TALKING EAR AND FOREHEAD THERMOMETER

OMEGA

INSTRUCTION MANUAL

MODEL: DX6635

Please read this manual before use

CE 0197

Manual of DX6635 Talking Multi-Functional Ear and Forehead Thermometer

- Thank you for purchasing our DX6635 Talking Multi-Functional Ear and Forehead thermometer. For a desirable use of this product, be sure to read this user manual before use.
- Firstly, open the battery case and gently pull out the plastic safety tab. The thermometer will not activate until the tab has been removed.
- For safe and proper use of this product, be sure to read and fully understand Safety Precautions steps outlined in this user manual.
- Keep this manual in a safe and accessible location for easy access and future reference.

SAFETY PRECAUTIONS

- Warning marks and symbols are displayed for your safety and to ensure proper use of this product and prevent any injuries.
- See table below for description of warning marks and symbols:

WARNING
Means a possibility of personal injury in case of improper use.

NOTICE
Means a possibility of personal injury or property damage* in case of improper use.

[*Property damage covers any damage to house,family property, domestic animal.]

MARKS OR SYMBOLS

PROHIBITION
Means Forbidden with detailed items expressed in words or figures within or beside the mark. The example here is 'General Forbidden'.

MUST OBSERVE
Means Obligatory with detailed items expressed in words or figures within or beside the mark. This example here is 'General compulsory'.

IMPLICATION OF SYMBOL
Means Type-B device.

INTENDED FOR USE

The device is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.

⚠ WARNING ⚠

It is dangerous for patients to perform a self-evaluation and self-treatment based on the measuring results. Be sure to follow doctors' instruction.
***A self-evaluation may cause deterioration of health.**

Don't touch or blow infrared sensor.

***A polluted infrared sensor may cause inaccuracy.**

Clean a polluted infrared sensor with a soft wet cloth in a gentle manner.

***Cleaning with a tissue or paper towel may scratch the infrared sensor, causing inaccuracy.**

Keep the machine out of children's reach.
***An unsupervised measurement may cause ear damage. For accidental swallowing of batteries, please consult the doctor.**

Measurement should be suspended until the ear has adjusted to room temperature.
***Immediate measurement after an outdoor activity in winter may cause a lower result.**

For temperature difference between storage area and measurement site, condition the thermometer for about 30minutes in room temperature (measurement site).
***Failing to do so may cause inaccuracy.**

⚠ NOTICE ⚠

Stop using the product in occurrence of any pain.

***It is likely to damage the ear hole.**

It is not recommended to use the product by users suffering ear diseases including otitis external and tympanitis.
***Affected part is likely to irritate.**

Don't use the product in a wet ear, eg. after swimming or bathing.

***It is possible to damage the ear hole.**

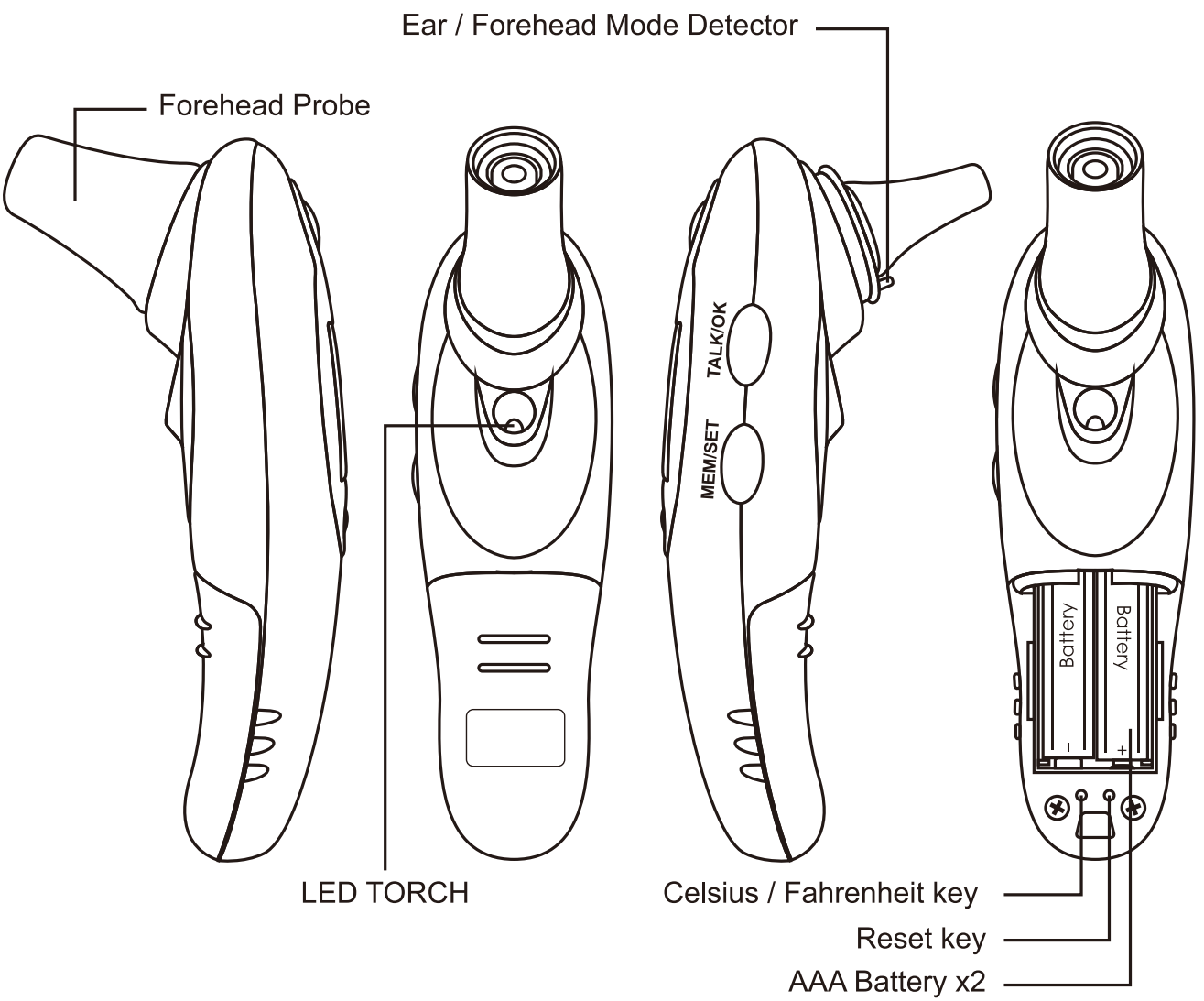
Don't throw batteries into fire.

***Battery is likely to explode in fire.**

RECOMMENDATIONS

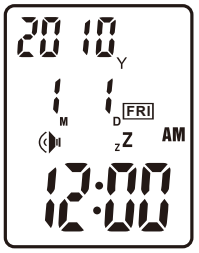
- Don't use the product for other purposes.
- It is not a waterproof device. Clean it only with damp cloth gently.
- It is forbidden to leave the product exposed to any chemical solvent, direct sunshine or high temperature.
- Don't drop, or impose any vibration or impact on the product.
- Don't use a mobile phone nearby when the thermometer is working.
- When disposing of battery and wastes, please act according to the law.
- Take out the batteries if you are not going to use the unit for a long period of time.

PRODUCT STRUCTURE



FUNDAMENTAL FUNCTIONS

1. Current date and time display :
   Range of date display falls within Gregorian calendar year 2001 ~ 2099, time display mode includes 12 hours shift or 24 hours shift (user selectable). The initial date for a powered system is set at 1st of the manufacturing year



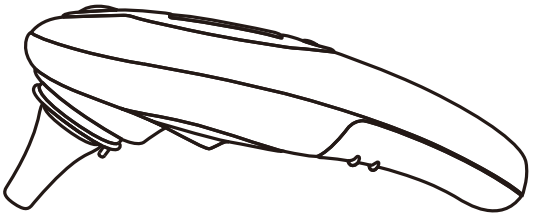
2. Measurement and display of temperature :
   Measurement ranges from 32.0°C to 42.9°C (89.6°F to 109.3°F).
3. 20 sets of measurement records :
   Maximum 20 sets of temperature records stored.
   Temperature is stored together with measuring date, time and measurement mode (Ear or Forehead).
4. Measurement and display of room temperature :
   Measurement ranges from 5.0°C to 59.9°C (41.0°F to 139.8°F).
5. Voice prompt: report measurement results, room temperature and current time. (English can report in °C or °F)
6. Built-in white LED torch.

PREPARATIONS

1. Replace any low-voltage battery to ensure full power supply.
2. For proper measurement, condition the thermometer for 30 minutes in measurement site.
3. An unexpected fluctuation of ambient temperature is likely to deteriorate the measuring accuracy. When a measurement site shows a different temperature with the area where a thermometer located, or an attempt to perform a measurement in front of an air conditioner, accurate results are impossible.
4. Be sure to keep ear clean since a ceriman-filled or wax-filled ear can cause inaccuracy.
5. Measurements should be done at a rest time to ensure an accurate result. Temperature is likely to increase immediately after exercise or bathing.

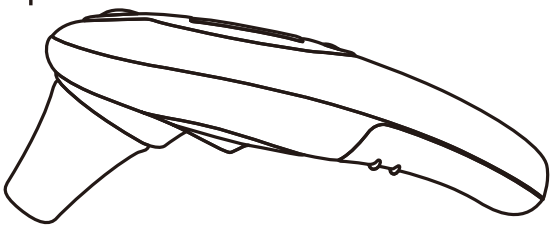
HOW TO TAKE MEASUREMENT

1) To measure ear temperature :



Pull **OUT** the FOREHEAD PROBE from the unit, insert the temperature probe along the eardrum as deep as possible into the ear, then press **[ ]** once to start the measurement & you will hear a beep sound.
Upon completion you will hear two beeps. Now you will hear the result via the speaker or see it from the LCD.

2) To measure forehead temperature :



Put **ON** the FOREHEAD PROBE onto the unit, then gently position the probe onto the center of the forehead, midway between the eyebrow and the hairline. Press **[ ]** once to start the measurement & you will hear a beep sound. Upon completion you will hear two beeps. Now you will hear the result via the speaker or see it from the LCD.

3) The result will be stored into memory automatically. If 20 sets of memory are stored already, the first set of data will be removed, and the new data will be stored at the top.

4) Measure a maximum of 3 times consecutively. Wait for 10 minutes for continuous measurements 4 times or above.

5) Display of measuring results:
   A. True value display for result falls between 32.0°C to 42.9°C (89.6°F to 109.3°F)
   B. "HI" displayed for result above 42.9°C / 109.3°F
   C. "LO" displayed for result below 32.0°C / 89.6°F

6) At completion of measurement, the unit automatically returns to time mode after 30 seconds.

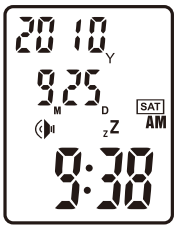
7) The display will turn off automatically 1 minute after last key pressed.
   (*if sleep mode is enabled*)

ADVANCED OPERATION (1)

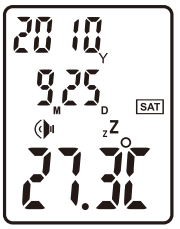
Clock mode :

1. Display time in a sequence of year, month, date, week, hour, minute with a flickering " : " stands for second. The LCD displays current time and room temperature in alternate 5 seconds.
2. Press **[T]** to report current time and room temperature.

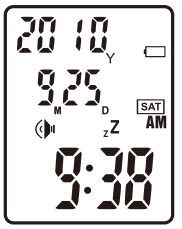
Clock Mode (Clock)



Clock Mode (Temperature)

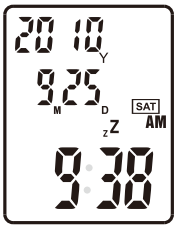


Clock Mode (Batt empty)

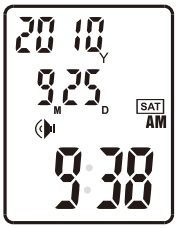


3. Press and hold **[T]** button for 2 seconds to toggle the language which you want or non talking function.
   However, during measurement, you will hear a beep sound despite if the unit is in talking or non-talking mode.
4. When the TALK function is enabled, the [ ] icon is turn on.
   If disabled, the [ ] icon is off. Default TALK function is enabled.

Clock non-talking



Clock non-sleep mode



5. Press **[M]** to retrieve the recorded temperature or hold **[M]** and **[T]** for 2 seconds to enter into set up mode.
6. Press **[°C / °F]** to toggle between Celsius or Fahrenheit.
7. Press any key to turn on the EL (backlight). The EL (backlight) will turn off automatically after 5 seconds.
8. Press hold the **[M]** key for 2 seconds to turn on the white LED and the white LED will turn off automatically after 5 seconds.
9. Sleep mode - System enters into sleep mode 1 minute after last key pressed.

ADVANCED OPERATION (2)

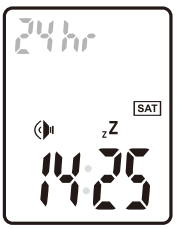
Setup mode :

Press hold **[M]** and **[T]** key for 2 seconds to enter into setup mode

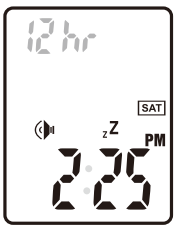
1. Press **[T]** to shift between a setting of 12Hr/24Hr,HOUR. MINUTE, YEAR, MONTH, DAY and SLEEP enable/disable.
2. Press **[M]** to increase the digit.
3. Hold **[M]** to increase the digit rapidly.

* Unit return to clock mode automatically 30 seconds after last key pressed.

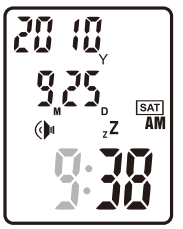
SET 12hr (12/24)



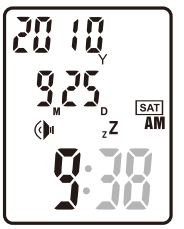
SET 24hr (12/24)



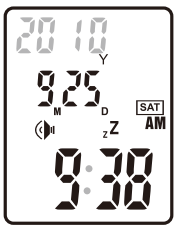
SET hour



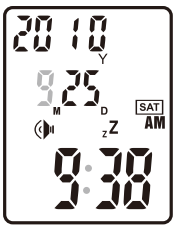
SET minute



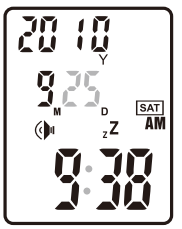
SET year



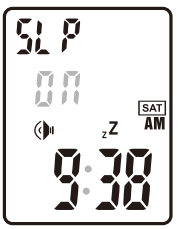
SET month



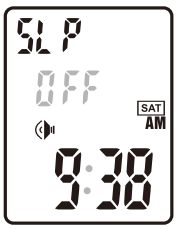
SET day



SET sleep enable



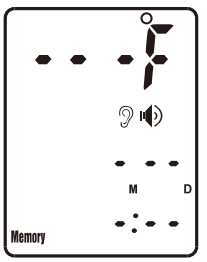
SET sleep disable



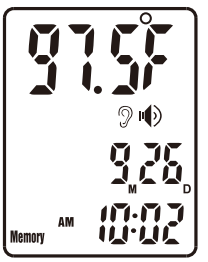
Memory mode

1. Press **[M]** in clock mode to enter into memory mode ;
2. "-" will be displayed if no data is stored ;
3. Maximum storage is 20 sets of data with date and time shown ;
4. Unit returns to clock mode automatically 5 seconds after last key pressed.

Memo. no data



Memo. data



Note :

- Press any key to stop the speech during it is announcing.
- The voice will turn off the white LED automatically, EL will hold 1 second then turn off automatically.
- When the EL is turned on, the white LED will be turned off automatically.
- When the Light is turned on, the EL will hold 1 second then turn off automatically.

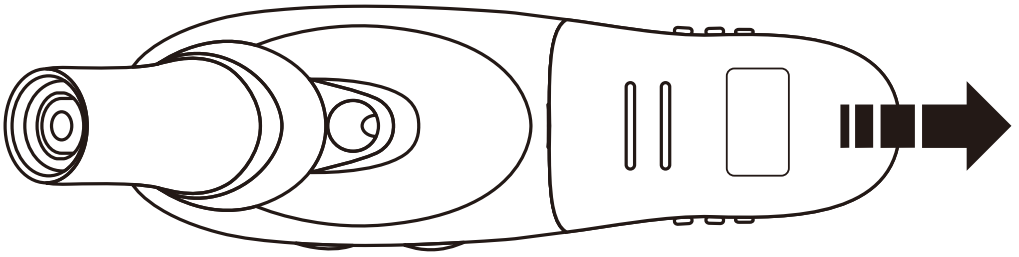
RECOMMENDATIONS

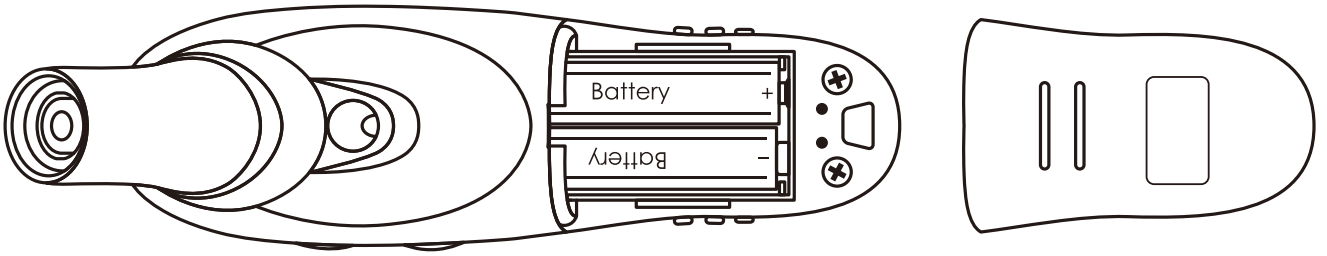
1. For new users, it is recommended to measure the same ear 3 times for the first time. The maximum reading shall be recorded in case of different results since any thermometer suffering a continuous operation is deemed to see a slight error of (+/- 0.3°C,+/- 0.5°F).
2. Wait about 30 seconds before measuring the same patient again to avoid excessive cooling of the skin.
3. For users in sound health, both ears are almost the same in terms of body temperature.
4. Please clean the ear before measuring.

REPLACE A BATTERY

Remove the battery compartment door. Use only new batteries (2 x AAA battery).

Replace the battery compartment tightly.





MAINTENANCE, STORAGE AND CALIBRATION

Maintenance:

1. Remove any stains on the body with a soft and dry cloth.
2. Don't wash with water or detergent containing abrasive or benzene.

Storage:

1. Clean the thermometer and use the cover to protect the lens after each use.
2. Don't leave the thermometer exposed to or at high risk of direct sunlight, high temperature, dampness, fire, flame, vibration or impact.
3. Remove the battery if the device will not be used for a long period of time.

Calibration:

This thermometer is calibrated at the time of manufactured. If the thermometer is used according to the instructions, periodic recalibration is not required. If at any time you question the accuracy of the measurement, please contact the retailer immediately.

Don't attempt to modify or reassemble the thermometer.

TROUBLES AND TROUBLESHOOTING

Troubles	Check lists	Countermeasures
No response/ Automatic reset when pull out insulator	Low battery power	Change battery
	Battery in wrong polarity	Take out battery, reinsert battery correctly
	Poor battery contact	
Battery symbol on LCD	Low battery	Change new battery
“Lo” on screen (result below 32.0℃ or 89.6℉)	Thermometer rightly pointed at the eardrum / forehead?	Follow user’s manual to point at the eardrum / forehead.
“Hi” on screen (result below 42.9℃ or 109.3℉)	Please check the operation method	Follow user’s manual for proper measurement.

SPECIFICATION

- Product Name: Talking Multi-Functional Ear and Forehead thermometer
- Model: DX6635
- Power supply: DC3V (2 x AAA battery)
  Power consumption: <30mA (for voice prompt)
- Temperature sensing Part: IR sensor
- Measuring range: 32.0℃ ~ 42.9℃ (89.6℉ ~109.3℉)
- Room Temperature: 5.0℃ ~ 59.9℃ (41.0℉ ~139.8℉)
- Measuring accuracy: +/- 0.2℃ (or +/- 0.4℉)
  from 35.5℃ ~ 42.0℃ (or 95.9℉ ~107.6℉)
  +/- 0.3℃ (+/- 0.5℉)
  from 35.0℃ ~ 35.4℃ (or 89.6℉ ~ 95.8℉)
  from 41.2℃ ~ 42.9℃ (or 107.7℉ ~ 109.3℉)
- Room Temperature: +/- 1℃ (2℉)
- Outer dimension: 130(L)x41(W)X57(D)mm
- Weight : 54g (without batteries)
- Working environment: 10℃ ~ 40℃ (50.0℉ ~ 104.0℉) For Ear
  15℃ ~ 40℃ (59.0℉ ~ 104.0℉) For Forehead
  Relative humidity: 20%RH~85%RH
- Storage environment: -10℃ ~ 55℃ (14℉ ~ 131℉)
  Relative humidity: 20%RH~85%RH
- Precision/repeatability: +/- 0.3℃ (+/- 0.5℉)

*Dispose of used batteries with care consult your distribution center for details.

SYMBOLS

Attention: Read the operating instructions before use !

Applied part of type B

Disposal in accordance with Directive 2002/96/EC (WEEE)

CE 0197

Complies with the European Medical Device Directive (93/42/EEC) and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)

LOT Batch code

SN Serial number

The name and the address of the manufacturer

GUIDANCE AND MAUFACTURER'S DECLARATION

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user assures that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group2	The device must emit electromagnetic e energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	
RF emissions CISPR 14-1	Complies	The device is not suitable for interconnection with other equipment.
RF emissions CISPR 15	Complies	The device is not suitable for interconnection with other equipment.

Guidance and manufacturer's declaration — electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 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 IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	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 IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 Cycles 70% UT (30% dip in UT) for 25 Cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 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.			

Guidance and- manufacturer's declaration. Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
			Portable and mobile RF Communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance.
Conducted R F IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d=[\frac{3.5}{V1}]\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=[\frac{3.5}{E1}]\sqrt{p}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{p}$ 800 MHz to 2.5 GHz
			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 meters (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. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE I At 80 MHz ends 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 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the as recommended below, according to the maximum output power of the communications equipment.

Rated maximum transmitter output power of W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d=[\frac{3.5}{V1}]\sqrt{p}$	150 kHz to 80 MHz $d=[\frac{3.5}{E1}]\sqrt{p}$	150 kHz to 80 MHz $d=[\frac{7}{E1}]\sqrt{p}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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) accordable 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.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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) accordable to the transmitter manufacturer.

NOTE 3 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARRANTY

Two-year warranty is available from purchasing date, excluding user-caused failures listed below:

(1) Failure resulted in unauthorized disassembly and modification

(2) Failure resulted in unexpected drop during application or transportation

(3) Failure resulted in operation away from proper instruction in user's manual.

Present the Warranty Card with seal of distribution center (incl. name and address) for repair free.

DECLARATION OF CONFORMITY

Shenzhen Dongdixin Technology Co., LTD declares that the DX6635 complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-1-4, ASTM E1965-98, ISO10993-5, ISO10993-10, ISO10993-1,ISO 14971,EN 12470-5.

1) Under the environment with electrostatic discharge, the unit may malfunction and may require user to reset the unit.
2) Dispose with care, please consult the retailer for details.

Distributed by:
Omega Medical Instruments Pty Ltd
Suite 8, Level 12 101 Bathurst Street NSW 2000 AUSTRALIA

Manufacturer:
Name: Shenzhen Dongdixin Technology Co., LTD.
Add: No.3 Building XiliBaimang Xusheng Industrial Estate, 518108 Nanshan, Shenzhen China

Authorized EC-representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg Germany

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