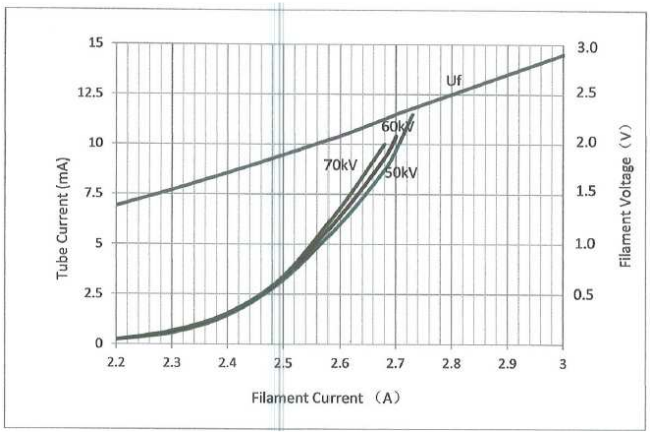
Max. rating charts (Absolute Max. rating charts)

2) Kailong X-ray tube for REMEX-K100

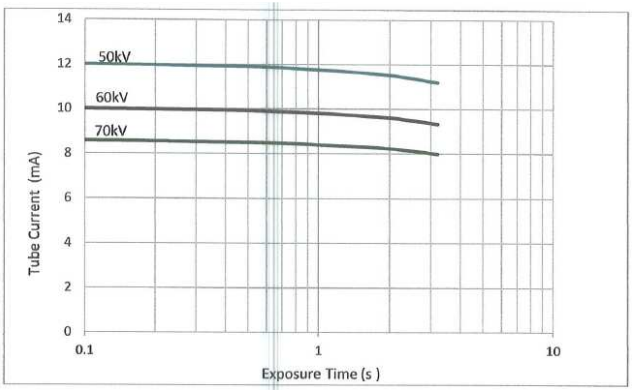
- Tube voltage range: 70 kV fixed
- Tube current range: Max. 9 mA
- Focal spot size: 0.4 mm
- Inherent filtration: Min. 0.8 mmAl
- Type: stationary
- Anode angle: 12.0°
- Anode material: Tungsten
- Filament characteristic: 2.0 ~ 3.5 V, 2.2 ~ 3.0 A (max. filament current)
- Anode heat storage capacity: 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)

5.4 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

5.5 Beam limiting device (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.

5.6 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

5.7 AC/DC adapter (This power supply is specified as a part of ME equipment.)

- Model name: YHY-12601500
- Manufacturer: SHENZHEN YINGHUI YUAN ELECTRONICS CO.,LTD
- Rated input: 100-240 Va.c., 50/60 Hz, 1.0 A
- Rated output: 12.6 Vd.c., 1.5 A

5.8 Software for REMEX-T(K)100

- Type: Built-in
- S/W name: RPG-F-0702
- S/W version: 2.02

5.9 Extra accessory

- X-ray exposure cover
- AC power cord

5.10 Minimum requirement for digital X-ray image receptor

- Min. resolution: more than 1000
- Min. size: more than 40 mm × 40 mm
- Max. pixel pitch: less than 40 μm

5.11 Protection against Residual Radiation

- To avoid residual radiation caused by using of REMEX-T(K)100, the operator should stay in the Significant zone of occupancy described in section 4.3 of this user manual and the alinement between the patient and REMEX-T(K)100 should be kept like [Figure 2].

5.12 Metrics about imaging performance

- To keep the imaging performance, The following parameters should be measured once for every year and performed by an authorized person or manufacturer.
  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 0.01 s, 0.1 s, 0.3 s, 0.65 s, 1.3 s / Tolerance ± 5 % + 50 ms
  4) Leakage radiation

5.13 Characteristics of the X-ray tube voltage waveform

- The rising phase: rise up to 70 kV within 15 ms, and kept it before push the exposure button.
- The falling phase: fall down to 0 kV within 7.8 ms after push the exposure button.
- The shape and amplitude of the X-ray tube voltage ripple: ripple is less than ± 10 % while 70 kV is maintained.

6. Maintenance

6.1 Replacement of Rechargeable battery

[Figure 4]

- Unfasten bolts(bolts of No.1 area in [Figure 4]) from the battery cover.
- Take out the battery from the main body.
- Disconnect the battery connector and change the new battery.

- Use only specified battery provided by manufacturer.
- The replacement should be performed by authorized person only.
- The battery should be performed periodic checking or replaced.

6.2 Periodic inspection (Quality Control Procedure)

We recommend to check this equipment annually.

- Only qualified people can check this equipment.
- Check items according to the Regulations of the country.

- Inspection period: 1 time / 1 year
- If the result is not satisfied the criteria, please contact to 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.

6.3 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.

6.4 Circuit diagram, component part list, etc to repair certain parts of the device

The circuit diagrams, component part lists, etc required to repair the device could be provided upon request. Please contact to Service center of REMEDI Co., Ltd.

6.5 Assessment of the leakage and stray radiation to the operator

- The leakage and stray radiation value to the operator is described in section 4.2.
- 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 while X-ray exposure.

7. Statements and tables for EMC

Table 1 - ELECTROMAGNETIC EMISSIONS – for REMEX-T(K)100

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">REMEX-T(K)100 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-T(K)100 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The REMEX-T(K)100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The REMEX-T(K)100 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the REMEX-T(K)100 or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 2 – electromagnetic IMMUNITY – for REMEX-T(K)100

Guidance and manufacturer's declaration – electromagnetic immunity			
The REMEX-T(K)100 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-T(K)100 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the REMEX-T(K)100 requires continued operation during power mains interruptions, it is recommended that the REMEX-T(K)100 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3 electromagnetic IMMUNITY – for REMEX-T(K)100 that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The REMEX-T(K)100 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-T(K)100 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 80 MHz to 800 MHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the REMEX-T(K)100 is used exceeds the applicable RF compliance level above, the REMEX-T(K)100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the REMEX-T(K)100. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the REMEX-T(K)100			
The REMEX-T(K)100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REMEX-T(K)100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REMEX-T(K)100 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $\sqrt{P}$ d = 1.17	80 MHz to 800 MHz $\sqrt{P}$ d = 1.17	800 MHz to 2,5 GHz $\sqrt{P}$ d = 2.33
0.01	0.117	0.117	0.233
0.1	0.370	0.370	0.736
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8. Product Warranty Policy

- This product is guaranteed for two years from the date of purchase.
- We will repair the product free of charge during the warranty period.
- Damage caused by the customer's negligence, even during the warranty period, does not apply to free repair.
- The product is manufactured under REMEDI Co., Ltd. thorough quality management, inspection and manufacture.
- Compensation criteria regarding product repairs and exchanges correspond to the Economic Planning Board's "Consumer Injury Compensation Rule."
- REMEDI Co., Ltd. warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness.
- Handling, storage and cleaning of this product as well as factors relating to the patient, diagnosis and other matters beyond REMEDI Co., Ltd.'s control directly affect the product and the results obtained from its use.
- REMEDI Co., Ltd.'s obligation under this warranty is limited to the repair or replacement of this product and REMEDI Co., Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product.
- REMEDI Co., Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product. REMEDI Co., Ltd. assumes no liability with respect to products reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for intended use, with respect to such product.

Contact Us: You can reach us through the following contact points to get detailed information on our services and products.

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Tel: +49 6196 4021549, Email: info@javitech.de

REMEDI Co., Ltd. homepage is available to you and provides a page where you can let us know if you have any complaints. If you have experienced any inconveniences during the use of our product or have any suggestions for improvement, except for product defects, please feel free to contact us and help us incorporate your ideas.