REMEDI

# User Manual

## REMEX-KA6

## Portable X-ray Equipment



**DOC No: REM-IFU-KA6 Rev.1**

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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.

Table of Content

## 1. About User Manual

This User Manual is provided to the user along with the REMEX-KA6.

This User Manual only pertains to the REMEX-KA6 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-KA6. 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.

### 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.

* This user manual is written in English.
* Countries other than English shall be produced in the language of the country in accordance with the translation guidelines of REMED Co., Ltd.

*User manual applied Country

| Country | Application | Country | Application | Country | Application |
|---|---|---|---|---|---|
| UK | O | Italy | | Denmark | |
| France | | Portugal | | Russia | |
| Germany | | Netherlands | | Poland | |
| Spain | | Swiss | | Ukraine | |
| Belgium | | Sweden | | Others | |

## 2. Precautions

### 2.1 General Cautions

| | **CAUTIONS** |
|---|---|
| 1. | This product is intended for use by a qualified and trained clinician 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 will not be responsible for the safe operation of the REMEX-KA6. |

### 2.2 General Prohibitions

| | **PROHIBITIONS** |
|---|---|
| 1. | Do not use with unauthorized AC/DC adapter. |
| 2. | Do not use it out of intended use. |
| 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. |
| 6. | There should be no one other than the user during use. |

### 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. |

**WARNINGS**

| | |
|---|---|
| 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. |
| 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.<br>There is a risk of fire or explosion if unspecified AC/DC adapters are used. |
| 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.<br>Using a damaged device due to falling may expose the patient or user to unwanted X-radiation. |
| 12. | After laying the tube tank, the amount of oil is checked through a transparent X-ray irradiator. If air bubbles or empty spaces are identified, there is leakage, so use the device should be stopped and contact the manufacturer for repair. |

## 3. Appearance and Specifications

3.1 Intended Use

REMEX-KA6 Portable X-ray Equipment is intended to be used by a qualified and trained clinician as an x-ray source for producing diagnostic x-ray images using image receptors. Its use is intended for adult, child subjects.

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-KA6 while cleaning. Use a non-alcohol based disinfectant only - wipes or a cloth dampened with liquid or spray. REMEX-KA6 and the accompanying adaptor are not designed to be subjected to any kind of sterilization procedure. REMEX-KA6 is not designed to be used to sterilize anything else.

REMEX-KA6 with radiation protection in accordance with IEC 60601-1-3:2013(EN 60601-1-3:2008/ A11:2016)
X-RAY EQUIPMENT for RADIOGRAPHY REMEX-KA6 IEC 60601-2-54:2009(EN 60601-2-54:2009)
X-RAY TUBE ASSEMBLY REMEX-KA6 IEC 60601-2-28:2010(EN 60601-2-28:2010)
There is no possibility of Deterministic effects (ICRP60) in normal use that the PATIENT can be exposed to RADIATION dose levels where deterministic effects.

3.1.1 Apllication specification

1) Intended medical indication
   - Portable X-ray equipment to obtain anatomical images

2) Intended patient population
   - Age : Not relevant
   - Health : Not relevant
   - Nationality : Not relevant
   - Patient condition : Not relevant

3) Intended part of the body or type of tissue applied to or interacted with

- Whole body

4) Operating principle

- REMEX-KA6 generates and controls X-rays using the power of the built-in battery, and irradiation is absolutely prohibited during charging. X-ray control is controlled by the designed electronic circuit and MCU, and among the conditions necessary for shooting, the tube voltage is from 40 kV to 70 kV and the tube current is from 2 mA to 6 mA. The irradiation time is from 0.06 s to 2.0 s, and the value adjusted by the MCU electronically controls the semiconductor switching element. Using this X-ray, it passes through the body part to be diagnosed to obtain an image with a detector so that it can be used for diagnosis. The irradiation time setting method sets the irradiation time by the user. After setting, press the shot button to perform investigation.

3.2 Specification

| **Model** | **REMEX-KA6** |
|---|---|
| Protection type from electrical shock | - ClassⅡ equipment (Charging mode)<br>- Internal power source equipment (Exposure mode)<br>- B type Applied part |
| Rated power of AC/DC adapter | - Input: 100-240 Vac, 50/60 Hz, 1.5 A<br>- Output: 24 Vdc, 2.0 A |
| Rated power of re-chargeable battery | 22.2 Vdc, 1800 mAh |
| Power input | 240 VA (At charging mode) |
| Tube voltage | 40 ~ 70 kV (Variable) |
| Tube current | 2 ~ 6 mA (Variable) |
| Exposure time range | 0.06 s ~ 2.0 s |
| Nominal Electric Power | 420 W (70kV, 6mA, 0.1s) |
| Focal spot size | 0.4 mm (complied with IEC 60336:1993) |
| Maximum symmetrical Radiation Field | 286.7 mm X 286.7 mm at SID 1000mm |
| The extent of the X-RAY BEAM | 63.1 mm X 63.1 mm at SID 220mm |
| Reproducibility | 0.05 or 0.05 less than |
| Linearity and constancy | Not more than 0.2 times different |

| | |
|---|---|
| Means to reduce the influence of RADIATION scattered | Not provided |
| Inherent filtration | 1.6 mmAl 70kV / HVL 2.5 mmAl |
| Additional filtration | 3.5 mmAl 70kV / HVL 2.5 mmAl |
| Total filtration | 5.1 mmAl 70kV / HVL 2.5 mmAl |
| Filament characteristic | 1.0 ~ 4.0 V, 2.2 ~ 3.0 A (max. filament current) |
| Anode angle | 12.5° |
| Thermal Characteristics | 4.3 kJ |
| Maximum Anode Heat Dissipation Rate | 430 W |
| Protection against ingress of water or particulate matter | IPX0 |
| Mode of operation | Continuous operation<br>(Re-charging time of high voltage tank is 10s.) |
| Expected service life | 5 years |
| Essential performance | - Accuracy of loading factors<br>Tube voltage accuracy: less than 10 %<br>Tube current accuracy: less than 20 %<br>Irradiation time accuracy: less than ±(10% + 1 ms)<br>Tube current time accuracy: ± (10 % + 0.2 mAs)<br>- Reproducibility of the radiation output: The coefficient of variation of measured values of air kerma: less than 0.05 |

Dosimetric indications

| Tube voltage | Tube current | Exposure time | Air Kerma (± 20 %) |
|---|---|---|---|
| 40 kV | 2 mA | 0.06 s | 0.000802mGy |
| | | 2.0 s | 0.025342mGy |
| | 4 mA | 0.06 s | 0.001345mGy |
| | | 2.0 s | 0.042875mGy |
| | 6 mA | 0.06 s | 0.001806mGy |
| | | 2.0 s | 0.059321mGy |
| 55 kV | 2 mA | 0.06 s | 0.002256mGy |
| | | 2.0 s | 0.077085mGy |
| | 4 mA | 0.06 s | 0.003801mGy |
| | | 2.0 s | 0.126958mGy |
| | 6 mA | 0.06 s | 0.005148mGy |
| | | 2.0 s | 0.175183mGy |
| 70 kV | 2 mA | 0.06 s | 0.004398mGy |
| | | 2.0 s | 0.145357mGy |
| | 4 mA | 0.06 s | 0.007200mGy |
| | | 2.0 s | 0.239477mGy |
| | 6 mA | 0.06 s | 0.009799mGy |
| | | 2.0 s | 0.331055mGy |

- RADIATION dose delivered to the PATIENT

| | Value | Value |
|---|---|---|
| Tube voltage | 70 kV | |
| Tube current | 6 mA | |
| Exposure time | 0.06 s (Min.) | 2.0 s (Max.) |
| RADIATION dose | 1.22 uGy・$m^2$ | 46.12 uGy・$m^2$ |

3.3 Safety Standards

| | |
|---|---|
| IEC 60601-1:2012<br>EN 60601-1:206/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014<br>EN 60601-1-2:2015 | 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<br>EN 60601-1-3:2008/A11:2016 | 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<br>EN 60601-1-6:2010 | Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard : usability |
| IEC 60601-2-28:2010<br>EN 60601-2-28:2010 | Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis |
| IEC 60601-2-54:2009<br>EN 60601-2-54:2009 | Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy |
| IEC 62304:2006<br>EN 62304:2008/AC:2008 | Medical device – Software life cycle |
| IEC 62366:2008<br>EN 62366:2008 | Medical devices - Application of usability engineering to medical devices |

3.4 Appearance

3.4.1 Front view of Main body

3.4.1.1 LED Cone


| No. | Name | Description |
|---|---|---|
| 1 | Beam limiting device | When irradiating X-rays, limit the irradiation range of the beam. |
| 1.1 | Collimator | It is a device to change the range of the irradiation field. When using the LED Cone, the collimator below can be used depending on the size.<br>- Chest, Spine: size 17 inch X 17 inch<br>- Abdomen, head: size 17 inch X 14 inch<br>- Hands and feet: size 12 inch X 10 inch |
| 2 | X-ray exposure button | Press this button to exposure the X-ray. |
| 3 | Eyelet for strap | Eyelet for strap |
| 4 | Exposure status LED | When the X-ray is irradiated, the yellow LED is turned on. |

3.4.1.2 Laser Cone(Option-Chest only)

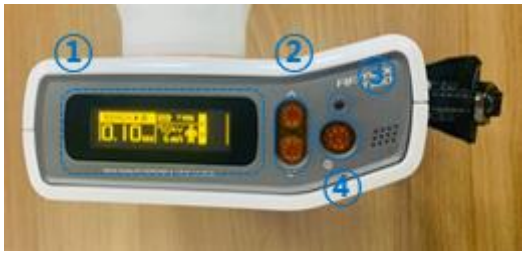

| No. | Name | Description |
|---|---|---|
| 1 | Beam limiting device | When irradiating X-rays, limit the irradiation range of the beam. |
| 2 | X-ray exposure button | Press this button to exposure the X-ray. |
| 3 | Eyelet for strap | Eyelet for strap |
| 4 | Exposure status LED | When the X-ray is irradiated, the yellow LED is turned on. |

3.4.2 Rear view of Main body

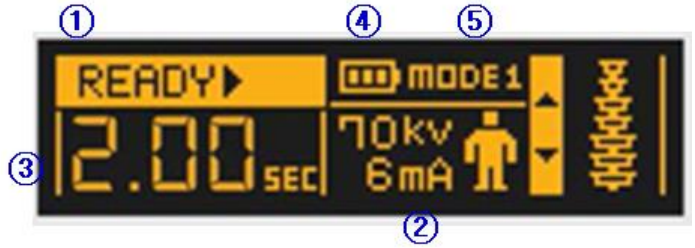

| No. | Name | Description |
|---|---|---|
| 1 | Battery cover | Remove this cover to replace a rechargeable battery. |
| 2 | Charging port | Connector for charging |

| | | |
|---|---|---|
| 3 | External port | External remote control connection port |

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 | Standby status LED | After power on, the green LED comes on in standby. It is off when X-ray irradiation. |
| 4 | Power button | Turn ON/OFF |




| No. | Name | Description |
|---|---|---|
| 1 | Status | Indicates the current status of the device.<br>READY : “Ready” condition.<br>READY ✲ : “Exposure” condition.<br>After exposure the X-ray, symbol ✲ is disappeared and “READY” is remained. |

| | | |
|---|---|---|
| 2 | Exposure mode setting | Change the default setting as intended use. Tube voltage range is 40 kV ~ 70 kV, tube current range is 2 mA ~ 6 mA, and it can be set using ↑(up), ↓(down) button.<br>⚠ 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.<br>⚠ The exposure time set in each mode is recommended by the manufacturer, and the time can be adjusted in each mode. |
| 3 | Exposure time select | Set the exposure time.(exposure time range is 0.06 s ~ 2.0 s) |
| 4 | Battery condition | Displays the remaining battery level. |
| 5 | Mode/Time/kV/mA exchange | Display [Mode],[Time],[kV],[mA]. |

* Conditions by mode (These modes are only examples/starting points, to be replaced by more specific protocols developed by the user.)

- Vertebra mode : 70 kV, 6 mA, 2.00s (Adult)
  70 kV, 6 mA, 1.30s (Kid)
- Breast mode : 70 kV, 6 mA, 0.65s (Adult)
  70 kV, 6 mA, 0.40s (Kid)
- Hand mode : 50 kV, 6 mA, 0.50s (Adult)
  45 kV, 6 mA, 0.40s (Kid)
- Foot mode : 55 kV, 6 mA, 0.60s (Adult)
  55 kV, 6 mA, 0.50s (Kid)
- Head mode : 70 kV, 6 mA, 1.50s (Adult)
  70 kV, 6 mA, 1.30s (Kid)
- Abdomen mode : 70 kV, 6 mA, 2.00s (Adult)
  70 kV, 6 mA, 1.20s (Kid)

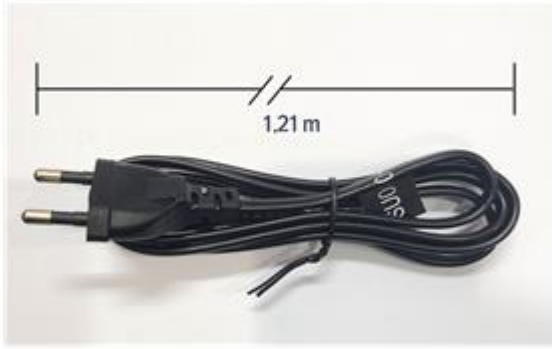
3.5 Dimension

3.5.1 Main body(LED Cone and Laser cone(Option))

- size: 165.3(Length) ✕ 176(Height) ✕ 255.6(Width) $mm^3$
- weight: 2.4 kg (including cone 190 g)


3.5.2 AC/DC adapter and power cord

- size: 115(Length) ✕ 30(Height) ✕ 50(Width) $mm^3$
- weight: 250 g

3.5.3 SSD Cage: It is used attached to the cone.

- size: 125.6(Length) mm ✕ 135.1(Width) mm
- weight: 78g

3.5.4 Wired remote control switch(Option) : External switch for X-ray irradiation at 3m distance

- size: Ø 30 ✕ 3000 mm
- weight: 120 g

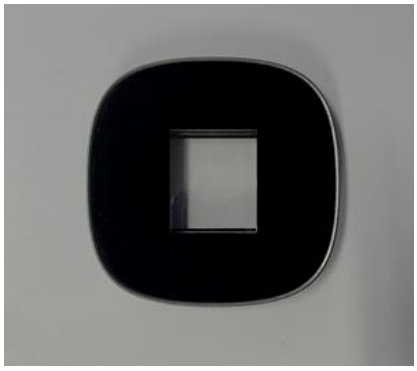
3.5.5 Hand strap

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

3.5.6 Collimator(Option)

1) Abdomen, head Collimator

- size: 83.5 mm × 83.5 mm
- weight: 60 g



2) Hands, feet Collimator

- size: 83.5 mm × 83.5 mm
- weight: 70 g

3.6 Operating condition

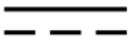
- Temperature: 15 ℃ ~ 40 ℃
- Related Humidity: 5 %R.H. ~ 85 %R.H. (Non-condensing)
- Atmospheric pressure: 80 kPa ~ 106 kPa
- Altitude: Less than 2,000 m

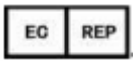
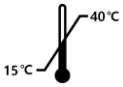
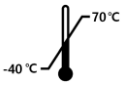
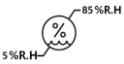
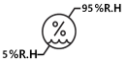
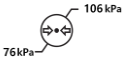
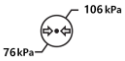
3.7 Storage and transportation condition

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

3.8 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 |  | Serial Number | Product Label |
| 2 |  | Date of manufacture | Product Label |
| 3 |  | TYPE B applied part | Product Label<br>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 |

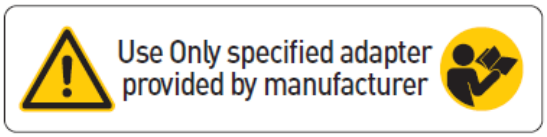
| | | | |
|---|---|---|---|
| 12 |  | Keep away from sunlight | Package |
| 13 |  | EC representative | Package<br>Product Label |
| 14 |  | Manufacturer | Package<br>Product Label |
| 15 |  | Operating temperature range | Product Label |
| 16 |  | Storage temperature range | Package |
| 17 |  | Operating humidity range | Product Label |
| 18 |  | Storage humidity range | Package |
| 19 |  | Operating Atmospheric pressure range | Product Label |
| 20 |  | Storage Atmospheric pressure range | Package |
| 21 | 0068<br>CE | CE marking, Complies with european medical devices directive | Package<br>Product Label |
| 22 |  | WEEE Mark | Package<br>Product Label |
| 23 |  | Warning: Hight voltage | Inside the device |
| 24 |  | Radiation hazard | Product Label<br>Product enclosure |

3.9 Labels of Main body

Label location: on the Bottom of equipment / REMEX-KA6

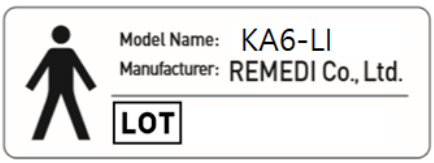

3.10 Label of AC/DC adapter connector

Label location: Near the AC/DC adaptor connector




3.11 Label of Cone

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




3.12 Label of Radiation hazard

Label location: Bottom back of device


3.13 Label of AC/DC adapter

Label location: On the adapter

AC/DC ADAPTER

Model: YHY-24002000

Input rate: 100-240VAC 50/60Hz 1.5A

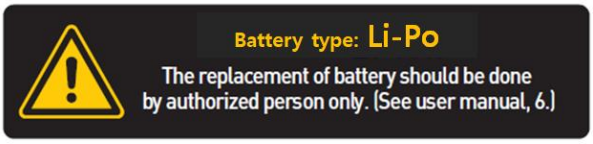
Output rate: 24.0V⎓ 2.0A

Manufacturer: SHENZHEN YINGHUIYUAN ELECTRONICS CO., LTD

Made in china

3.14 Label of re-chargeable battery

Label location: On the battery pack

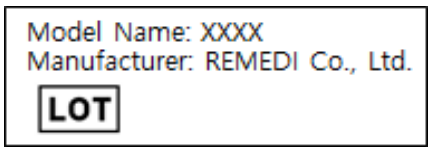



3.15 High voltage tank

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

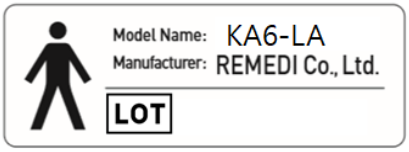

3.16 Wired remote control switch

Label location: On the hand grip of the switch




3.17 Laser Cone (Option)

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



3.18 Label of protective cover

Label location: On the cover

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

4.1 Frequently used functions

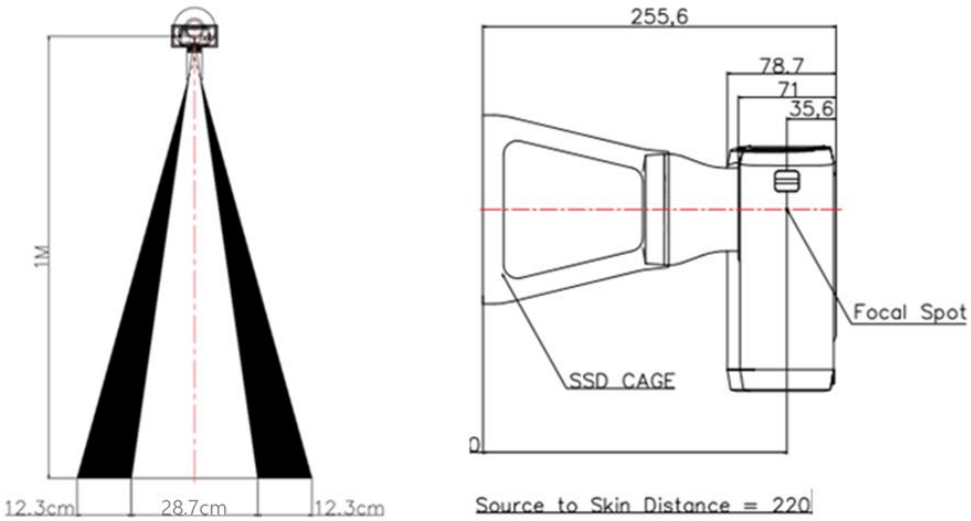
- Connecting “Charging cable”
- Checking “Charging condition”
- Mounting “Cone”
- Pushing “ON/OFF button”
- Setting “Exposure time”
- Setting “Mode”
- Checking “Display LCD”
- Pushing “X-ray exposure button”

4.2 Pre-procedure

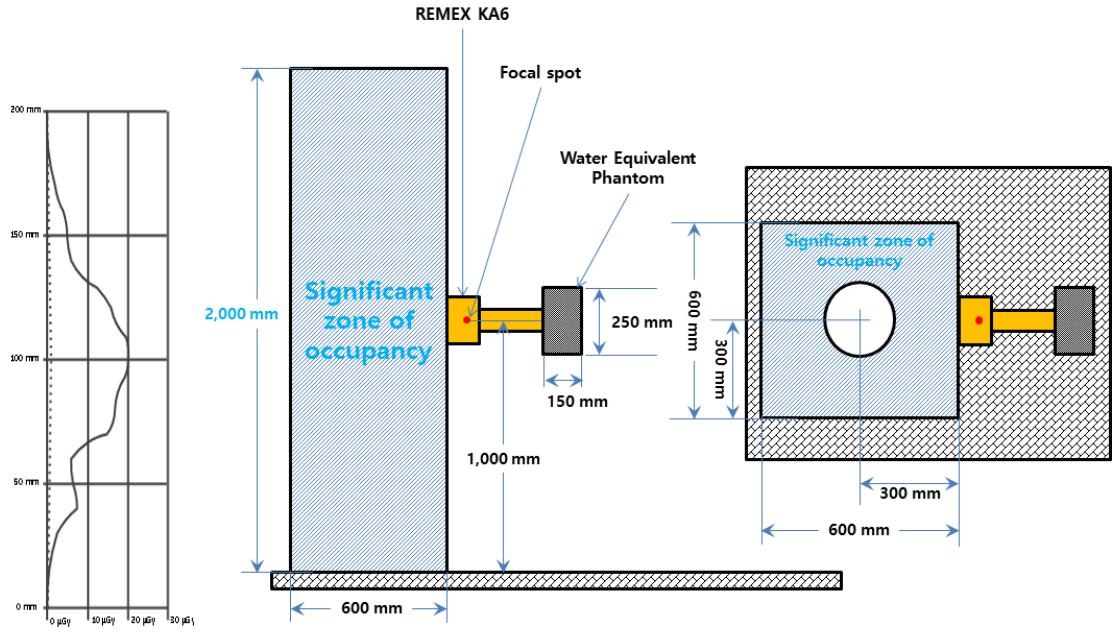
1. The operator of REMEX-KA6 must be a qualified and trained clinician having received appropriate license.
2. Understand warnings, cautions and user manual.
3. Check the Charging condition of battery before use. If the battery is not charged enough, charge the battery using AC/DC adapter. (While charging mode, REMEX-KA6 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.




[Dose]




[Significant zone of occupancy]

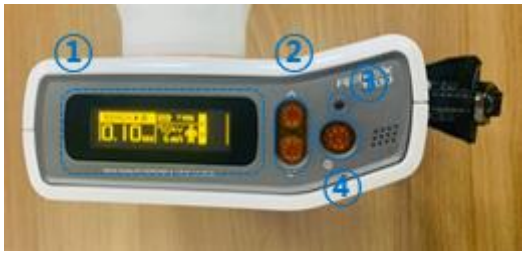
- The case thickness of water equivalent phantom is less than 10 mm, the material of it is PMMA. The size of it is 250 × 250 × 150 $mm^3$.
- In this area, the all performance of REMEX-KA6 can be used.
- Operator Dose rate in center of the significant zone of occupancy: 20 μGy/h

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.<br>If you are holding the device with one hand for a long period of time, you should provide a warning that the device may be dropped. |

1. Press ON button for a few seconds (about 2s ~ 3s) (No.4 button in [Figure 2]), and turn on the REMEX-KA6.
2. Change the default setting as intended use. Tube voltage range is 40 kV ~ 70 kV, tube current range is 2 mA ~ 6 mA, exposure time range is 0.06 s ~ 2.0 s and it can be set using ↑(up), ↓(down) button.

[Figure 2]




3. Set the location intended to exposure X-ray. The plane of the intended location should be perpendicular to the cone.

4. Press “Exposure” button for a few seconds (about 1.5s) (No.2 button in [Figure 3]) after the all setting are finished. While the X-ray exposure, yellow LED lamp(No.1 LED in [Figure 3]) turns on.

| | |
|---|---|
| ⚠ | 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. |


[Figure 3]

| | |
|---|---|
| ⚠ | 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 2.0 s, care should be taken not to move the patient for a while, and the operator should be careful not to move. User should wait 1minute for re-shooting.) |

| | |
|---|---|
| ⚠ | The most important thing for the X-ray is the distance of SSD. In order to get the best image from the equipment, keep SID 150cm. The X-ray is irradiated while the SSD is maintained to be 45cm or more. The distance from the focal point to the cone surface is 25.5 cm, so the patient's skin to the cone should always be at least 20 cm. The distance between the cone and the patient's skin depends on the body part of the patient to be measured, and the tube voltage, tube current and exposure time must be adjusted to obtain an optimal image according to the increase in the distance. The change in SSD affects the patient's radiation dose, the shorter the SSD, the greater the patient's radiation dose, and the longer the SSD, the less the patient's radiation dose. |

4.4 Storage and Cleaning after use

1. Press “ON/OFF button”(No.4 button in [Figure 2]) to Turn off REMEX-KA6.
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-KA6 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-KA6 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-KA6.
- Setting of REMEX-KA6: exposure time 2.0 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 | Inner temperature of tube tank is over specified limit. | The device turned off after display “Error 1” on the LCD with the single buzzer sounds. |
| ERROR 2 | Voltage error | Voltage of X-ray is over specified limit. | The device turned off after display “Error 2” on the LCD with the double buzzer sounds. |
| ERROR 3 | Simultaneous error (Error 1 + Error 2) | Error 1 and error 2 occurred at the same time. | The device turned off after display “Error 3” on the LCD with the triple buzzer sounds. |
| ERROR 4 | Exposure button error | When user presses exposure button while turning on the device. | The device turned off after display “Error 4” on the LCD with the single buzzer sounds. |
| ERROR 5 | Exposure button error | When user presses exposure button more than 10 seconds after X-ray exposure. | The device turned off after display “Error 5” on the LCD with the single buzzer sounds. |

## 5. Technical Data

5.1 Specifications

- Electrical classification(Battery): Internally Power, Type B applied part
- Electrical classification(AC/DC Adaptor): Class II
- Mode of operation: Continuous operating
- Radiation quantity: Max. entrance surface dose 216 mR at 70 kV / 6 mA / 2.0 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

- Tube voltage range: 40 kV ~ 70 kV
- Tube current range: 2 mA ~ 6 mA
- Exposure time range: 0.06 s ~ 2.00 s

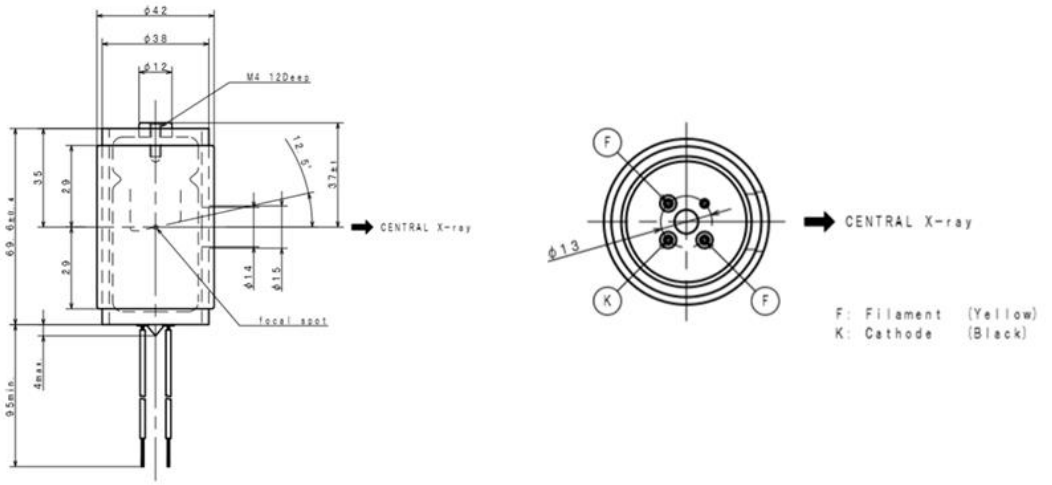
* Conditions by mode (These modes are only examples/starting points, to be replaced by more specific protocols developed by the user.)

- Vertebra mode : 70 kV, 6 mA, 2.00s (Adult)
  70 kV, 6 mA, 1.30s (Kid)
- Breast mode : 70 kV, 6 mA, 0.65s (Adult)
  70 kV, 6 mA, 0.40s (Kid)
- Hand mode : 50 kV, 6 mA, 0.50s (Adult)
  45 kV, 6 mA, 0.40s (Kid)
- Foot mode : 55 kV, 6 mA, 0.60s (Adult)
  55 kV, 6 mA, 0.50s (Kid)
- Head mode : 70 kV, 6 mA, 1.50s (Adult)
  70 kV, 6 mA, 1.30s (Kid)
- Abdomen mode : 70 kV, 6 mA, 2.00s (Adult)
  70 kV, 6 mA, 1.20s (Kid)

5.3 X-ray tube assembly

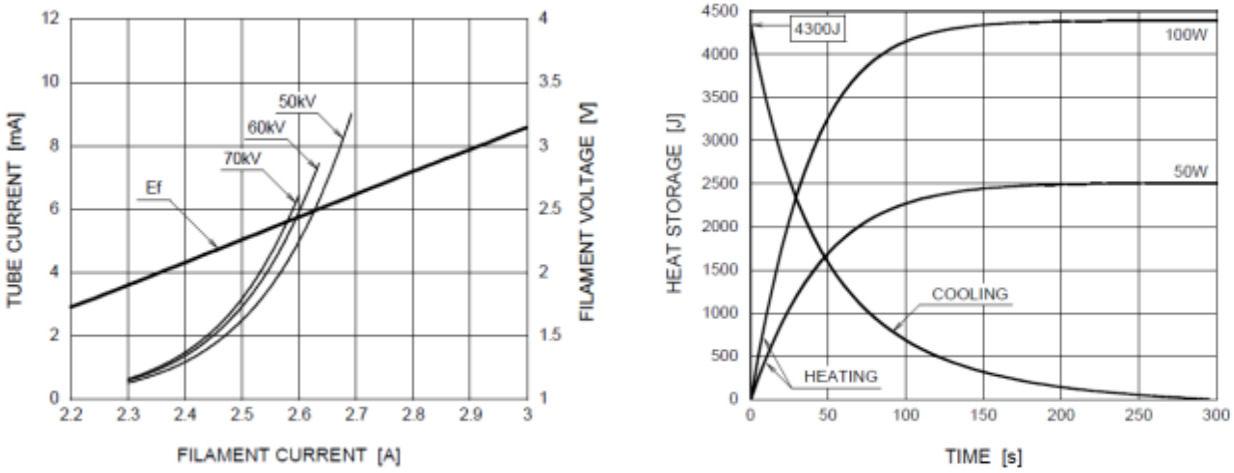
- Tube voltage range: 40 kV ~ 70 kV
- Tube current range: 2 mA ~ 6 mA
- Focal spot size: 0.4 mm
- Inherent filtration: Min. 1.0 mmAl
- Type: stationary

- 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 weight: 260 g
- X-ray tube drawing



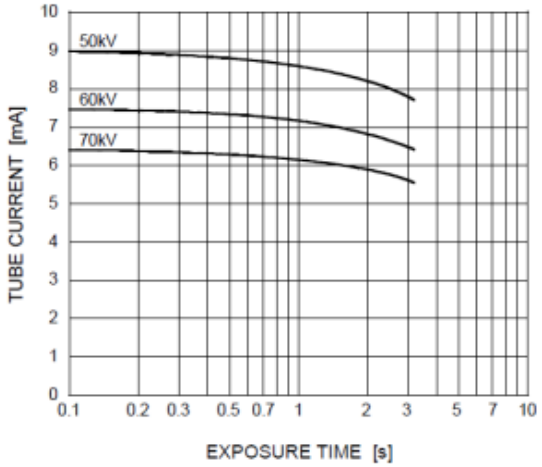

- X-ray tube Characteristic curve

Emission & Filament characteristics




Anode Thermal characteristics

Max. rating charts (Absolute Max. rating charts)




5.4 High voltage tank

- Type: 40 kHz, inverter type
- Tube voltage: 40~70 kV constant potential
- Tube current: Max. 2~6 mA direct current
- Additional filtration: Min. 0.5 mmAl
- Total filtration: Min. 1.5 mmAl
- Rated power: 22.2 Vd.c, 25 A

5.5 Beam limiting device

- Type: Square
- Source to Skin Distance (SSD): 220 mm

⚠ The beam limiting device is lined with Pb because of leakage radiation.

5.6 Re-chargeable battery

- Model name: ALLRUNBATTERY653496
- Manufacturer: SHENZHEN JURUIYUAN SMARTECH Co., LTD
- Type: Li-Po Battery
- Output voltage: 22.2 Vd.c.
- Capacity: 1,800 mAh
- Size: 102(Length)✕39(Height)✕39(Width) $mm^3$

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

- Model name: YHY-24002000
- Manufacturer: SHENZHEN YINGHUIYUAN ELECTRONICS CO., LTD
- Rated input: 100-240 Va.c., 50/60 Hz, 1.5 A

- Rated output: 24 Vd.c., 2.0 A

5.8 Software for REMEX-KA6

- Type: Built-in
- S/W name: RPG-F-0706
- S/W version: 1.03

5.9 Extra accessory

- Wired remote control switch(Option)

5.10 Minimum requirement for digital X-ray image receptor

- Size / weight: 17inch × 17inch × 15.5mm / 3.2kg
- Pixel size: 140μm
- X-ray sensitive pixel: 3072 × 3072 pixels
- X-ray sensitive area: 430.08 x 430.08mm

5.11 Protection against Residual Radiation

- To avoid residual radiation caused by using of REMEX-KA6, 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-KA6 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 6 mA / Tolerance ± 20 %
  3) Exposure time: measurement point 0.06 s ~ 2.0 s / Tolerance ±(10% + 1 ms)
  4) Leakage radiation
  5) Setting of exposure modes

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.
- When an unauthorized person (unskilled person) replaces the battery, there is a danger of overheating, fire or explosion.
- 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 |
|---|---|---|
| Appearance inspection | Inspect the entire exterior of the device for signs of damage. | No signs of damage. |
| Cone inspection | Inspect the Cone, Cone connector and Cone for any foreign objects. | No foreign objects. |
| 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 6 mA, and measure the value of irradiating the X-ray. | Within 6 mA ± 20 %<br><br>Within (0.06~2.0) s ± (10% + 1ms) |
| Battery voltage | Open the battery cover. Connect the oscilloscope to battery terminal and measure the value of battery DC voltage. | More than 20 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-KA6

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| REMEX-KA6 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-KA6 should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The REMEX-KA6 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-KA6 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:<br>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-KA6 or shielding the location. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Table 2 – electromagnetic IMMUNITY – for REMEX-KA6

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The REMEX-KA6 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-KA6 should assure that it is used in such an environment. | | | |
| IMMUNITY test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD)<br><br>EN 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 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<br><br>EN 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>EN 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV line(s) to line(s)<br>± 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<br><br>EN 61000-4-11 | <5 % UT<br>(>95 % dip in UT)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT)<br>for 5 s | <5 % UT<br>(>95 % dip in UT)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT)<br>for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the REMEX-KA6 requires continued operation during power mains interruptions, it is recommended that the REMEX-KA6 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>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-KA6 that are not LIFE-SUPPORTING

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The REMEX-KA6 is intended for use in the electromagnetic environment specified below. The customer or the user of the REMEX-KA6 should assure that it is used in such an environment. | | | |
| IMMUNITY test | IEC 60601 TEST LEVEL | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>EN 61000-4-6<br><br>Radiated RF<br>EN 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2,5 GHz | 3 Vrms<br><br>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.<br>Recommended separation distance<br>$\sqrt{P}$<br>d = 1.17<br>$\sqrt{P}$<br>d = 1.17 80 MHz to 800 MHz<br>$\sqrt{P}$<br>d = 2.33 80 MHz to 800 MHz<br>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).<br>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<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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-KA6 is used exceeds the applicable RF compliance level above, the REMEX-KA6 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-KA6.<br><br>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-KA6 | | | |
|---|---|---|---|
| The REMEX-KA6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REMEX-KA6 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REMEX-KA6 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.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>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

- 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.

**[Manufacturer / Customer Service Team]:** REMEDI Co., Ltd., #24232, 2F, 69-14, Sakju-ro 145beon-gil, Chuncheon-si, Gangwon-do, Korea
Tel: +82-2-6930-5891, Fax: +82-2-6930-5892, E-mail: sales@remedihc.com
Homepage: http://www.remedihc.com

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.
The product does not train the user, it is used by the user referring to the user manual.

[EU Representative]: JaviTech e.K.
Address: Sachsenhausener Straße 16, 65824 Schwalbach am Taunus ,Germany

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

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