REMEX-T100
REMEX-K100

User Manual

REMEDI Co.,Ltd.

Portable X-ray Equipment EN

REMEDI

CE
0068

▪ 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.

▪ #24232, 2F, 69-14, Sakju-ro 145beon-gil, Chuncheon-si, Gangwon-do, Korea
▪ **Tel**: +82-2-6968-2044
▪ **Fax**: +82-2-6968-2042

REMEDI Co.,Ltd.

Table of
CONTENT

1.0

• 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

- This document contains proprietary information that is protected by copyright.
- 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.

CE
0068

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 "**WARNING.**" It is associated with possible matters that may harm or cause irreversible damage to the product or 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.

2.1 • General Cautions

CAUTIONS

01	• This product is intended for use by a dentist or dental technician having received appropriate license.
02	• Please read and understand the instructions carefully and then use your device.
03	• 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

01	• Do not use with unauthorized AC/DC adapter.
02	• Do not use it out of intended use. (For dental use only)
03	• Do not use without mounting the cone.
04	• Do not disassemble the unit.
05	• Do not use the device outside of the significant zone of occupancy.

CE 0068

2.3 • General Warnings

WARNINGS

01	• 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.
02	• 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.
03	• This x-ray unit may be dangerous to patient and operator unless safe exposure values are used and correct operating procedures are observed.
04	• 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.
05	• 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.
06	• Do not connect the power cord to supply mains with wet hands.
07	• 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.
08	• Always use the cone(Beam limiting device) when using the device. If used without a cone, it may be exposed to unwanted X-radiation.

NEXT ▶

2.0

• Precautions

WARNINGS ⚠

09	• 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.

3.0

• 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.

CE 0068

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** [Exposure mode] • **Internal power source equipment** [Charging 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]

NEXT ▶

• Specification

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

CE 0068

3.3

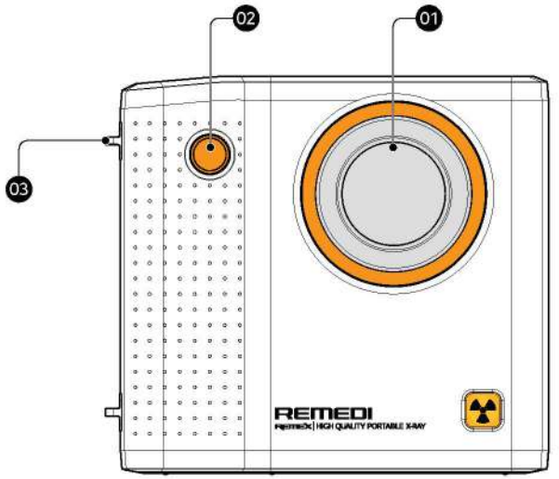
• Safety Standards

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



FRONT

01 **Beam limiting device**
When irradiating X-rays, limit the irradiation range of the beam.

02 **X-ray exposure button**
Press this button to exposure the X-ray.

03 **Eyelet for Strap**

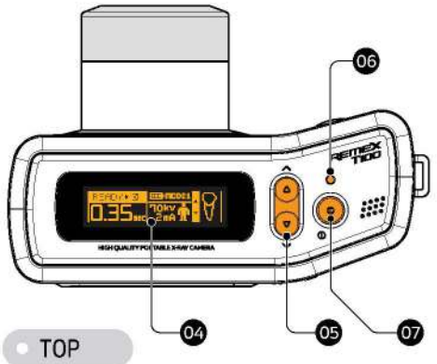
✱ Example

NO Name
Description

CE 0068

3.4

3.4.2 Top view of Main body



TOP

04 **LCD display window**
Display the exposure conditions (kV, mA, exposure time, Mode, battery status).

05 **Mode control button**
Set the X-ray exposure mode.

06 **Exposure status LED**
When the X-ray is irradiated, the yellow LED is turned on.

07 **Power button**
Turn ON/OFF

3.4

3.4.3 Rear view of Main body

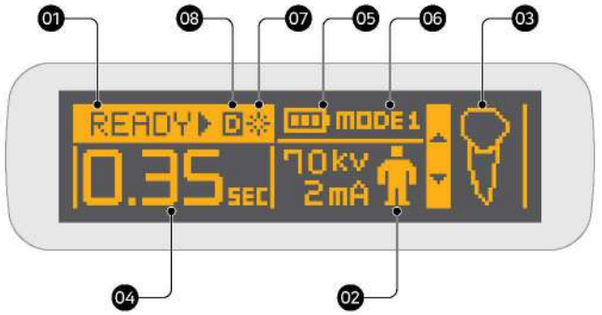
REAR

08 **Battery cover**
Remove this cover to replace a rechargeable battery.

09 **Charging port**
Connector for charging

3.4

3.4.4 LCD display Window



01 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.

02 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

WARNINGS	Cone should not be placed in a direction other than face. Especially when the patient is child, the exposur e time should be selected carefully.
NOTE	The exposure time set in each mode is recommended by the manufacturer, and the time can be adjusted in each mode.

CE 0068

3.4

03 Tooth selection

- Selecting three maxillary **[front teeth] [canines] [molar teeth]**and three mandibles **[front teeth] [canines] [molar teeth].**

04 Exposure time select

- Set the exposure time.

05 Battery condition

- Displays the remaining battery level.

06 Time/Mode exchange

- Display [TIME] or [MODE].

07

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)

08 D/F select

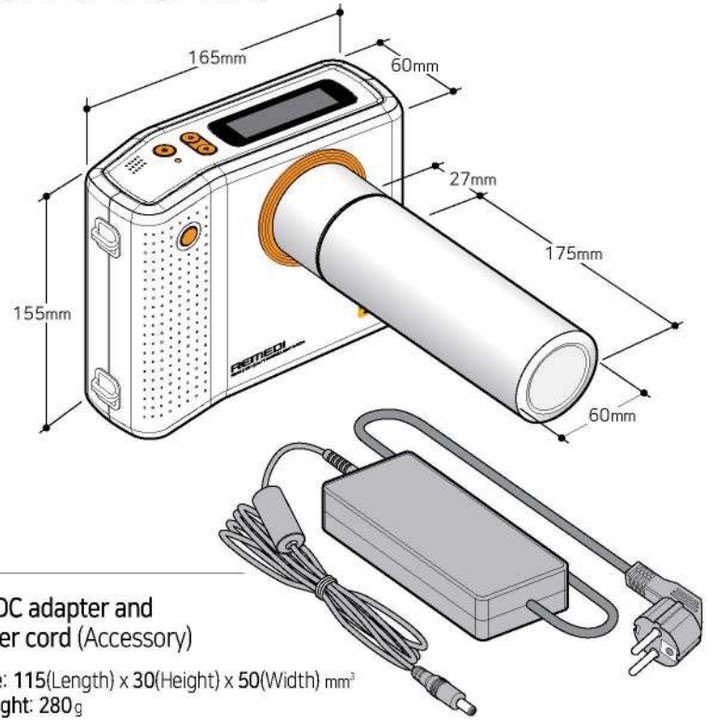
- Choice of tooth image acquisition device [D Digital image] [F Film image]

3.5

• Dimension

3.5.1 Main body

- Size: 165(Length) x155(Height) x 60(Width) mm³
- Weight: 1.9 kg (including cone 190 g)



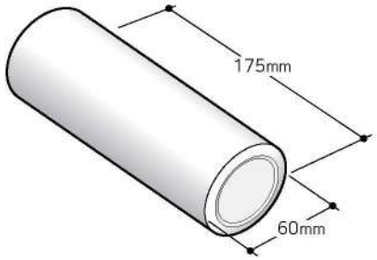
3.5.2 AC/DC adapter and power cord (Accessory)

- Size: 115(Length) x 30(Height) x 50(Width) mm³
- Weight: 280 g

CE 0068

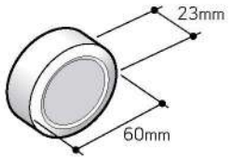
3.5.3 Cone (Accessory)

- Size: 175(Length) x 60(Diameter)mm³
- Weight: 190g



3.5.4 X-ray exposure cover (Accessory)

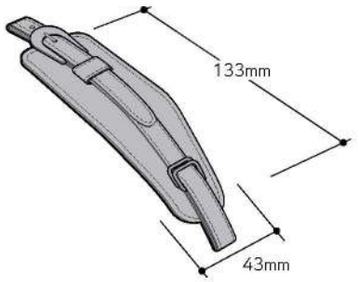
- Size: 23(Length) x 60(Diameter)mm³
- Weight: 20g



3.6

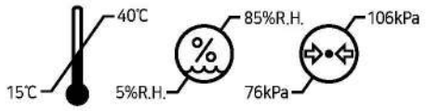
• Hand strap

- Size: 130(Length) x 43(Width)mm,
- Strap length: 333mm
- Weight: 20g



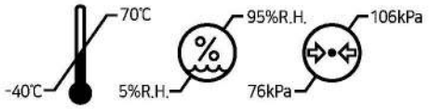
3.7 • Operating condition

- 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	✱ Example	SYMBOL	• Description / Location
01	SN		• Batch code / Product Label
02			• Date of manufacture / Product Label
03			• TYPE B app7lied part / Product Label, Cone connector
04			• Follow instructions for use / Product Label

NO	✱ Example	SYMBOL	• Description / Location
05			• Note / User manual
06			• General Caution, Warning (safety sign) / User manual
07			• Warning: Electrical / Inside of equipment
08			• General Prohibition (safety sign) / User manual
09			• Alternating current / Product Label
10			• Direct current / Product Label
11			• Keep dry / Package
12			• Keep away from sunlight / Package
13		EC REP	• 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 0068	• CE marking, Complies with euro-pean 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

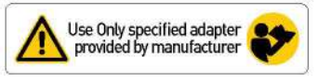
• Label location: on the Bottom of equipment / REMEX-T100

• 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

CE 0068

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

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)

4.0

• 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.)

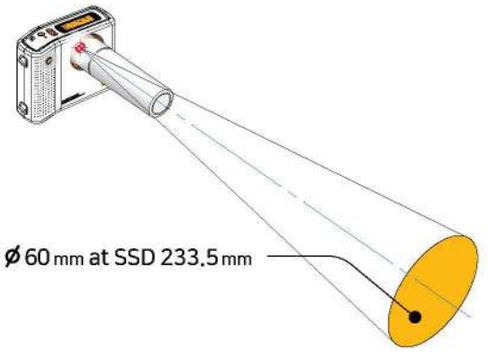
WARNINGS

- 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.

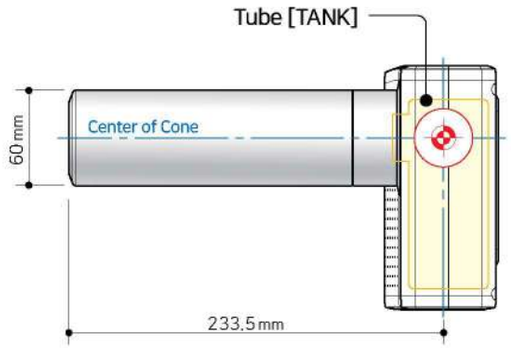
4. Please establish significant zone of occupancy as following and puts individual defense tool such as apron(protective device provided by manufacturer is beam limiting device(cone)) in this area and face in radiography.

CE 0068

• Radiation filed Area

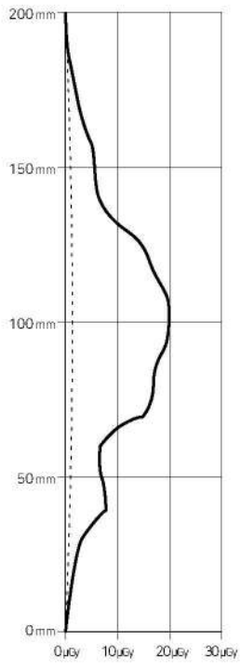


• Geometric position of focal spot

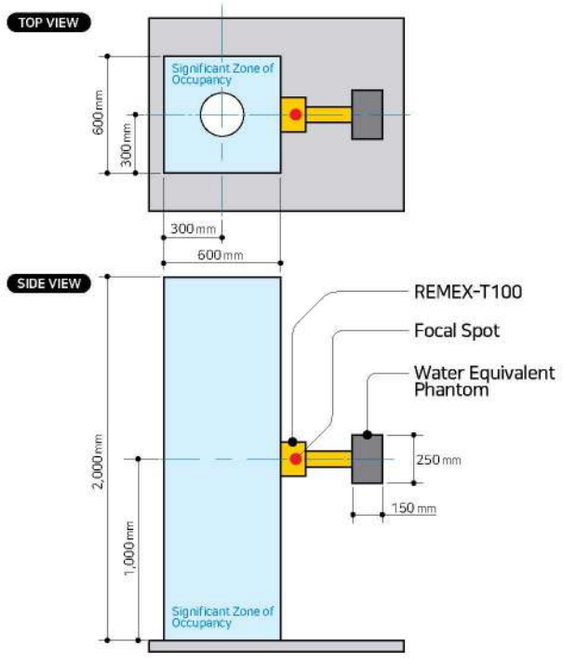


4.2

• 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

CE 0068

4.3

• Operation Procedure

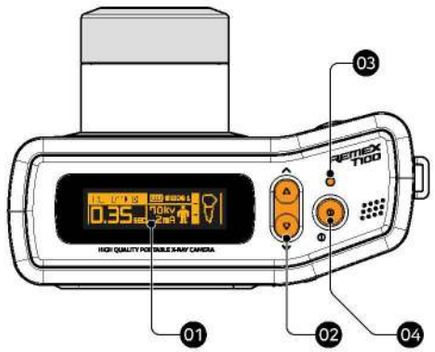
NOTE	• Always use the device with the cone(Beam limiting device) attached. The cone should be turned clockwise and tightened until there is no gap between the cone and the device.

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 01



01 LCD display window
02 Mode control button
03 Exposure status LED
04 Power button

4.3

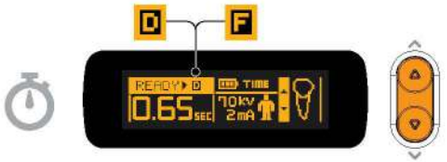
FIGURE 02

MODE1
Adult mode

MODE2
Child mode

FIGURE 03

TIME
Time mode



3. For Adult Mode (**MODE1**), Adult image will be displayed,
   For Child Mode (**MODE2**), Child image will be displayed. [Figure 2]
   For Time Mode, "**TIME**" will be displayed. [Figure 3]

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(△▽) [Figure 2]

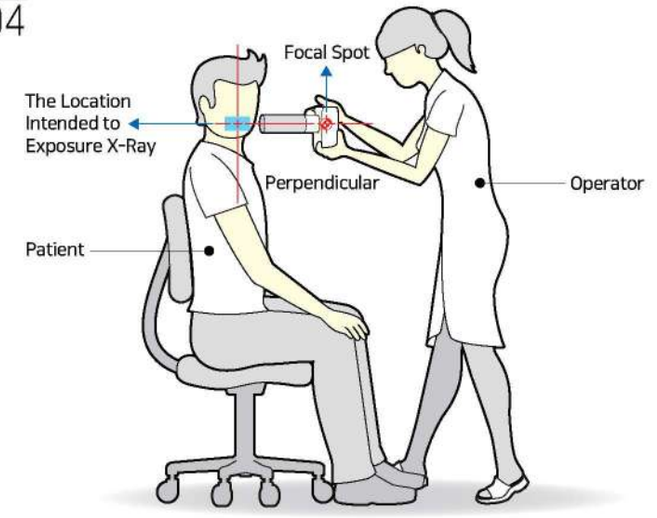
5. To adjust the irradiation time in Adult Mode and Child Mode (**MODE1 & MODE2**), press down the Up and Down buttons(△▽) for more than half a second and the irradiation time can be controlled by 0.01 seconds. [Figure 2]

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(△▽) [Figure 3]

7. D/F Settings can only be set by manufacturer or seller. (Users are prohibited from setting) [Figure 3]

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 4].). See the below [Figure 4].

FIGURE 04



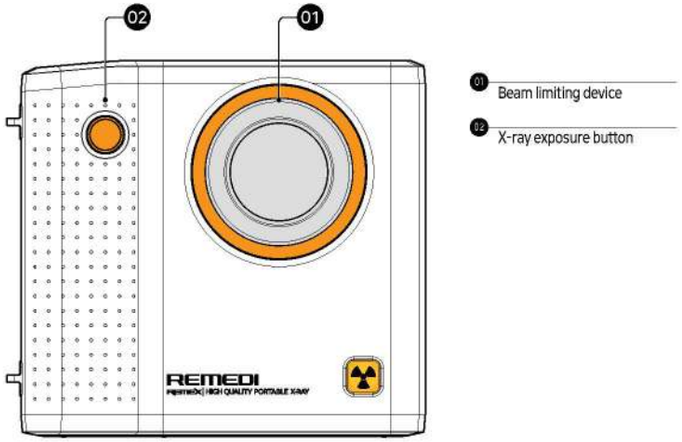
9. When all settings are completed, press the "Exposure" button (No.2 Button in [Figure 5]) for few seconds (about 2 seconds).

   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).

4.3

⚠ NOTE	• 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.
⚠ NOTE	• 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 1.3s, care should be taken not to move the patient for a while, and the operator should be careful not to move.)

FIGURE 05



01 Beam limiting device

02 X-ray exposure button

CE 0068

4.3

⚠ WARNINGS	• The most important thing for the X-ray is the distance of SSD. In order to get the best image from the equipment, please exposure the Xray contacting the cone to skin. Because of **REMEX-T(K)100** supplies the suitable distance with its cone.

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.

⚠ WARNINGS	• 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.

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

4.4

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

WARNINGS	
	• 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.

CE 0068

4.6

Error code	Name & Detail	Description
ERROR1	**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.
ERROR2	**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.
ERROR3	**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.

4.7

• Exposure time setting

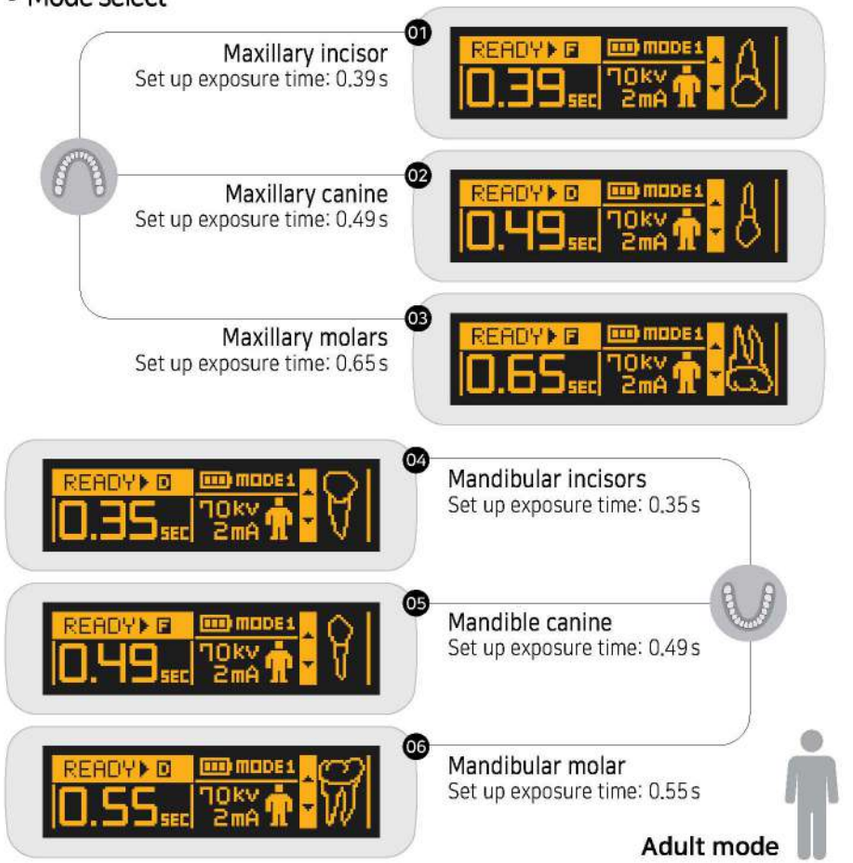
WARNINGS	
	• The exposure time table below is only for the reference. If the X-ray image is vague or dark, adjust exposure time.

4.7

Type of receptor	Exposure part		Recommended exposure time
• Analog Film	Upper	Incisor	0.70 sec ~ 0.80 sec
		Canine	0.90 sec ~ 1.00 sec
		Molar	1.10 sec ~ 1.20 sec
	Lower	Incisor	0.50 sec ~ 0.60 sec
		Canine	0.60 sec ~ 0.70 sec
		Molar	0.70 sec ~ 0.80 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 ~ 0.42sec
		Canine	0.39 sec ~ 0.59 sec
		Molar	0.44 sec ~ 0.66 sec

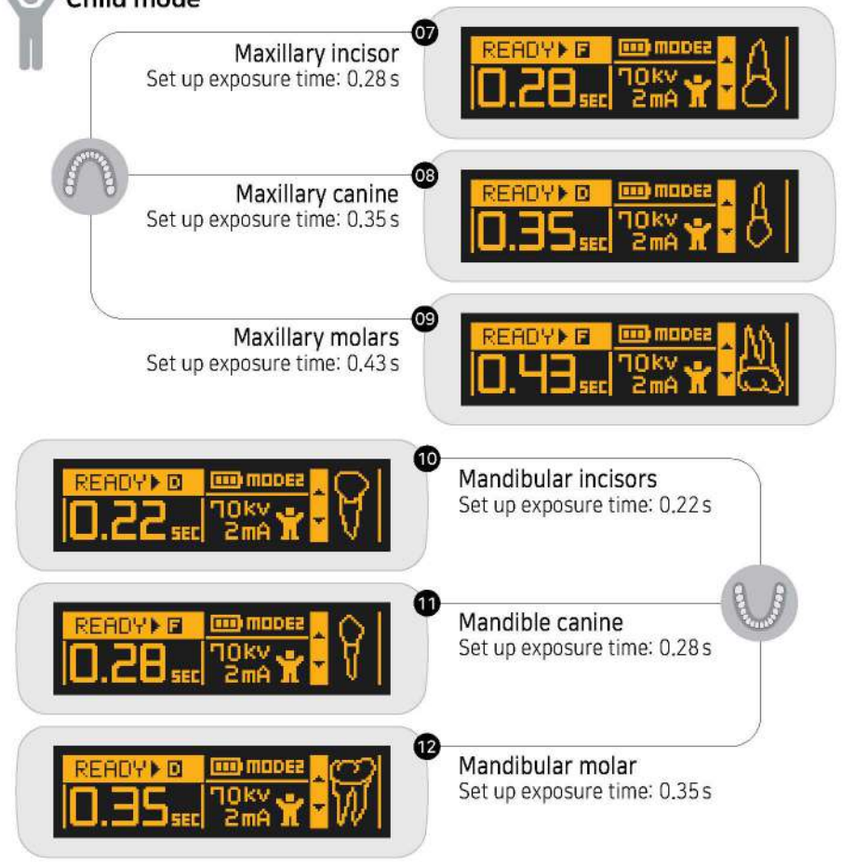
4.8

• Mode select



4.8

Child mode



CE 0068

4.8

No	Name		Description
01 Adult mode	Maxillary	Incisor	Set up exposure time: 0.39 s 01
		Canine	Set up exposure time: 0.49 s 02
		Molar	Set up exposure time: 0.65 s 03
	Mandibular	Incisor	Set up exposure time: 0.35 s 04
		Canine	Set up exposure time: 0.49 s 05
		Molar	Set up exposure time: 0.55 s 06
02 Child mode	Maxillary	Incisor	Set up exposure time: 0.28 s 07
		Canine	Set up exposure time: 0.35 s 08
		Molar	Set up exposure time: 0.43 s 09
	Mandibular	Incisor	Set up exposure time: 0.22 s 10
		Canine	Set up exposure time: 0.28 s 11
		Molar	Set up exposure time: 0.35 s 12

5.0

• 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

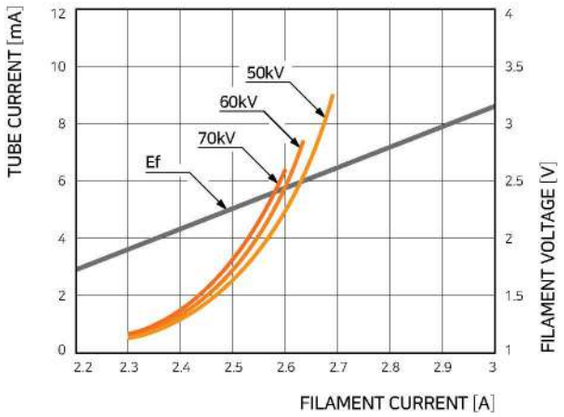
- **Tube voltage range:** 70 kV fixed
- **Tube current range:** Max. 9 mA
- **Focal spot size:** 0.4 mm
- **Inherent filtration:** Min. 1.0 mmAl
- **Type:** stationary
- **Anode angle:** 12.5°

CE 0068

5.3

- **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**

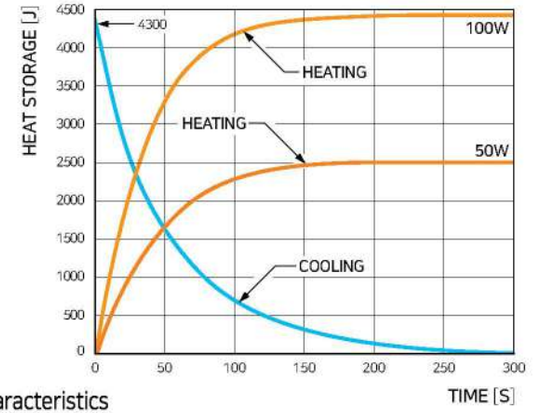
GRAPH 01



- Emission & Filament characteristics

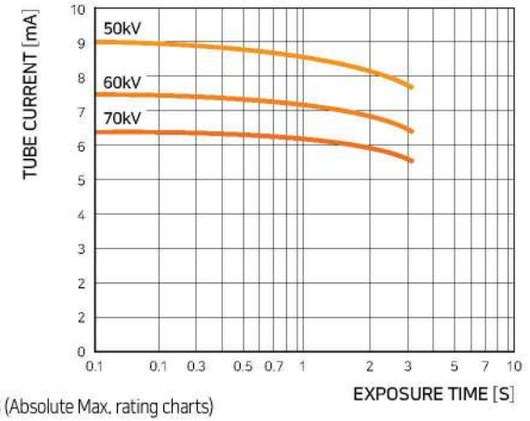
5.3

GRAPH 02



• Anode Thermal characteristics

GRAPH 03



• Max. rating charts (Absolute Max. rating charts)

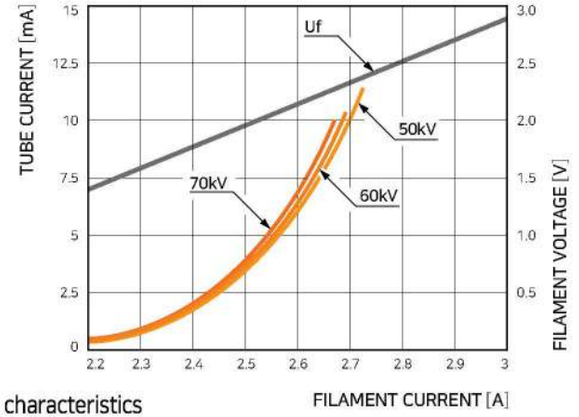
CE 0068

5.3

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**

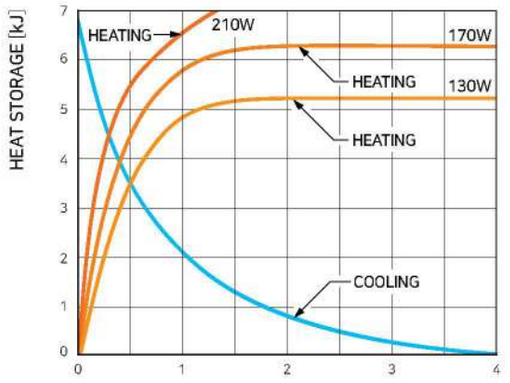
GRAPH 04



• Emission & Filament characteristics

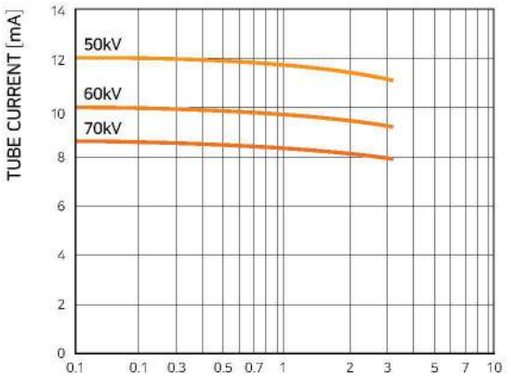
5.3

GRAPH 05



• Anode Thermal characteristics

GRAPH 06



• Max. rating charts (Absolute Max. rating charts)

CE 0068

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

⚠ NOTES

- 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
- **Capacity**: 1,500 mAh
- **Output voltage**: 11.1 Vd.c.
- **Size**: 85(Length)x32(Height)x42(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**: 100-240Va.c., 50/60 Hz, 1.0A
- **Rated output**: 12.6Vd.c., 1.5A

5.8

• Software for **REMEX-T(K)100**

- **Type**: Built-in
- **S/W name**: RPG-F-0702
- **S/W version**: 2.01

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

CE 0068

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.

6.1

• Replacement of Rechargeable battery

FIGURE 04

01 Battery cover
02 Charging port

- 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.

WARNINGS

- 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.

WARNINGS

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

CE 0068

6.2

- **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 voltage of 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.

CE 0068

7.1

Electromagnetic EMISSIONS – for **REMEX-T(K)100** 01 TABLE

Guidance and manufacturer's declaration - **Electromagnetic immunity**		
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.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group **1**	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.
RF emissions CISPR 11	Class **A**	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: ⚠ **WARNINGS** 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.
Harmonic emissions IEC 61000-3-2	Class **B**	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TABLE 02 Electromagnetic IMMUNITY – for **REMEX-T(K)100**

Guidance and manufacturer's declaration - **Electromagnetic immunity**			
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 line(s)	± 1 kV line(s) to line(s) ± 2 kV line(s) to line(s)	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 cycle 70 % UT(30% dip in UT) for 25 cycle < 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 cycle 70 % UT(30% dip in UT) for 25 cycle < 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.			

CE 0068

Electromagnetic IMMUNITY 03 TABLE for **REMEX-T(K)100** that are not **LIFE-SUPPORTING**

Guidance and manufacturer's declaration - **Electromagnetic immunity**			
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 Conducted RF EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 Vrms 80 kHz to 2.5 MHz	3 Vrms 150 kHz to 80 MHz 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 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 04 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 $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
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.

CE 0068

8.1

★★★★★
WARRANTY
POLICY

• 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.

8.0

• Product Warranty Policy

8.2

• Contact Us

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

• Manufacturer / Customer Service Team

Country	Repubric of Korea
Company	REMEDI Co.,Ltd.
Address	#24232, 2F, 69-14, Sakju-ro 145beon-gil, Chuncheon-si, Gaonwon-do, Korea
Tel	+82-2-6968-2041
Fax	+82-2-6968-2042
Email	sales@remedihc.com
Homepage	http://www.remedihc.com

• EC Representative

Country	Germany
Company	JaviTech e.K.,
Address	Sachsenhausener Straße 16, 65824 Schwalbach am Taunus ,Germany
Tel	+49 6196 4021549
Fax	
Email	info@javitech.de
Homepage	

CE 0068

9.2

- **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.

• MEMO

CE 0068

9.0 • MEMO

INDEX

INDEX

REMEX-T100
REMEX-K100

High Quality Portable X-Ray Digital Camera

CAUTION
AUTHORIZED PERSONNEL ONLY
RADIOLOGICAL CONTROLS REQUIRED TO WORK ON SURFACE

RADIOACTIVE
MATERIAL DO NOT OPEN

- 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.

REMEDI Co.,Ltd.