Operator's Manual

Transmitter ZM-520PA, ZM-521PA ZM-530PA, ZM-531PA





0614-904743G

About This Manual

In order to use this product safely and fully understand all its functions, read this manual before using the product. Keep this manual near the instrument or in the reach of the operator and refer to it whenever the operation is unclear.

The manual is only included on the CD. We recommend printing a copy of the electronic data for reference in case of emergency. If you require printed version of the manual, contact your Nihon Kohden representative.

Copyright Notice

The entire contents of this manual are copyrighted by Nihon Kohden. All rights are reserved. No part of this document may be reproduced, stored, or transmitted in any form or by any means (electronic, mechanical, photocopied, recorded, or otherwise) without the prior written permission of Nihon Kohden.

This product stores personal patient information. Manage the information appropriately. Patient names on the screen shots and recording examples in this manual are fictional and any resemblance to any person living or dead is purely coincidental.

The contents of this manual are subject to change without notice. If you have any comments or suggestions on this manual, please contact us at: https://www.nihonkohden.com/

Contents

GENERAL HANDLING PRECAUTIONS	i
WARRANTY POLICY	iii
Equipment Authorization Requirement	iv
Compliance with FCC Requirements	iv
EMC RELATED CAUTION	
Conventions Used in this Manual and Instrument	vii
Warnings, Cautions and Notes	vii
Explanations of the Symbols in this Manual and Instrument	viii
Intended Use	1
General	1
Receiving Monitor	
Panel Description	4
Top Panel	4
Front Panel	5
Rear Panel	
Important Safety Information	
General	
Output Signal	11
Battery	
Transmitter Channel Management	
For Patients Using Implantable Pacemaker	
ECG Monitoring	
SpO ₂ Monitoring	15
Maintenance	
Preparation on Transmitter	
Batteries	
Handling Batteries	
Battery Lifetime	
Installing (Replacing) Batteries	
Situations Requiring Battery Replacement	
Battery Level Indication	
Attaching a Strap to the Transmitter	
Turning On the Transmitter	
Check Items Before Use	
Check Items After Power On	
Check Items After Use	
Turning Off the Transmitter	
Changing the Transmitter Channel	
Changing Parameter and System Setup Settings	
Changing PARAMETER SETUP Settings	

Parameter Setup Setting List	. 25
Displaying the PARAMETER SETUP Screen	
Changing Parameter Setup Settings	. 27
Changing SYSTEM SETUP Settings	. 30
System Setup Setting List	. 30
Displaying the SYSTEM SETUP Screen	. 31
Changing System Setup Settings	
Initializing Settings	. 35
Attaching Electrodes and SpO ₂ Probe to the Patient	. 36
Attaching Electrodes	. 36
Selecting Electrode Lead	. 36
Connecting the Electrode Lead to the Transmitter	. 36
Electrode Position	. 37
Attaching Electrodes to the Patient and Connecting the Electrode Leads to	
Disposable Electrodes	. 40
Checking ECG on the Transmitter Screen	. 41
Attaching the SpO ₂ Probe	. 41
Selecting the SpO ₂ Probe	. 41
Connecting the SpO ₂ Probe to the Transmitter	. 44
Attaching the Probe to the Patient	. 45
Locking the Keys on the Transmitter	. 47
Monitoring	. 48
Screen Descriptions	. 48
Check Electrodes Screen	. 49
Numeric and Waveform Screen	. 50
Waveform Review Screen	. 51
Numeric Review Screen	. 52
Display Off	. 52
Basic Monitoring Operation	. 53
Using the Function Key	. 53
Suspending Alarms on the Receiving Monitor	. 54
Pausing Monitoring	. 55
Resuming Monitoring after Pause	
Confirming the Patient	. 57
Turning the Display Off	. 58
Turning the Display On after It was Turned Off	. 59
ECG and Respiration Monitoring	. 60
Turning ECG Measurement On/Off	
Turning Respiration Measurement On/Off	
Electrode Detachment	. 63
SpO ₂ Monitoring	. 64
Indications and Messages	. 68

Indication	. 68
Messages	. 68
Message Display Priority	. 71
Troubleshooting	. 72
Transmitter	. 72
ECG/Respiration	. 73
SpO ₂	. 74
Maintenance	. 75
1. External Check	. 75
2. Transmitter Channel	. 75
3. Transmitting/Receiving Signal	. 76
4. Display	. 76
5. Key Operation	. 78
6. ECG Check	. 79
7. Respiration Check	. 80
8. SpO ₂ Check	. 80
Maintenance Check Sheet	
Lifetime and Disposal	. 84
Disposing of Used Batteries	. 84
Battery Lifetime	. 84
Disposal	. 84
Disposing of Electrodes and SpO ₂ Probes	. 84
Disposing of Transmitter	. 84
Cleaning, Disinfection and Sterilization	. 85
Transmitter and Electrode Leads	. 85
Cleaning	. 85
Disinfection	. 85
SpO ₂ Probe	. 86
Periodic Replacement Schedule	. 86
Repair Parts Availability Policy	. 86
Specifications	
ZM-520PA/ZM-530PA	. 87
Measured Parameters	. 87
Transmitted Data	. 87
Display	. 87
Displayed Data	. 87
ECG	. 87
Respiration Measurement	
SpO ₂ Measurement (ISO 9919: 2005 compliance)	
Transmitter	. 91
Power Requirements	. 92
Dimension and Weight	. 92

Environment	
Safety Standards	
Electromagnetic Compatibility	
Electromagnetic Emissions	
Electromagnetic Immunity	
Recommended Separation Distances between Portable and Mobile RF	
Communications Equipment	
Recovery Time after Defibrillation	
System Composition for EMC Test	
ZM-521PA/ZM-531PA	
Measured Parameters	
Transmitted Data	
Display	
Displayed Data	
ECG	
Respiration Measurement	
SpO ₂ Measurement (ISO 9919: 2005 compliance)	
Transmitter	101
Power Requirements	102
Dimension and Weight	102
Environment	102
Safety Standards	102
Electromagnetic Compatibility	103
Electromagnetic Emissions	103
Electromagnetic Immunity	104
Recommended Separation Distances between Portable and Mobile RF	
Communications Equipment	106
Recovery Time after Defibrillation	106
System Composition for EMC Test	107
Standard Accessories	108
Options	109
Transmitter	109
ECG/RESP	109
SpO ₂	110
Transmission Frequencies	111

GENERAL HANDLING PRECAUTIONS

This device is intended for use only by qualified medical personnel. Use only Nihon Kohden approved products with this device. Use of nonapproved products or in a non-approved manner may affect the performance specifications of the device. This includes, but is not limited to, batteries, recording paper, pens, extension cables, electrode leads, input boxes and AC power.

Please read these precautions thoroughly before attempting to operate the instrument.

- 1. To safely and effectively use the instrument, its operation must be fully understood.
- 2. When installing or storing the instrument, take the following precautions.
 - (1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and dust, saline or sulphuric air.
 - (2) Place the instrument on an even, level floor. Avoid vibration and mechanical shock, even during transport.
 - (3) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.
 - (4) The power line source to be applied to the instrument must correspond in frequency and voltage to product specifications, and have sufficient current capacity.
 - (5) Choose a room where a proper grounding facility is available.

3. Before Operation

- (1) Check that the instrument is in perfect operating order. Check for cracks and breaks on the case.
- (2) Check that the instrument is grounded properly.
- (3) Check that all cords are connected properly.
- (4) Pay extra attention when the instrument is in combination with other instruments to avoid misdiagnosis or other problems.
- (5) All circuitry used for direct patient connection must be doubly checked.
- (6) Check that battery level is acceptable and battery condition is good when using batteryoperated models.

4. During Operation

- (1) Both the instrument and the patient must receive continual, careful attention.
- (2) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.
- (3) Avoid direct contact between the instrument housing and the patient.
- (4) Avoid dropping the transmitter. This may damage the transmitter LCD display. When dropped, the LCD display may show no image (white screen) or a partial image.

5. To Shutdown After Use

- (1) Turn power off with all controls returned to their original positions.
- (2) Remove the cords gently; do not use force to remove them.
- (3) Clean the instrument together with all accessories for their next use.
- 6. The instrument must receive expert, professional attention for maintenance and repairs. When the instrument is not functioning properly, it should be clearly marked to avoid operation while it is out of order.
- 7. The instrument must not be altered or modified in any way.

8. Maintenance and Inspection

- (1) The instrument and parts must undergo regular maintenance inspection at the interval which is specified after the GENERAL HANDLING PRECAUTIONS section.
- (2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition.
- (3) Technical information such as parts list, descriptions, calibration instructions or other information is available for qualified user technical personnel upon request from your Nihon Kohden representative.
- 9. When the instrument is used with an electrosurgical instrument, pay careful attention to the application and/or location of electrodes and/or transducers to avoid possible burn to the patient.
- 10. When the instrument is used with a defibrillator, make sure that the instrument is protected against defibrillator discharge. If not, remove patient cables and/or transducers from the instrument to avoid possible damage.

WARRANTY POLICY

Nihon Kohden Corporation (NKC) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery are excluded from the warranty.

NKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the operator's and service manuals.

No other party is authorized to make any warranty or assume liability for NKC's products. NKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKC or its authorized agents without prior consent of NKC may be cause for voiding this warranty.

Defective products or parts must be returned to NKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

In the USA and Canada other warranty policies may apply.

CAUTION

United States law restricts this device to sale by or on the order of a physician.

Equipment Authorization Requirement

Compliance with FCC Requirements

This device complies with Part 15 of the FCC (Federal Communications Commission) Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Part 95 Subpart H of the FCC Rules to be used in wireless medical telemetry service.

Operation of this equipment requires the prior coordination with a frequency coordinator designated by FCC for the Wireless Medical Telemetry Service.

CAUTION

To comply with the FCC radio frequency (RF) exposure compliance requirements, no change to the antenna or the device is permitted. Any change to the antenna or the device could result in the device, exceeding the RF exposure requirements and void user's authority to operate this device.

NOTE

- · Use this device only indoors.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines as this equipment has very low levels of RF energy. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- The devices require registration and deployment by an authorized frequency coordinator. The ASHE (American Society for Healthcare Engineering) has been designated by the FCC to manage the WMTS frequencies. This device has frequency bands which may not be used in some areas. For details, contact your Nihon Kohden representative. For details on the guidelines, refer to the ASHE home page.

EMC RELATED CAUTION

This equipment and/or system complies with the International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in the IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

- Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorized radio station. Keep the emitter source such as cellular phone away from the equipment and/or system.
- Effect of direct or indirect electrostatic discharge Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it.
- 3. Electromagnetic interference with any radio wave receiver such as radio or television

If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

4. Electromagnetic interference with any radio wave receiver such as radio or television

If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

5. Interference of lightning

When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system. In such a case, disconnect the AC power cord from the equipment and/or system and operate the equipment and/or system by battery power, or use an uninterruptible power supply.

6. Warning: Use with other equipment

When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before use, check that the equipment and/or system operates normally with the other equipment.

7. Warning: Use of unspecified accessory, transducer and/or cable When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

8. Use of unspecified configuration

When the equipment and/or system is used with the unspecified system configuration different than the configuration of EMC testing, it may cause increased electromagnetic emission or decreased electromagnetic immunity. Only use this equipment and/or system with the specified configuration.

9. Measurement with excessive sensitivity

The equipment and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the equipment and/or system is used with excessive sensitivity, artifact may appear by electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove this artifact source.

10. Use with radiation therapy equipment

When the equipment and/or system is used in a radiotherapy room, it may cause failure or malfunction due to electromagnetic radiation or corpuscular radiation. When you bring the equipment and/or system into a radiotherapy room, constantly observe the operation. Prepare countermeasures in case of failure or malfunction.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

Conventions Used in this Manual and Instrument

Warnings, Cautions and Notes

Warnings, cautions and notes are used in this manual to alert or signal the reader to specific information.

WARNING

A warning alerts the user to the possible injury or death associated with the use or misuse of the instrument.

CAUTION

A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

NOTE

A note provides specific information, in the form of recommendations, prerequirements, alternative methods or supplemental information.

Explanations of the Symbols in this Manual and Instrument

The following symbols found in this manual/instrument bear the respective descriptions as given.

On Panel

Symbol	Description	Symbol	Description
ð	Change screen	-I <u>∳</u> , ŀ	Defibrillation proof type BF applied part
\triangle	Attention, consult operator's manual	ł	Defibrillation proof type CF applied part
	Moves cursor, scrolls data	SN	Serial number
\triangleright	Direction for attaching battery cover	\bigwedge	Date of manufacture
•	Direction for inserting battery	(((•)))	RF transmitter Non-ionizing radiation
	Direct current		cCSAus mark
÷	Call key		

On LCD

Symbol	Description	Symbol	Description
	Batteries are fully charged		Batteries are almost empty Replace battery
	Batteries are getting low	$\Delta \Sigma_2$	Alarm suspended
	Batteries are low		QRS/pulse sync mark

Intended Use

General

The ZM-520PA and ZM-521PA transmitters transmit ECG and respiration from a patient to a Nihon Kohden monitor for continuous monitoring. The front LCD displays ECG, numeric values of monitoring parameters, messages and battery condition.* They also display the compressed waveform and numeric data of the latest 10 minutes.

The ZM-530PA and ZM-531PA transmitters transmit ECG, respiration and pulse waveforms and SpO₂ from a patient to a Nihon Kohden monitor for continuous monitoring. The front LCD displays ECG (or pulse wave), numeric values of monitoring parameters, messages and battery condition.* They also display the compressed waveform and numeric data of the latest 10 minutes.

* Essential performance of this transmitter.

The difference between ZM-520PA/530PA and ZM-521PA/531PA is the transmission frequency range.

ZM-520PA/530PA:

608.0250 to 613.9750 MHz (channel number 9002 to 9478)

ZM-521PA/531PA:

1395.0250 to 1399.9750 MHz (channel number E002 to E398)

1427.0250 to 1431.9750 MHz (channel number E502 to E898)

NOTE

- The transmitter channel can be changed with a QI-901PK channel writer.
- Read the operator's manual for the receiving monitor together with this manual before use.

WARNING

Do not diagnose a patient based only on data acquired by the transmitter. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the transmitter and by reading the biomedical signals acquired by other instruments.

WARNING

Do not use the same transmitter for more than one patient at the same time. Do not connect different sensors from different patients to the same transmitter.

CAUTION

- Do not use the same channel for different patients. If the same channel is used for two patients, the two patients' data will be lost due to mutual modulation interference, or another patient's data may appear on the receiving monitor screen.
- Do not use two transmitters with adjacent channels in the same hospital. If transmitters with adjacent channels are used, their radio waves interfere with each other.

CAUTION

Signal loss and artifact may occur because of the multipath cancellation* when using a transmitter.

* Multipath Cancellation (Standing Wave Interference):

When a radio wave reflects off a surface, there may be some points in the room where the reflected and direct waves are exactly out of phase. At these points in the room, the reflected and direct waves cancel each other out so that the signal strength is decreased. Locations where signal loss occurs are called "null spots". If the transmitter is moving or nearby people or objects are moving, null spots can occur anytime and anywhere.

NOTE

- To prevent interference between channels, assign a channel administrator in the hospital and only he or she should manage channel assignment.
- Use Nihon Kohden parts and accessories to assure maximum performance from your instrument.
- For stable signal reception, it is recommended to use a diversity antenna system on the receiving monitor. Otherwise, spike noise from transient fading of electric field strength (for example, people moving) may interfere with the transmitter signal and may be mistaken as an arrhythmia on the receiving monitor.
- For details on antennas and antenna construction, contact your Nihon Kohden representative. You can also refer to the Telemetry System Installation Guide.
- To prevent damage, avoid dropping the transmitter. Dropping may damage the transmitter LCD display and may result in no image (white screen) or a partial image on the screen.

Receiving Monitor

Any Nihon Kohden receiving monitor (central monitor with multiple patient receiver) can receive signals from this transmitter as long as the protocol version and channel setting are the same on the receiving monitor and transmitter.

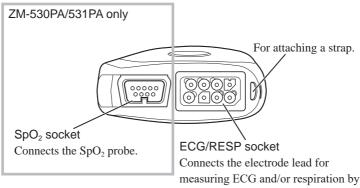
If the transmitter LCD display is damaged, it may display no image (white screen) or a partial image. However, all features remain functional, including alarms and transmission of patient physiological data (ECG, respiration, SpO_2 and pulse waveform) to the multiple patient receivers, central monitors and/or bedside monitors.

NOTE

- For details on the receiving monitor and upgrade information, contact your Nihon Kohden representative.
- The transmitter does not give any alarm other than a "low battery" alarm. Alarms must be managed on the receiving monitor.
- To use protocol 51, an ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required. For the protocol setting, refer to the "Changing SYSTEM SETUP Settings" section.

Panel Description

Top Panel



WARNING

Before defibrillation, all persons must keep clear of the bed and must not touch the patient or any equipment or cord connected to the patient. Failure to follow this warning may cause electrical shock or injury.

the impedance method.

WARNING

When performing defibrillation, discharge as far as possible from electrodes, patches and any gel, cream or medicine on the chest of the patient. If there is a possibility that the defibrillator paddle could touch these materials, remove them from the patient. If the defibrillator paddle directly contacts these materials, the discharged energy may cause skin burn to the patient.

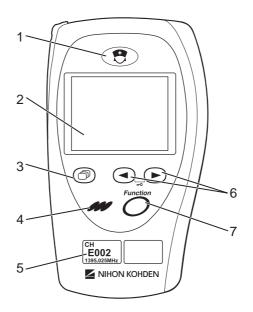
WARNING

When the transmitter is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the transmitter, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

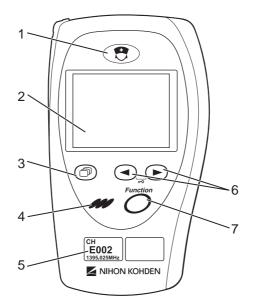
CAUTION

Do not shake or swing the transmitter while holding the leads or cables connected to the transmitter. The transmitter may come off and injure someone or damage surrounding instruments.

Front Panel

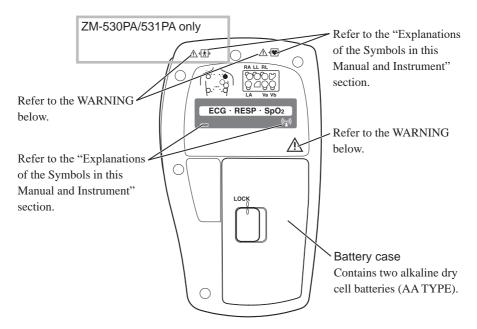


<u>No.</u>	<u>Name</u>	Description
1	CALL key	When this key is pressed, a "peep" sounds at the transmitter,
		and "CALL" message appears at the monitor. Depending on
		the settings on the monitor, an ECG waveform is recorded when
		this key is pressed.
2	LCD	Displays numeric values, ECG or pulse wave, messages and
		battery status. For details, refer to the "Screen Descriptions" section.
3	Screen key	Toggles the screen in the following order.
		After power on: Start up \rightarrow Check electrodes \rightarrow Numeric and waveform \rightarrow Waveform review \rightarrow Numeric review \rightarrow Display off \rightarrow Check electrodes
		After auto display off: Numeric and waveform \rightarrow Waveform review \rightarrow Numeric review \rightarrow Display off \rightarrow Check electrodes \rightarrow Numeric and waveform
		On a SETUP or CHECK screen, this key cancels changing setting or exits the screen.



<u>No.</u>	<u>Name</u>	Description
4	Infrared receiver	Used for upgrading the transmitter software.
5	Channel number label	Indicates the channel number of the transmitter.
6	Lead/Scroll keys	On the numeric and waveform screen, these keys change the ECG lead.
		On the waveform review screen, these keys scroll data.
		On a SETUP screen, these keys move the cursor.
7	Function key	Depending on the setting on the transmitter, this key suspends alarms, pauses monitoring on the receiving monitor or transmits the "Patient confirmed" message.
		On a SETUP screen, this key registers the selected setting and moves the cursor to the next setting item.
		On a CHECK screen, this key starts or stops the maintenance test.

Rear Panel



WARNING

Close the battery case cover during operation. If the transmitter is used with the battery case cover open, anyone who touches the opened battery case may receive an electrical shock when defibrillation is performed. Touching the opened battery case may cause electrostatic discharge and intermittently interfere with the waveform or data.

WARNING

This transmitter is not waterproof. If detergent or liquid spills into the transmitter, stop using it and contact your Nihon Kohden representative. If a wet transmitter is used, the patient or operator may receive an electrical shock or injury.

Important Safety Information

General

WARNING

Never use the transmitter in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

WARNING

Do not take this transmitter into the MRI test room. This transmitter is not designed to be used during MRI tests.

WARNING

Before defibrillation, all persons must keep clear of the bed and must not touch the patient or any equipment or cord connected to the patient. Failure to follow this warning may cause electrical shock or injury.

WARNING

When the transmitter is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the transmitter, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

WARNING

Never use the transmitter in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

WARNING

When performing MRI test, remove all electrodes and probe from the patient which are connected to this transmitter. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

WARNING

When performing defibrillation, discharge as far as possible from electrodes, patches and any gel, cream or medicine on the chest of the patient. If there is a possibility that the defibrillator paddle could touch these materials, remove them from the patient. If the defibrillator paddle directly contacts these materials, the discharged energy may cause skin burn to the patient.

WARNING

Do not damage the transmitter by dropping it. This may result in no image (white screen) or a partial image on the LCD display of the transmitter.

WARNING

Do not use the same transmitter for more than one patient at the same time. Do not connect different sensors from different patients to the same transmitter.

WARNING

This transmitter is not waterproof. If detergent or liquid spills into the transmitter, stop using it and contact your Nihon Kohden representative. If a wet transmitter is used, the patient or operator may receive an electrical shock or injury.

Do not diagnose a patient based only on data acquired by the transmitter. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the transmitter and by reading the biomedical signals acquired by other instruments.

WARNING

WARNING

Close the battery case cover during operation. If the transmitter is used with the battery case cover open, anyone who touches the opened battery case may receive an electrical shock when defibrillation is performed. Touching the opened battery case may cause electrostatic discharge and intermittently interfere with the waveform or data.

WARNING

When the signal is unstable, keep the patient under close observation. When the signal is unstable, the monitoring and alarm are not reliable and the receiving monitor cannot detect a sudden change of the patient's condition. This may cause critical changes in the patient condition to be overlooked. Install an appropriate antenna system to ensure stable signal condition.

WARNING

While the "ALARMS SUSPENDED" message is displayed on the transmitter, all alarms on the receiving monitor are suspended so keep the patient under close observation.

WARNING

When the patient returns to the bed, turn on the transmitter and check that the monitoring is resumed on the receiving monitor.

WARNING

If the transmitter is not turned off and monitoring continues for the selected interval, pause monitoring is canceled and monitoring continues. Check that the monitoring is resumed on the receiving monitor.

CAUTION

Only use Nihon Kohden specified electrodes, electrode leads and SpO₂ probes. Otherwise, the maximum performance from the transmitter cannot be guaranteed.

CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may be mistaken as pulse waves or respiration waves and the displayed data may be incorrect.

CAUTION

Signal loss and artifact may occur because of the multipath cancellation* when using a transmitter.

* Multipath Cancellation (Standing Wave Interference):

When a radio wave reflects off a surface, there may be some points in the room where the reflected and direct waves are exactly out of phase. At these points in the room, the reflected and direct waves cancel each other out so that the signal strength is decreased. Locations where signal loss occurs are called "null spots". If the transmitter is moving or nearby people or objects are moving, null spots can occur anytime and anywhere.

CAUTION

The measurement values and displayed waveforms on the transmitter and receiving monitor may be different due to timing delay of the display or difference in detection settings.

CAUTION

- Do not use the same channel for different patients. If the same channel is used for two patients, the two patients' data will be lost due to mutual modulation interference, or another patient's data may appear on the receiving monitor screen.
- Do not use two transmitters with adjacent channels in the same hospital. If transmitters with adjacent channels are used, their radio waves interfere with each other.

CAUTION

Do not shake or swing the transmitter while holding the leads or cables connected to the transmitter. The transmitter may come off and injure someone or damage surrounding instruments.

CAUTION

Do not reuse disposable parts and accessories.

CAUTION

When monitoring respiration is needed, measure respiration with an instrument. The transmitter calculates SpO_2 of arterial blood based on the principle of pulse oximeter and does not measure respiration.

CAUTION

When monitoring SpO_2 only, detection of arrhythmia and asystole is not available and arrhythmia alarms such as ASYSTOLE, VF or VT are not available. If the patient requires ECG monitoring, monitor the ECG.

CAUTION

When monitoring SpO_2 only (without ECG monitoring), turn on both the upper and lower limit alarms for PR and SpO_2 on the receiving monitor. If the patient's pulse is not detected during asystole or other condition, a "CANNOT DETECT PULSE" or "CHECK PROBE" alarm occurs instead of an SpO_2 limit alarm. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO_2 value to be displayed.

Output Signal

WARNING

Do not use the output signal from the receiving monitor as the synchronization signal for other equipment such as IABP, MRI, echocardiography or defibrillator. There may be time delay between the monitor and the other equipment caused by waveform transmission delay and spike noise may interfere on the output signal and be mistaken as a trigger.

Battery

WARNING

Do not use NiMH batteries for this transmitter. Some operating environments may cause NiMH batteries to produce gas and explode.

CAUTION

Do not handle the batteries with wet hands.

CAUTION

Battery replacement must be performed by the operator. When replacing the batteries of a transmitter that is currently used for a patient, disconnect the electrode leads from the transmitter before replacing batteries or do not touch the patient during replacement.

CAUTION

Refer to the battery manual for details on handling the batteries.

CAUTION

When the transmitter is not in use, remove the batteries. When the batteries are installed, battery power is consumed even when measurement is not performed.

Transmitter Channel Management

WARNING

The following actions must be taken to properly receive the transmitter signal of the correct patient on the receiving instrument. Otherwise, there may be signal loss or signals may mix causing a serious accident, such as monitoring a different patient.

- Assign a channel administrator in the hospital and only he or she should manage channel assignment.
- The channel administrator must manage the channels in the facility so that there is no signal interference.
- When the transmitter channel is changed, the channel administrator must check that the channel on the receiving monitor is also changed and the signal is properly received.
- The channel administrator must replace the channel number label on the transmitter with the new one after changing the channel.

For Patients Using Implantable Pacemaker

WARNING

The bioelectric impedance measurement sensor of a minute ventilation rate-adaptive implantable pacemaker may be affected by transmitter which is connected to the same patient. If this occurs, the pacemaker may pace at its maximum rate and the transmitter may give incorrect data to the monitor. If this occurs, disconnect the electrode leads from the patient or change the setting on the pacemaker by referring to the pacemaker's manual. For more details, contact your pacemaker representative or Nihon Kohden representative.

ECG Monitoring

WARNING

After attaching the electrode to the patient and connecting the electrode lead to the transmitter, check that electrodes are attached to the patient and check that the electrode lead is connected to the transmitter properly. When the electrodes are removed from the patient, do not touch the metal part of the electrode with bare hands or let the metal part of the electrode contact the metal part of the bed or any other conductive parts. Failure to follow this warning may cause electrical shock or injury to the patient by discharged energy.

WARNING

The pacemaker pulse can be overlooked or detected as QRS. You cannot confirm the pacemaker operation only from the detected pacemaker pulse.

WARNING

The transmitter detects the pacemaker pulse and rejects the pacemaker pulse from the heart rate count. However, all of the pacemaker pulse might not be rejected. If the pacemaker pulse is not rejected, the pacemaker pulse is detected as QRS and false heart rate may be indicated. Keep pacemaker patients under close observation.

* For the pacemaker pulse rejection capability of the ZM-520PA/521PA/530PA/531PA transmitter refer to the "Specifications -ECG" section.

CAUTION

Only use Nihon Kohden specified electrodes and electrode leads. When other type of electrodes or electrode leads are used, the "CHECK ELECTRODES" message may be displayed and ECG monitoring may stop.

CAUTION

Hold the connector of the electrode lead when connecting/disconnecting the electrode lead. If you disconnect the electrode lead by pulling the lead, it damages the electrode lead.

CAUTION

When the "CHECK ELECTRODES" message is displayed on the receiving monitor, ECG is not monitored properly and the ECG alarm does not function. Check the electrode, electrode leads, and if necessary, replace with new ones.

SpO₂ Monitoring

WARNING

SpO₂ measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- When using an electrosurgical unit.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the pulse wave is small (insufficient peripheral circulation).

WARNING

- When using the TL-201T finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or pressure necrosis from poor blood circulation.
- When using probes other than the TL-201T finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or pressure necrosis from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

WARNING

When monitoring SpO_2 of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity.

The SpO₂ probes manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is less than 5.5 mW.

WARNING

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes (every 8 hours for TL-631T series probe). The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or pressure necrosis. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- · Patient with a fever
- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

WARNING

When not monitoring SpO_2 , disconnect the SpO_2 cable from the transmitter. Otherwise, noise from the probe sensor may interfere and incorrect data is displayed on the screen.

CAUTION

The disposable probe is not sterilized. Use the disposable probe only for a single patient. Never reuse the disposable probe for another patient because it causes cross infection.

CAUTION

Do not attach the probe to the same limb that is used for NIBP measurement or an IBP catheter. The SpO₂ measurement may be incorrect.

CAUTION

When a message indicates a faulty probe, stop monitoring and replace the probe with a new one.

CAUTION

Do not use a damaged or disassembled probe. It causes incorrect measurement and may injure the patient.

CAUTION

Refer to the probe instruction manual for details.

CAUTION

While a patient is on medication which causes vasodilation, the pulse waveform may change and in rare cases the SpO₂ value might not be displayed.

CAUTION

Normal external light does not affect monitoring but strong light such as a surgical light or sunlight may affect monitoring. If affected, cover the measuring site with a blanket.

CAUTION

Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed.

CAUTION

When the probe is attached on an appropriate site with sufficient circulation and the error message confirming the probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

CAUTION

Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn on the patient from the probe temperature increase due to the short circuit of the probe cable, and incorrect measurement data. If the probe is broken, replace it with a new one.

- Do not immerse any part of the probe cable other than the disposable probe in chemical solutions or water.
- Do not pull or bend the probe cable.
- Do not let caster feet run over the probe cable.

CAUTION

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

CAUTION

If the skin gets irritated or redness appears on the skin from the probe, change the attachment site or stop using the probe. Take extreme care for the patients with delicate skin.

Maintenance

CAUTION

This transmitter is not waterproof. If detergent or liquid spills into the transmitter, stop cleaning or disinfecting it and contact your Nihon Kohden representative. The transmitter needs to be checked for safety and function before use.

CAUTION

Do not immerse the electrode lead connector in liquid.

CAUTION

Never disassemble or repair the transmitter. If there is any problem with the transmitter, contact your Nihon Kohden representative.

CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

Preparation on Transmitter

Batteries

Handling Batteries

WARNING

Do not use NiMH batteries for this transmitter. Some operating environments may cause NiMH batteries to produce gas and explode.

CAUTION

Refer to the battery manual for details on handling the batteries.

CAUTION

Do not handle the batteries with wet hands.

CAUTION

When the transmitter is not in use, remove the batteries. When the batteries are installed, battery power is consumed even when measurement is not performed.

NOTE

Remove the batteries from the transmitter before disposing of it.

Battery Lifetime

Use two AA (LR6) type alkaline dry cell batteries. With new Nihon Kohden recommended alkaline batteries, the transmitter can continuously measure for the following number of days at room temperature. Operation time depends on the thickness of the SpO_2 probe attachment site.

Transmitter	Operating Time (Measuring parameters)		Operating Time (Measuring parameters)	
Transmitter	ECG, Resp, SpO ₂	ECG, Resp		
ZM-520PA/ZM-530PA	2.5 days	3.5 days		
ZM-521PA/ZM-531PA	2.0 days	2.5 days		

Recommended Batteries

Alkaline primary: Nihon Kohden Medipower (equivalent to Panasonic LR6 (G))

NOTE

- Use Nihon Kohden Medipower to ensure specified performance. Outdated, mismatched or poor-quality batteries can give unacceptable performance (e.g., insufficient low battery indication). The use of fresh high quality alkaline batteries is strongly recommended.
- When the display is on, it consumes battery power. Instruct the patient not to turn on the display during monitoring.

Installing (Replacing) Batteries

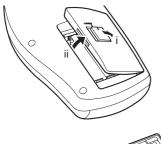
CAUTION

Battery replacement must be performed by the operator. When replacing the batteries of a transmitter that is currently used for a patient, disconnect the electrode leads from the transmitter before replacing batteries or do not touch the patient during replacement.

If electrode leads are attached to the patient and the person replacing batteries touches the patient during battery replacement, excess patient leakage current may flow into the patient.

NOTE

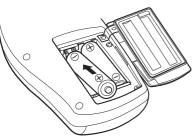
- Replace all batteries at the same time.
- · Do not use different types of batteries together.
- Insert the batteries with the correct polarity (+ and –).

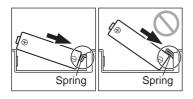




2. Insert two new batteries into the battery case observing the correct polarity.

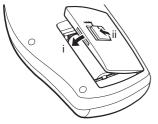
The transmitter is automatically turned on when the batteries are installed.





NOTE

- As shown in the diagram, slide each battery into the compartment so the negative terminal of the battery is pressing against the spring. Inserting a battery at the wrong angle may deform the spring and cause a short circuit or damage the battery compartment.
- Inserting the positive terminal first and then forcing the battery into the compartment may damage the battery or the transmitter.
- 3. Close the cover.



Situations Requiring Battery Replacement

Replace the batteries when any of the following occurs.

- The transmitter displays the "BATTERY WEAK" message or \blacksquare icon.
- The transmitter generates a constant alarm (continuous "peep" sound).
- The transmitter LCD does not display anything when the power is turned on.
- The receiving monitor displays a battery replacement message.

Battery Level Indication

The following icons on the LCD indicate the battery level. When "PROTOCOL" on the SYSTEM SETUP screen is set to 51, the battery level indication is transmitted to the receiving monitor. To use protocol 51, the ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.

Indication	Battery Level	Message on the Receiving Monitor
	Batteries are fully charged.	
	Batteries are getting low.	There is no message on the monitor.
4	Batteries are low.	
	Batteries are almost empty. Replace batteries.	Message requiring battery replacement is displayed.
No indication	Dead batteries	No signal can be transmitted to the monitor. There is no indication on the monitor.

Attaching a Strap to the Transmitter

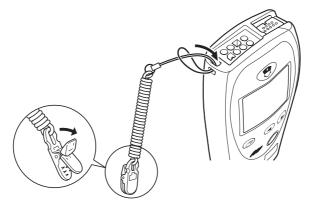
NOTE

Do not attach the clip to hard objects such as thick cloth or a zipper. It will break the clip.

Attach a strap to the transmitter and fasten the clip to the patient's clothes or bed sheets.

If the transmitter falls off, the transmitter may be damaged and the batteries may come out. If the patient touches the battery terminal when putting the batteries back in the transmitter, excess patient leakage current may flow into the patient.

If the transmitter falls into water or a toilet, stop using the transmitter and contact your Nihon Kohden representative.



Turning On the Transmitter

When the batteries are installed correctly, the power is turned on. A "peep" sounds for one second, the startup screen appears, then the check electrodes screen appears. (There is no "peep" sound when there is no battery power.)



After checking that the ECG is stable on the check electrodes screen, press the Screen key to display the numeric and waveform screen.



For details on the screen, refer to the "Screen Descriptions" section.

Check Items Before Use

Before turning on the transmitter power, check the following to confirm that the transmitter can be used in normal and safe condition.

Appearance

- There are no damaged or dirty parts on the outside of the transmitter (LCD, keys, sockets, battery case cover, battery case, etc.).
- The transmitter is completely dry.
- The electrodes, electrode lead and SpO₂ probe are not broken.

Batteries

- The battery polarity is correct.
- The battery case spring is firmly attached and the battery is not loose.
- The battery case cover is firmly closed.

Channel Setting

- The transmitter channel matches the receiving monitor channel.
- There is no nearby transmitter with the same channel.

Other

• When performing defibrillation, set the hum filter to ON on the receiving monitor. The waveform recovery may become slow due to electrode polarization when the hum filter is set to OFF.

Check Items After Power On

After turning on the power, check the following.

Power On

- The transmitter generates a one second "peep" sound and the startup screen appears.
- The transmitter displays the check electrodes screen.
- The transmitter is not too hot.
- The transmitter does not display the "BATTERY WEAK" message.
- The transmitter does not interfere with the operation of other medical instruments.

Daily Check

- The "signal loss" message is not displayed on the receiving monitor when the transmitter is inside the receiving range of the monitor.
- The battery replacement message is not displayed on the monitor.
- The keys on the transmitter function properly.
- The LCD brightness is appropriate. To adjust brightness, refer to the "Changing SYSTEM SETUP Settings" section.

Check Items After Use

To use the transmitter in safe and optimum condition for next time, check the following.

Before Turning Power Off

- Temporarily changed settings are changed back to the previous settings.
- There was no malfunction on the transmitter.

Storage

- ECG electrode leads and SpO₂ probe are cleaned and disinfected.
- If the transmitter got wet, liquid is wiped off and the transmitter is thoroughly dried.
- There are enough consumables, such as disposable electrodes.
- The transmitter power is turned off by removing batteries from the transmitter.
- Dead batteries are disposed of properly.

Turning Off the Transmitter

To turn off the power, remove the batteries. When the power is turned off, the saved waveform and numeric data are deleted.

Changing the Transmitter Channel

The channel of the transmitter can be changed with the optional QI-901PK channel writer.

WARNING

The following actions must be taken to properly receive the transmitter signal of the correct patient on the receiving instrument. Otherwise, there may be signal loss or signals may mix causing a serious accident, such as monitoring a different patient.

- Assign a channel administrator in the hospital and only he or she should manage channel assignment.
- The channel administrator must manage the channels in the facility so that there is no signal interference.
- When the transmitter channel is changed, the channel administrator must check that the channel on the receiving monitor is also changed and the signal is properly received.
- The channel administrator must replace the channel number label on the transmitter with the new one after changing the channel.

NOTE

- The software version of the QI-901PK channel writer must be 02-01 or later to change the channel on the transmitter.
- The channel writer must be used outside the patient environment.

The channel is displayed in the upper left corner of the screen.



Changing Parameter and System Setup Settings

The initial settings on the PARAMETER SETUP and SYSTEM SETUP screens can only be changed before monitoring. Changing these settings during monitoring interrupts monitoring.

NOTE

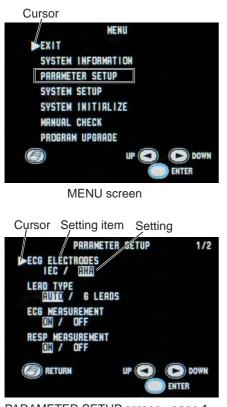
Changing Parameter and System Setup settings must be done by qualified personnel.

Changing PARAMETER SETUP Settings Parameter Setup Setting List

The factory default settings are underlined.

Setting Item	Description	Settings
ECG ELECTRODES	Select the electrode lead type.	IEC, <u>AHA</u>
LEAD TYPE	Select the type of ECG leads.	<u>AUTO</u> , 6 LEADS
ECG MEASUREMENT	Turn ECG monitoring on or off. When electrodes are attached to the patient and ECG leads are connected, ECG monitoring starts even when this setting is set to OFF. If this setting is set to OFF, the same setting on the receiving monitor must also be set to OFF. NOTE When "PROTOCOL" on the transmitter is set to 51 and the receiving monitor is able to receive protocol 51, ECG measurement on the receiving monitor is automatically set to OFF when this setting is set to OFF on the transmitter. To use protocol 51, the ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.	<u>ON,</u> OFF
RESP MEASUREMENT	Turn respiration monitoring on or off. When this setting is set to OFF, the same setting on the receiving monitor is automatically set to OFF.	<u>ON,</u> OFF
SpO ₂ RESPONSE	Select the SpO ₂ response mode.	FAST, NORMAL, <u>SLOW</u>

Displaying the PARAMETER SETUP Screen



PARAMETER SETUP screen - page 1

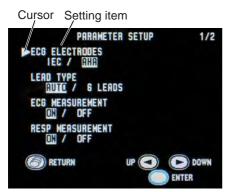
7. Press the \blacktriangleleft or \blacktriangleright key to move the cursor to "EXIT".

- 1. Turn off the transmitter by removing one battery.
- 2. While pressing the Function key, turn on the transmitter (insert the battery). The MENU screen appears.
- 3. Press the ► key to move the cursor to "PARAMETER SETUP".
- 4. Press the Function key to enter PARAMETER SETUP. The current settings are highlighted.
- 5. Change the settings:
 - To move the cursor and select the setting item, press the ◄ or ► key then press the Function key.
 - To select and register the setting, press the
 ✓ or ► key then press the Function key.
 - To cancel changing the setting of the selected item, press the Screen key.
- 6. When changing settings on the PARAMETER SETUP screen is complete, press the Screen key to return to the MENU screen.
- 8. Press the Function key. The numeric and waveform screen appears.

Changing Parameter Setup Settings

ECG ELECTRODES

Select the electrode lead type.



- On the PARAMETER SETUP screen, press the ► key to move the cursor to "ECG ELECTRODES".
- 2. Press the Function key. The cursor moves to the selection item.



- 3. Press the ► key to select "IEC" or "AHA".
- Press the Function key to register the selected setting. The cursor returns to "ECG ELECTRODES".

LEAD TYPE

Select the type of ECG leads. In normal use, select "AUTO". When using DIN type lead with 6 electrodes, select "6 LEADS".

- 1. On the PARAMETER SETUP screen, press the ► key to move the cursor to "LEAD TYPE".
- 2. Press the Function key.
- 3. Press the ► key to select "AUTO" or "6 LEADS".
- 4. Press the Function key to register the selected setting. The cursor returns to "LEAD TYPE".

ECG MEASUREMENT

Turn ECG monitoring on or off. When electrodes are attached to the patient and ECG leads are connected, ECG monitoring starts even when this setting is set to OFF.

If this setting is set to OFF, the same setting on the receiving monitor must also be set to OFF.

NOTE

When "PROTOCOL" on the transmitter is set to 51 and the receiving monitor is able to receive protocol 51, ECG measurement on the receiving monitor is automatically set to OFF when this setting is set to OFF on the transmitter. To use protocol 51, the ORG-9100A/ORG-9110A multiple patient receiver software version 03-03 or later is required.

- 1. On the PARAMETER SETUP screen, press the ► key to move the cursor to "ECG MEASUREMENT".
- 2. Press the Function key.
- 3. Press the \blacktriangleright key to select "ON" or "OFF".
- 4. Press the Function key to register the selected setting. The cursor returns to "ECG MEASUREMENT".

RESP MEASUREMENT

Turn respiration monitoring on or off. When this setting is set to OFF, the same setting on the receiving monitor is automatically set to OFF.

- 1. On the PARAMETER SETUP screen, press the ► key to move the cursor to "RESP MEASUREMENT".
- 2. Press the Function key.
- 3. Press the \blacktriangleright key to select "ON" or "OFF".
- 4. Press the Function key to register the selected setting. The cursor returns to "RESP MEASUREMENT".

SpO2 RESPONSE

Select the response mode from FAST, NORMAL or SLOW. For details on the response time, refer to the "Specifications - SpO₂ Measurement (ISO 9919: 2005 compliance)" section in this manual.

NOTE

When measurement condition is unstable due to strenuous movement of the patient, etc., response may become slower in all modes.



PARAMETER SETUP screen - page 2

- On the PARAMETER SETUP screen, press the ► key to move the cursor to "SpO2 RESPONSE". "SpO2 RESPONSE" is on the second page of the PARAMETER SETUP screen.
- 2. Press the Function key.
- Press the ► key to select "FAST", "NORMAL" or "SLOW".
- Press the Function key to register the selected setting. The cursor returns to "SpO2 RESPONSE".

Changing SYSTEM SETUP Settings

System Setup Setting List

The factory default settings are underlined.

Setting Item	Description	Settings
PROTOCOL	 Select the transmitting protocol. 51: New protocol. A central monitor with an ORG-9100A or ORG-9110A multiple patient receiver whose software version 03-03 or later can receive this protocol. 41: Old protocol. A central monitor with an ORG-9100A, ORG-9110A or ORG-9700A multiple patient receiver can receive this protocol. 	<u>51</u> , 41
	NOTE When 51 is set, the receiving monitor must be able to receive protocol 51. Otherwise, signals from the transmitter cannot be received. To use protocol 51, an ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.	
BRIGHTNESS	Select the screen brightness.	<u>DARK,</u> BRIGHT
FUNCTION KEY	Select the function of the Function key. SUSPEND ALARM & PAUSE: Suspends alarm on the receiving monitor for 2 minutes. Pauses monitoring on the transmitter and receiving monitor. SUSPEND ALARM: Suspends alarm on the receiving monitor for 2 minutes. CONFIRM: Displays the "PATIENT CONFIRMED" message on the transmitter screen and transmits the message to the receiving monitor. OFF: No function. NOTE "SUSPEND ALARM & PAUSE" and "CONFIRM" can only be set when PROTOCOL is set to 51. To use protocol 51, the ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.	SUSPEND ALARM & PAUSE, SUSPEND ALARM, CONFIRM, OFF

Setting Item	Description	Settings
AUTO RESUME AFTER PAUSE	Select the interval to resume monitoring after PAUSE.	10 s, <u>30 s</u> , 1 min, 2 min, 3 min
SELECTABLE SCREEN TIME OUT PERIOD (min)	Select the display time-out period.	5, 10, 15, <u>30</u> , 60, 120, 240

Displaying the SYSTEM SETUP Screen







SYSTEM SETUP screen - page 1

- 1. Turn off the transmitter by removing one battery.
- 2. While pressing the Function key, turn on the transmitter by inserting the battery. The MENU screen appears.
- Press the ► key to move the cursor to "SYSTEM SETUP".
- 4. Press the Function key to enter SYSTEM SETUP. The current settings are highlighted.
- 5. Change the settings.
 - To move the cursor and select the setting item, press the ◄ or ► key then press the Function key.
 - To select and register the setting, press the
 ✓ or ► key then press the Function key.
 - To cancel changing the setting of the selected item, press the Screen key.

The SYSTEM SETUP screen has two pages. To display the second page, press the \blacktriangleright key when the cursor is at "BRIGHTNESS".

- 6. When changing settings on the SYSTEM SETUP screen is complete, press the Screen key to return to the MENU screen.
- 7. Press the \blacktriangleleft or \blacktriangleright key to move the cursor to "EXIT".
- 8. Press the Function key. The numeric and waveform screen appears.

Changing System Setup Settings

PROTOCOL

Select the transmitting protocol. For differences between protocols, refer to the table below.

- 51: New protocol. A central monitor with an ORG-9100A or ORG-9110A multiple patient receiver whose software version 03-03 or later can receive this protocol.
- 41: Old protocol. A central monitor with an ORG-9100A, ORG-9110A or ORG-9700A multiple patient receiver can receive this protocol.

NOTE

When 51 is set, the receiving monitor must be able to receive protocol 51. Otherwise, signals from the transmitter cannot be received.

Differences Between Protocols

Function	Protocol 41	Protocol 51
Setting ECG MEASUREMENT to OFF on the transmitter automatically turns off the ECG measurement setting on the receiving monitor	No (ECG measurement must be turned off on the receiving monitor)	Yes
Pause monitoring on the receiving monitor from the transmitter	No	Yes
Transmit "PATIENT CONFIRMED" message	No	Yes
Display battery level of the transmitter on the receiving monitor	No	Yes
Transmit SpO ₂ messages	Some messages (refer to the "Indication and Message List" section)	All messages
Transmit RESP message	No	Yes



- Press the ► key to move the cursor to "PROTOCOL".
- 2. Press the Function key.
- 3. Press the \blacktriangleright key to select "51" or "41".



NOTE

FUNCTION KEY (on the second page of the SYSTEM SETUP screen) can be set to "SUSPEND ALARM & PAUSE" or "CONFIRM" only when PROTOCOL is "51". If PROTOCOL is changed to "41", FUNCTION KEY is automatically changed to "OFF".

 Press the Function key to register the selected setting. The cursor returns to "PROTOCOL".

BRIGHTNESS

Select the screen brightness.

- 1. Press the \blacktriangleright key to move the cursor to "BRIGHTNESS".
- 2. Press the Function key.
- 3. Press the ► key to select "DARK" or "BRIGHT".
- 4. Press the Function key to register the selected setting. The cursor returns to "BRIGHTNESS".

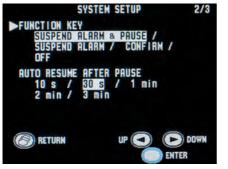
FUNCTION KEY

Select the function of the Function key. For details on using these functions, refer to "Basic Monitoring Operation" in the "Monitoring" section.

SUSPEND ALARM & PAUSE:	Suspends alarm on the receiving monitor for 2 minutes. Pauses
	monitoring on the transmitter and receiving monitor.
SUSPEND ALARM:	Suspends alarm on the receiving monitor for 2 minutes.
CONFIRM:	Displays the "PATIENT CONFIRMED" message on the
	transmitter screen and transmits the message to the receiving
	monitor.
OFF:	No function.

NOTE

"SUSPEND ALARM & PAUSE" and "CONFIRM" can only be set when PROTOCOL is set to 51.



SYSTEM SETUP screen - page 2

- On the SYSTEM SETUP screen, press the

 key to move the cursor to "FUNCTION KEY". It is on the second page of the SYSTEM SETUP screen.
- 2. Press the Function key.
- 3. Press the \blacktriangleright key to select the function.
- Press the Function key to register the selected setting. The cursor returns to "FUNCTION KEY".

AUTO RESUME AFTER PAUSE

Select the interval to resume monitoring after PAUSE. When either of the following conditions is met, monitoring resumes on the receiving monitor.

- · Heart rate is properly monitored for the selected interval
- SpO₂ is properly monitored for the selected interval
- 1. Press the ► key to move the cursor to "AUTO RESUME AFTER PAUSE". It is on the second page of the SYSTEM SETUP screen.
- 2. Press the Function key.
- 3. Press the \blacktriangleright key to select the interval.
- 4. Press the Function key to register the selected setting. The cursor returns to "AUTO RESUME AFTER PAUSE".

SELECTABLE SCREEN TIME OUT PERIOD (min)

Select the display time-out period. If no key is pressed for the selected time, the display is automatically turned off. The selected time is shown on the Select Screen Time Out Period screen. Refer to the "Turning the Display Off" section for details.



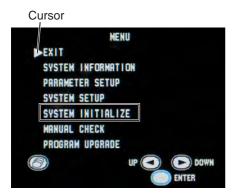
SYSTEM SETUP screen - page 3

- Press the ► key to move the cursor to "SELECTABLE SCREEN TIME OUT PERIOD (min)". It is on the third page of the SYSTEM SETUP screen.
- 2. Press the Function key.
- Press the ◄ or ► key to select time-out period.

4. Press the Function key to register the selected setting. The cursor returns to "SELECTABLE SCREEN TIME OUT PERIOD (min)".

Initializing Settings

Do the following procedure to initialize all settings, except for channel, to the factory default settings.







- 1. Turn off the transmitter by removing a battery.
- 2. While pressing the Function key, turn on the transmitter by inserting the battery. The MENU screen appears.
- Press the ► key to move the cursor to "SYSTEM INITIALIZE".
- 4. Press the Function key to enter the SYSTEM INITIALIZE screen.
- 5. Press the Function key. A confirmation message appears.

To return to the MENU screen, press the Screen key.

6. Press the Function key to initialize settings.

To cancel initializing, press the \blacktriangleright key. The screen returns to the MENU screen.

Attaching Electrodes and SpO₂ Probe to the Patient

Attaching Electrodes Selecting Electrode Lead

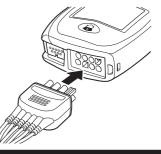
CAUTION

Only use Nihon Kohden specified electrodes and electrode leads. When other type of electrodes or electrode leads are used, the "CHECK ELECTRODES" message may be displayed and ECG monitoring may stop.

Select the disposable electrodes and electrode leads which are appropriate for the number of electrodes (leads). Refer to the "Options" section for details.

Connecting the Electrode Lead to the Transmitter

Connect the electrode lead to the ECG/RESP socket on the transmitter.



WARNING

After attaching the electrode to the patient and connecting the electrode lead to the transmitter, check that electrodes are attached to the patient and check that the electrode lead is connected to the transmitter properly. When the electrodes are removed from the patient, do not touch the metal part of the electrode with bare hands or let the metal part of the electrode contact the metal part of the bed or any other conductive parts. Failure to follow this warning may cause electrical shock or injury to the patient by discharged energy.

CAUTION

Do not shake or swing the transmitter while holding the leads or cables connected to the transmitter. The transmitter may come off and injure someone or damage surrounding instruments.

CAUTION

Hold the connector of the electrode lead when connecting/disconnecting the electrode lead. If you disconnect the electrode lead by pulling the lead, it damages the electrode lead.

Electrode Position

Follow the physician's instructions for electrode placement when available.

For ECG monitoring, electrodes are attached only on the chest to allow patient movement and obtain continuous stable ECG. The following leads are examples. When also monitoring respiration, refer to the "Electrode Position for Respiration Monitoring" section.

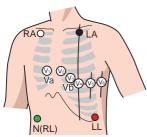
NOTE

The optimum electrode positions for ECG measurement are not always optimum for respiration measurement. Select positions that are suitable for both ECG and respiration measurement or positions which give priority to either ECG or respiration measurement.

Electrode Positions for ECG Monitoring

6-electrode Leads

Va and Vb can be any of the standard 12 leads V_1 to V_6 .



 V_1 : Fourth intercostal space at the right border of the sternum V_2 : Fourth intercostal space at the left border of the sternum V_3 : Halfway between V_2 and V_4

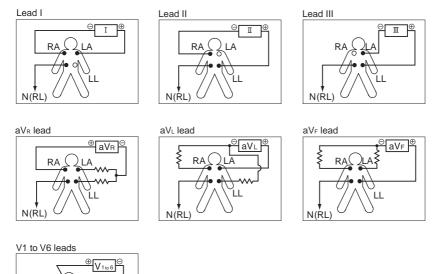
V4: Fifth intercostal space on the left midclavicular line

V₅: Left anterior axillary line at the same level as V₄

V₆: Left midaxillary line at the same level as V₄

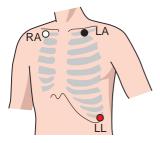
	Electro	de Lead	Electrode Placement	
Symbol	Lead Color	Clip or Hook Color		
RA	White	White	Right infraclavicular fossa	
LA	Black	Black	Left infraclavicular fossa	
LL	Red	Red	Lowest rib on the left anterior axillary line	
N (RL)	Green	Green	Right anterior axillary line at the same level as LL	
Va	Brown - Red	Red	Any two of the V_1 to V_6 positions	
Vb	Brown - Green	Green	Any two of the \mathbf{v}_1 to \mathbf{v}_6 positions	

N is the electrical reference point.



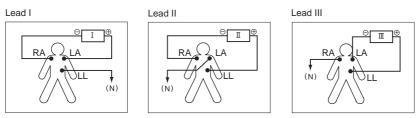
3-electrode Leads

N(RL)



	Electrode Lead			
Symbol	Lead Color	Clip or Hook Color	Electrode Placement	
RA	White	White	Right infraclavicular fossa	
LA	Black	Black	Left infraclavicular fossa	
LL	Red	Red	Lowest rib on the left anterior axillary line	

N is the electrical reference point.

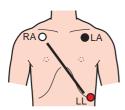


Electrode Positions for Respiration Monitoring

Place the RA and LL electrodes so that the lungs are between the electrodes.

Position 1

In this position, respiration measurement is available; however, there is a difference in amplitude between different patients.



RA	LL	
Right infraclavicular fossa	Fifth intercostal space on the	
Right miraciavicular lossa	left midclavicular line, V4	

Position 2

In this position, the waveform amplitude is usually large and the ECG lead is similar to Lead MII. This position can be generally recommended.



RA	LL
Right infraclavicular fossa	Fifth intercostal space on the
Right infractavicular fossa	left midaxillary line, V ₆

Position 3

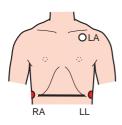
In this position, the respiration waveform is optimum, but the ECG lead is unusual.

$\left(\right)$	2	-01	A
	RA		

RA	LL
Right midaxillary at the	Fifth intercostal space on the
horizontal level of V ₆	left midaxillary line, V ₆

Position 4

In this position, the respiration measurement is influenced by the impedance variation of the abdomen, so the cardiac pulse wave included in the respiration wave is reduced. Note that the waveform is inverted in phase compared with the chest movement (the waveform goes down during inspiration). It is difficult to measure the ECG at the same time.



RA	LL
Lowest rib on the right	Lowest rib on the left anterior
anterior axillary line	axillary line

Attaching Electrodes to the Patient and Connecting the Electrode Leads to Disposable Electrodes

Prepare the Patient Skin

Shave off excessive body hair.

To reduce skin impedance, clean the electrode site with cream or with a cotton pad moistened with alcohol. Thoroughly dry the skin with a clean cotton pad.

NOTE

- For a patient with frequent body movement, rub the sites with skinPure skin preparation gel. However, do not use skinPure skin preparation gel on sensitive skin.
- Do not place electrodes on a wound or on an inflamed, wrinkled or uneven skin surface.

Attaching Electrodes to the Patient

CAUTION

Do not reuse disposable parts and accessories.

NOTE

- To maintain good contact between the electrode and skin, check that the paste of the disposable electrode is not dry.
- When contact between the disposable electrode and skin becomes poor, replace electrodes with new ones immediately. Otherwise, contact impedance between the skin and the electrode increases and accurate ECG and respiration waveforms cannot be obtained.

Refer to the electrode operator's manual for details.





- 1. Carefully remove the backing paper from the electrode. Avoid touching the adhesive surface.
- 2. Place the electrode on the previously cleaned skin. Pay attention to the electrode lead color and symbol.
- 3. Clip the electrode lead to the electrode.
- 4. Fasten the electrode lead wire with surgical tape with an extra length of wire between the tape and the electrode. This lessens the movement of electrode leads by body movement and helps stable monitoring.

Checking ECG on the Transmitter Screen

After attaching electrodes and connecting ECG leads, check that the electrodes are properly attached to the patient and the ECG waveform is acquired on the check electrodes screen. For details on the screen, refer to the "Screen Descriptions" section.

Attaching the SpO₂ Probe Selecting the SpO₂ Probe

Select an appropriate probe for the patient.

CAUTION

Only use Nihon Kohden specified electrodes, electrode leads and SpO₂ probes. Otherwise, the maximum performance from the transmitter cannot be guaranteed.

CAUTION

Do not use a damaged or disassembled probe. It causes incorrect measurement and may injure the patient.

Reusable Probes

When using a TL-201T finger probe, choose the appropriate cable length for attachment.

Probe	Cable Length	Patient	Attachment Site
Finger probe TL-201T	0.6 m	Adult or child 20 kg or more	Finger
	1.6 m		
Multi-site probe TL-220T		Adult or infant	Finger or toe
Attac	chment tape	3 kg or more	
		Neonate	Instep and sole
		3 kg or less	
Finger probe		Adult or child	Finger or toe
TL-631T1, TL-631T3	TL-631T1:	20 kg or more	
Attachment tape	0.6 m		
	TL-631T3: 1.6 m		

Disposable Probes

CAUTION

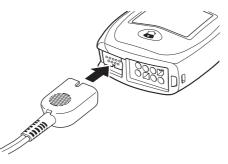
The disposable probe is not sterilized. Use the disposable probe only for a single patient. Never reuse the disposable probe for another patient because it causes cross infection.

Probe	Patient	Attachment Site
TL-051S, TL-052S	Adult 50 kg or more	Finger
Cable length TL-051S: 0.8 m TL-052S: 1.6 m	Neonate 3 kg or less	Instep and sole
TL-061S, TL-062S	Adult or child 15 to 50 kg	Finger
Cable length TL-061S: 0.8 m TL-062S: 1.6 m	Chiled or infant 3 to 15 kg	Тое
TL-271T, TL-271T3	Adult 30 kg or more	Finger or toe
TL-272T, TL-272T3	Child 10 to 50 kg	

Probe	Patient	Attachment Site
TL-273T, TL-273T3	Adult	Finger or toe
	40 kg or more	
	Neonate	Instep and sole
***	3 kg or less	
Cable length TL-273T: 0.8 m TL-273T3: 1.6 m		
TL-274T, TL-274T3	Infant	Finger or toe
	3 to 20 kg	
Cable length TL-274T: 0.8 m		
TL-274T3: 1.6 m		

Connecting the SpO₂ Probe to the Transmitter

Connect the probe to the SpO_2 socket on the transmitter.



CAUTION

Do not shake or swing the transmitter while holding the leads or cables connected to the transmitter. The transmitter may come off and injure someone or damage surrounding instruments.

CAUTION

Do not use a damaged or disassembled probe. It causes incorrect measurement and may injure the patient.

Attaching the Probe to the Patient

Attach the probe to the patient by referring to the probe's manual. Make sure that the light emitter and photo detector of the probe face each other at the attachment site.

WARNING

- When using the TL-201T finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or pressure necrosis from poor blood circulation.
- When using probes other than the TL-201T finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or pressure necrosis from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

WARNING

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes (every 8 hours for TL-631T series probe). The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or pressure necrosis. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree. Patient with a fever

- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

WARNING

When monitoring SpO_2 of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity.

The SpO₂ probes manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is less than 5.5 mW.

CAUTION

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

CAUTION

If the skin gets irritated or redness appears on the skin from the probe, change the attachment site or stop using the probe. Take extreme care for the patients with delicate skin.

CAUTION

Refer to the probe instruction manual for details.

CAUTION

When the probe is attached on an appropriate site with sufficient circulation and the error message confirming the probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

CAUTION

Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed.

CAUTION

The disposable probe is not sterilized. Use the disposable probe only for a single patient. Never reuse the disposable probe for another patient because it causes cross infection.

Locking the Keys on the Transmitter

To prevent the patient from pressing the keys on the transmitter during monitoring, you can lock the keys.

To lock the keys:

Press the \blacktriangleleft and \blacktriangleright keys at the same time and hold for more than 3 seconds. The "Key locked" screen appears.



When the screen time-out period is set to "1 min" (factory default), the "Key locked" screen is displayed for 5 seconds, then the display turns off if there is no key operation.

When the screen time-out period is set to a certain number of minutes, the "Key locked" screen is displayed for 5 seconds, then it changes to the numeric and waveform screen. If there is no key operation, the display turns off when the remaining time elapses. Refer to the "Turning the Display Off" section for details.

To unlock the keys:

Press the \blacktriangleleft and \blacktriangleright keys at the same time and hold for more than 3 seconds.

Monitoring

CAUTION

The measurement values and displayed waveforms on the transmitter and receiving monitor may be different due to timing delay of the display or difference in detection settings.

NOTE

Do not let the transmitter continuously contact the patient's skin directly. The transmitter heats up by 2 or 3°C (4 or 5°F) during operation and it may cause low temperature burn to the patient.

Screen Descriptions

When the transmitter is turned on, the startup screen appears, then the check electrodes screen to check the electrode attachment appears.

The screen changes in the following order when the Screen key is pressed.

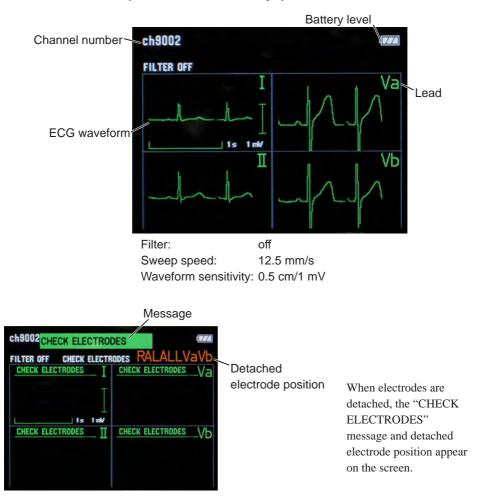
Check electrodes \rightarrow numeric and waveform \rightarrow waveform review \rightarrow numeric review \rightarrow display off \rightarrow check electrodes . . .



Check Electrodes Screen

You can check whether the electrodes are properly attached to the patient and the ECG waveform is acquired.

When 6 leads are used, the I, II, Va and Vb lead waveforms are displayed. When 3 leads are used, only the lead II waveform is displayed.

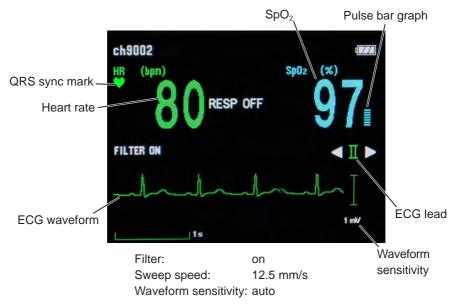


NOTE

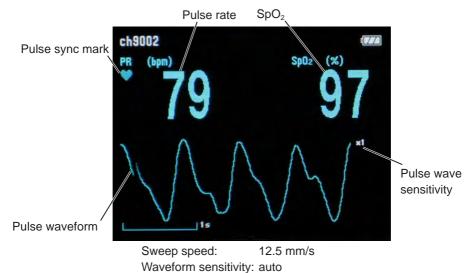
When ECG measurement is set to OFF on the PARAMETER SETUP screen, the check electrodes screen does not appear.

Numeric and Waveform Screen

Numeric values and waveforms of the monitoring parameters are displayed. You can change the ECG lead with the \blacktriangleleft and \blacktriangleright keys.



When ECG and respiration measurement is turned off



NOTE

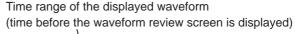
The pulse wave amplitude varies according to the ratio of the pulsation component to the entire transmitted IR signal. When the pulsation component ratio is 1%, the pulse wave amplitude is about 5 mm at ×1 sensitivity on the screen.

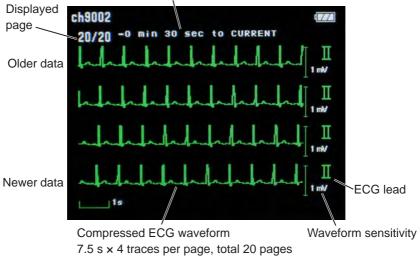
Waveform Review Screen

ECG full disclosure for up to 10 minutes can be saved and reviewed. When ECG measurement is turned off and SpO_2 is monitored, the pulse waveform is saved.

When ECG lead is changed on the numeric and waveform screen, the ECG full disclosure of the changed lead is saved.

The saved data is deleted when the transmitter is turned off.





To scroll the waveform, press the \blacktriangleleft or \blacktriangleright key. The waveform is scrolled by 30 seconds.

Numeric Review Screen

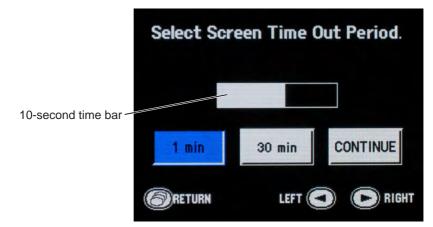
Numeric data of heart rate (or pulse rate when ECG is turned off), SpO_2 and respiration rate for up to 10 minutes are saved at 1 minute intervals.

	ch9002			.[77]
Older data	-10[min] - 9[min]	(bpm) 80	Sp02 (%) 97	RR (/min) 20 20
	- 8[min] - 7[min]	80 80 80	97 97	20
Time before the numeric review screen is displayed.	6[min] - 5[min]	80 80	97 97	20 20
	- 4[min] - 3[min]	80 80	97 97	20
Newer data	- 2[min] - 1[min]	80 80	97 97	20 20

The saved data is deleted when the transmitter is turned off.

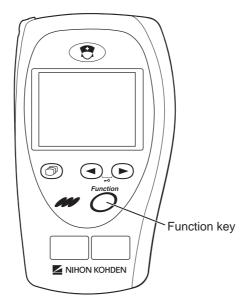
Display Off

The display can be turned off any time. Refer to the "Turning the Display Off" section for details.



Basic Monitoring Operation

Using the Function Key



One of the following functions can be assigned to the Function key on the SYSTEM SETUP screen. Refer to the "Changing SYSTEM SETUP Settings" section.

SUSPEND ALARM:Suspends alarms on the receiving monitor, before they occur, for 2 minutes.PAUSE:Pauses monitoring on the transmitter and receiving monitor.CONFIRM:Transmits the signal that the patient is confirmed and displays the
"PATIENT CONFIRMED" message on the transmitter.

NOTE

To use the Function key for PAUSE or CONFIRM, you must set "PROTOCOL" on the SYSTEM SETUP screen of the transmitter to 51 and the receiving monitor must be able to receive protocol 51. To use protocol 51, an ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.

Suspending Alarms on the Receiving Monitor

WARNING

While the "ALARMS SUSPENDED" message is displayed on the transmitter, all alarms on the receiving monitor are suspended so keep the patient under close observation.

When the FUNCTION KEY is set to "SUSPEND ALARM" or "SUSPEND ALARM & PAUSE" on the SYSTEM SETUP screen, alarms can be suspended for 2 minutes on the receiving monitor before they occur.

To suspend alarms:

1. Press the Function key. The "Suspend alarms" confirmation screen appears.



 Press the ► key to suspend alarms. To cancel suspending alarms and return to the previous screen, press the Screen key.

When the alarms are suspended, the "ALARMS SUSPENDED" message and alarm suspended icon with the remaining minutes in alarm suspension appear on the transmitter screen.



To cancel suspending alarms during 2 minute alarm suspension:

1. Press the Function key while the "ALARMS SUSPENDED" message is displayed. The confirmation screen appears.

Can	cel alarm suspe
C	ancel alarm suspend?

Press the ► key to cancel alarm suspension.
 Press the Screen key to not cancel alarm suspension.

Pausing Monitoring

When FUNCTION KEY is set to "SUSPEND ALARM & PAUSE" on the SYSTEM SETUP screen, you can pause monitoring on the receiving monitor from the transmitter when the patient cannot be monitored, such as during X-ray examination.

NOTE

To use the Function key for PAUSE, you must set "PROTOCOL" on the SYSTEM SETUP screen of the transmitter to 51 and the receiving monitor must be able to receive protocol 51. To use protocol 51, an ORG-9100A or ORG-9110A multiple patient receiver software version 03-03 or later is required.

Monitoring on the receiving monitor resumes when one of the following conditions is met. When OFF is selected for "AUTO RESUME AFTER PAUSE" on the SYSTEM SETUP screen, monitoring does not automatically resume.

- Heart rate is properly monitored on the transmitter for the interval selected for "AUTO RESUME AFTER PAUSE".
- SpO₂ is properly monitored on the transmitter for the interval selected for "AUTO RESUME AFTER PAUSE".

To pause monitoring:

1. Press the Function key. The "Suspend alarms" confirmation screen appears.



2. Press the Function key for 3 seconds to display the "Pause monitoring" confirmation screen.

ause monitor	ring
Pause monitoring] ?

- Press the ► key to pause monitoring. To cancel pause monitoring, press the Screen key.
- 4. Wait about 5 seconds until the "Turn power off" screen appears.



5. Turn off the transmitter.

If the transmitter is not turned off and monitoring continues for the interval set for "AUTO RESUME AFTER PAUSE" on the SYSTEM SETUP screen, pause monitoring is cancelled and monitoring continues.

Resuming Monitoring after Pause

To resume monitoring after pause, check that the electrodes, electrode leads and probe are attached to the patient then turn on the transmitter.

WARNING

When the patient returns to the bed, turn on the transmitter and check that the monitoring is resumed on the receiving monitor.

WARNING

If the transmitter is not turned off and monitoring continues for the selected interval, pause monitoring is canceled and monitoring continues. Check that the monitoring is resumed on the receiving monitor.

Confirming the Patient

When the FUNCTION KEY is set to "CONFIRM" on the SYSTEM SETUP screen, pressing the Function key sends a signal to the receiving monitor to indicate that the patient or patient condition is confirmed by medical staff.

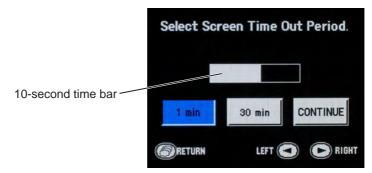


Turning the Display Off

The display can be turned off any time.

To turn off the display:

1. Press the Screen key several times until the following screen appears.



2. Select the timing for turning off the display with the ◀ or ► key. The selected item is highlighted in blue. A 10 second countdown starts. You can select a different time within the 10 second countdown.

1 min (factory default):	Turns the display off 1 minute later.
--------------------------	---------------------------------------

 5, 10, 15, 30, 60, 120 or 240 min: Turns the display off when the selected time elapses. To set the time, refer to "SELECTABLE SCREEN TIME OUT PERIOD (min)" in the "Changing System Setup Settings" section.
 CONTINUE: Keep the display turned on.

NOTE

If longer than "1 min" is selected, it reduces the battery lifetime.

3. Wait 10 seconds until the countdown ends. When the countdown ends, the numeric and waveform screen appears.

Or, press the Screen key before the countdown ends. The check electrodes screen appears.

When the selected time elapses without any key operation, the display turns off automatically. If a key is pressed, the countdown resets.

- When displaying the check electrodes screen after selecting the time-out period, the screen automatically changes to the numeric and waveform screen 2 minutes later if there is no key operation, then the display turns off when the remaining time elapses.
- When displaying another screen after selecting the time-out period, the screen changes to the numeric and waveform screen 1 minute later if there is no key operation, then the display turns off when the remaining time elapses.
- When "1 min" is selected, the display turns off without changing to the numeric and waveform screen.

When the display is turned off automatically or the power is turned off, the setting returns to "1 min" (factory default).

Turning the Display On after It was Turned Off

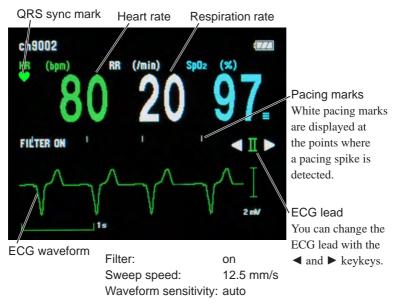
Press the Screen key. One of the following screen appears.

The previous screen: The Screen key is pressed within 5 minutes after the display turned off.
 Numeric and waveform screen: The Screen key is pressed more than 5 minutes after the display turned off.
 "Key locked" screen: The Screen key is pressed after the display turned off and the "Key locked" screen was the last screen before the display turned off.

ECG and Respiration Monitoring

When the electrodes are attached and the ECG leads are connected, the heart rate, ECG waveform, respiration rate and respiration waveform appear on the receiving monitor. Refer to the operator's manual of the receiving monitor for details.

When 6 leads are used on this transmitter, up to 8 leads (I, II, III, aVR, aVL, aVF, Va and Vb) of ECG waveforms can be displayed on the receiving monitor. The heart rate is also measured. When 3 leads are used, one channel ECG waveform of lead II can be displayed on the receiving monitor. Refer to the operator's manual of the monitor for details.



CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may be mistaken as pulse waves or respiration waves and the displayed data may be incorrect.

NOTE

- ECG cannot be monitored on a neonate using this transmitter.
- When performing defibrillation, set the hum filter to ON on the receiving monitor. The waveform recovery may become slow due to electrode polarization when the hum filter is set to OFF.

Use with a Pacemaker

When monitoring a pacemaker patient, the transmitter detects pacemaker pulse and rejects the pacemaker pulse from the heart rate count.

WARNING

The bioelectric impedance measurement sensor of a minute ventilation rate-adaptive implantable pacemaker may be affected by transmitter which is connected to the same patient. If this occurs, the pacemaker may pace at its maximum rate and the transmitter may give incorrect data to the monitor. If this occurs, disconnect the electrode leads from the patient or change the setting on the pacemaker by referring to the pacemaker's manual. For more details, contact your pacemaker representative or Nihon Kohden representative.

WARNING

The transmitter detects the pacemaker pulse and rejects the pacemaker pulse from the heart rate count. However, all of the pacemaker pulse might not be rejected. If the pacemaker pulse is not rejected, the pacemaker pulse is detected as QRS and false heart rate may be indicated. Keep pacemaker patients under close observation.

* For the pacemaker pulse rejection capability of the ZM-520PA/521PA/530PA/531PA transmitter, refer to the "Specifications - ECG" section.

WARNING

The pacemaker pulse can be overlooked or detected as QRS. You cannot confirm the pacemaker operation only from the detected pacemaker pulse.

NOTE

- If an electric blanket is used and incorrect heart rate is displayed on the monitor, turn off the pacing spike detection on the monitor.
- Turn the pacing spike detection to ON on the receiving monitor when monitoring a pacemaker patient. Pacing pulse is detected by the transmitter and transmitted to the monitor. If the pacing spike detection is turned OFF, QRS and pacemaker spike might not be distinguished and pacemaker failure might not be recognized.

Use with an Electrosurgical Unit

For use with an electrosurgical unit (ESU), this transmitter has a circuit to protect the patient from skin burn and to reduce ESU interference on the ECG waveform. However, the effectiveness of this circuit depends on electrode position and transmitter setup. With an ESU, pay attention to the following points.

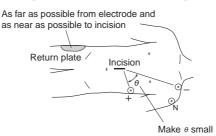
WARNING

When the transmitter is used with an electrosurgical unit (ESU), firmly attach the entire area of the ESU return plate. Otherwise, the current from the ESU flows into the electrodes of the transmitter, causing electrical burn where the electrodes are attached. For details, refer to the ESU manual.

NOTE

Noise generated from an electrosurgical unit may interfere on an ECG waveform, but will not damage it.

- Measure with 3-electrode lead Use the minimum number of electrodes. Use new electrodes.
- · Minimize noise
- 1. Select an ECG lead where the active ECG electrodes are located as far from the incision as possible.
- 2. Position the + and electrodes as close as possible.
- 3. Select the leads where the angle (θ) between the active electrodes and the incision is as small as possible.
- 4. Set the electrosurgical return plate as close to the incision as possible.



Turning ECG Measurement On/Off

ECG measurement can be turned on or off on the PARAMETER SETUP screen. When electrodes are attached to the patient and ECG leads are connected, ECG monitoring starts even when ECG is turned off.

When PROTOCOL on the SYSTEM SETUP screen is set to 51:

ECG measurement on the receiving monitor is automatically set to off.

NOTE

ECG measurement on the transmitter cannot be turned on or off from the receiving monitor.

When PROTOCOL on the SYSTEM SETUP screen is set to 41:

If ECG measurement is turned off on the transmitter, ECG measurement on the receiving monitor must also be turned off.

Turning Respiration Measurement On/Off

Respiration measurement can be turned on or off on the PARAMETER SETUP screen. If respiration measurement is turned off, respiration measurement on the receiving monitor is also turned off.

Electrode Detachment

In the following conditions, the "CHECK ELECTRODES" message is displayed on the transmitter and receiving monitor.

- Electrode is detached from skin.
- Electrode lead is disconnected from the electrode.
- Polarization voltage between the electrode and skin is excessively high.

In these cases, check the cause and if necessary, replace electrodes with new ones.

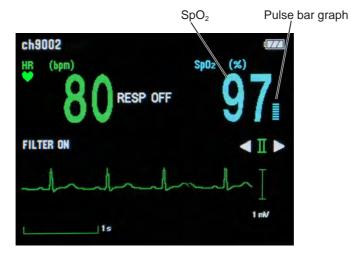
CAUTION

When the "CHECK ELECTRODES" message is displayed on the receiving monitor, ECG is not monitored properly and the ECG alarm does not function. Check the electrode, electrode leads, and if necessary, replace with new ones.

SpO₂ Monitoring

The SpO₂ monitoring is only available on the ZM-530PA and ZM-531PA transmitter.

When monitoring starts, SpO_2 and the pulse waveform are sent to the receiving monitor and SpO_2 and the pulse level bar graph are displayed on the transmitter screen. When ECG is not measured, the pulse waveform and pulse rate are also displayed.



NOTE

During SpO_2 monitoring, the transmitter constantly checks the light intensity of the probe and adjusts the light intensity to maintain optimum measurement condition. During adjustment, the pulse wave becomes flat for about 0.5 seconds.

WARNING

SpO₂ measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- When using an electrosurgical unit.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the pulse wave is small (insufficient peripheral circulation).

WARNING

Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes (every 8 hours for TL-631T series probe). The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or pressure necrosis. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree. Patient with a fever

- Patient with insufficient peripheral circulation
- Neonate or low birth weight infant with delicate skin

WARNING

When not monitoring SpO_2 , disconnect the SpO_2 cable from the transmitter. Otherwise, noise from the probe sensor may interfere and incorrect data is displayed on the screen.

WARNING

When monitoring SpO_2 of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity.

The SpO₂ probes manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is less than 5.5 mW.

CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may be mistaken as pulse waves or respiration waves and the displayed data may be incorrect.

CAUTION

Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn on the patient from the probe temperature increase due to the short circuit of the probe cable, and incorrect measurement data. If the probe is broken, replace it with a new one.

- Do not immerse any part of the probe cable other than the disposable probe in chemical solutions or water.
- Do not pull or bend the probe cable.
- Do not let caster feet run over the probe cable.

CAUTION

When the probe is attached on an appropriate site with sufficient circulation and the error message confirming the probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

CAUTION

While a patient is on medication which causes vasodilation, the pulse waveform may change and in rare cases the SpO₂ value might not be displayed.

CAUTION

Normal external light does not affect monitoring but strong light such as a surgical light or sunlight may affect monitoring. If affected, cover the measuring site with a blanket.

CAUTION

When a message indicates a faulty probe, stop monitoring and replace the probe with a new one.

CAUTION

Do not attach the probe to the same limb that is used for NIBP measurement or an IBP catheter. The SpO₂ measurement may be incorrect.

NOTE

- In order to maintain sufficient blood circulation, keep the measurement site warm by covering it with a blanket or something similar. Warming the site is effective, especially for a patient with a small pulse amplitude.
- When monitoring a patient who has an IABP and SpO₂ cannot be measured, monitor the patient on a wired monitor. If the monitor has a sensitivity mode, set the mode to "MAX".

Indications and Messages

Indication

Indication	Cause	Countermeasure
	Batteries are fully charged.	
	Batteries are getting low.	
	Batteries are low.	
4	Batteries are almost empty.	Replace the batteries.
2	Alarms on the receiving monitor were suspended by pressing the Function key on the transmitter.	Alarms resume when the suspend interval elapses. To cancel alarm suspension, press the Function key again.

Messages

When PROTOCOL on the SYSTEM SETUP screen is set to 51, all messages are transmitted. When PROTOCOL is set to 41, the messages marked with * are not transmitted.

Message	Cause	Countermeasure
ALARMS SUSPENDED	Alarms on the receiving monitor are suspended by pressing the Function key on the transmitter	Alarms resume when the 2-minute suspend interval elapses. To cancel alarm suspension, press the Function key again.
BATTERY WEAK	Dead batteries	Replace the batteries.
	Poor blood circulation for measuring the SpO ₂ value	Check the patient condition, probe attachment or change the attachment site.
CANNOT	The probe is attached too tightly and is obstructing the blood circulation	Reattach the probe.
DETECT PULSE*	The probe is not attached to the patient properly	Attach the probe to the patient properly.
	"LIGHT INTERFERENCE", "CHECK PROBE SITE" or "DETECTING PULSE" message is displayed for more than 30 seconds	Refer to the cause and countermeasure for each message in this Messages table and remove the cause.

Message	Cause	Countermeasure	
CANNOT	Poor contact between the disposable	Replace electrodes with new ones	
MEASURE*	electrode and skin	immediately.	
	Electrode lead is disconnected from	Firmly connect the electrode lead to	
	the electrode	the electrode.	
	Electrode lead is disconnected from	Firmly connect the electrode lead to	
	the transmitter	the transmitter.	
CHECK ELECTRODES	Electrode lead discontinuity	Replace the electrode lead with a new one.	
	Electrode is not firmly attached to		
	the skin	Replace the electrode with a new	
	Polarization voltage is abnormally	one.	
	high		
	The probe is not attached to the	Attach the probe to the patient	
	patient properly	properly.	
	The probe is not attached at the	Attach the probe to an appropriate	
CHECK PROBE	appropriate site	site indicated in the probe manual.	
	The probe is disconnected from the	Connect the probe cable to the	
	transmitter	transmitter.	
	The probe is past its expiration date	Replace the probe with a new one.	
	The probe is not attached at the	Attach the probe to an appropriate	
CHECK PROBE	appropriate site	site indicated in the probe manual.	
SITE*	The probe is deteriorated		
	The probe is past its expiration date	Replace the probe with a new one.	
	Searching for the correct pulse wave for SpO ₂ monitoring	Wait until the pulse wave is detected.	
DETECTING	The SpO ₂ value cannot be obtained		
PULSE	because the waveform is unstable	Attach the probe to the patient	
	The probe is not attached to the	properly.	
	patient properly		
LIGHT	The SpO ₂ measurement site is under	Cover the measurement site with a	
INTERFERENCE	fluorescent light, surgical light,	blanket or cloth.	
	sunlight, or other strong light		
	Considerable body movement	When the message is displayed	
M	The probe is not attached to the	frequently, check the patient condition	
	patient properly	and, if necessary, change the	
		attachment site.	

Message	Cause	Countermeasure
PATIENT CONFIRMED*	Function key is pressed and the "PATIENT CONFIRMED" signal is transmitted to the receiving monitor (when "PATIENT" is assigned as the function for the Function key on the SYSTEM SETUP screen)	—
	The probe is past its expiration date	Replace the probe with a new one.
PROBE	Probe is damaged or short-circuited	
FAILURE*	Transmitter failure	Contact your Nihon Kohden representative.
SpO ₂ MODULE ERROR*	Transmitter failure	Contact your Nihon Kohden representative.
	Poor peripheral circulation	Check the patient condition and change the probe attachment site.
WEAK PULSE*	The probe is attached too tightly and is obstructing the blood circulation	Check the probe attachment condition and if necessary, reattach the probe.
RESP OFF "RESP MEASUREMENT" on the PARAMETER SETUP screen is set to OFF		If respiration monitoring is necessary, set "RESP MEASUREMENT" to ON.

Message Display Priority

When more than one message condition occurs on the transmitter, only the message with the highest priority is displayed.

Priority	Message
High	PATIENT CONFIRMED
▲	PROBE FAILURE
	CHECK ELECTRODES
	SpO ₂ MODULE ERROR
	CHECK PROBE
	CHECK PROBE SITE
	CANNOT DETECT PULSE
	LIGHT INTERFERENCE
	CANNOT MEASURE
	DETECTING PULSE
	WEAK PULSE
♦	ALARMS SUSPENDED
Low	BATTERY WEAK

Troubleshooting

If a problem occurs, use the following tables to find and fix it. If the problem still remains after troubleshooting according to these tables, contact your Nihon Kohden representative.

Transmitter

Problem	Possible Cause	Action
Nothing is displayedBatteries are not installedon the LCD aftercorrectly. The battery polarity isturning the power on.wrong.		Install the batteries correctly.
	Batteries are completely discharged.	Replace the batteries with new ones.
LCD is difficult to see (too dark or too light).	LCD brightness is not appropriate.	Change the LCD brightness on the SYSTEM SETUP screen. Refer to the "Changing SYSTEM SETUP Settings" section.
LCD shows no image (white screen) or a partial image.	The LCD display or the electrical circuits for displaying images were damaged by dropping or impact.	Contact your Nihon Kohden representative. You can confirm transmission of patient physiological data (ECG, respiration, SpO ₂ and pulse waveform) on the central monitors and/or bedside monitors.
Nothing is displayed on the receiving monitor after turning the transmitter power on	The channel of the transmitter and monitor does not match. The software version of the multiple patient receiver or	Set the correct channel on the monitor. Upgrade the multiple patient receiver or central monitor software to receive
on.	Protocol on the transmitter and monitor does not match. Protocol on the transmitter is set to 51 but the monitor cannot	signal from the transmitter. Contact your Nihon Kohden representative. Set the same protocol on the transmitter and monitor. Set the protocol on the transmitter to 41 Before to the "System Seture
	receive protocol 51.	to 41. Refer to the "System Setup Setting List" section.

Problem	Possible Cause	Action
Signal receiving	Another transmitter with the	Turn the transmitter power off. If the
condition is poor.	same channel is used nearby.	monitor still receives a signal, there
		is a high probability that another
		transmitter of the same channel is
		used nearby. Follow the instruction
		of your channel administrator and use
		another transmitter with a different
		channel.
	Signals of another patient are	Follow the instructions of your
	mixing.	channel administrator and use another
		transmitter of a different channel.
	The transmitter is damaged.	Contact your Nihon Kohden
		representative.

ECG/Respiration

Problem	Possible Cause	Action
The heart rate is unstable.	Pacing detection setting on the monitor is not correct.	Turn off the pacing detection setting on the receiving monitor. When monitoring a pacemaker patient, turn on pacing detection.
The "CHECK ELECTRODES"	Electrode lead is disconnected from the electrode.	Firmly connect the electrode lead to the electrode.
message appears on the receiving	Electrode lead discontinuity.	Replace the electrode lead with a new one.
monitor.	Electrode is not firmly attached to the skin.	Replace the electrode with a new one.
	Polarization voltage is abnormally high.	Use Nihon Kohden specified electrodes.
ECG baseline is thick (AC hum).	The gel on the electrode is dried out.	Replace the electrode with a new one.
	The gel on the electrode is coming off.	
	An electric blanket is used.	Cover the blanket with a shield cover.
	The hum filter is set to OFF on the monitor.	Set the filter to ON.

Problem	Possible Cause	Action
61		Turn OFF the pacing pulse detection on the receiving monitor.
No heart rate or ECG is displayed.	"ECG MEASUREMENT" on the PARAMETER SETUP screen is set to OFF.	If ECG monitoring is necessary, set "ECG MEASUREMENT" to ON.
Respiration waveform	The gel on the electrode is dried out.	Replace the electrode with a new one.
measurement is unstable.	The gel on the electrode is coming off.	
No respiration rate is displayed.	"RESP MEASUREMENT" on the PARAMETER SETUP screen is set to OFF.	If respiration monitoring is necessary, set "RESP MEASUREMENT" to ON.

SpO₂

Problem	Possible Cause	Action
SpO_2 data is unstable and not reliable.	The probe size is not appropriate for the patient.	Use the appropriate probe for the patient.
	Probe attachment condition is poor. The probe is partly detached from the skin. External light is entering the probe.	Firmly attach the probe according to the procedure in the probe operator's manual.
	Measurement site is dirty. Patient is wearing nail polish.	Remove dirt and nail polish.
	The probe is attached to the same limb that is used for NIBP measurement.	Attach the probe to the opposite limb. Avoid a site where blood circulation condition changes greatly.

Maintenance

The transmitter contains parts which gradually deteriorate with use. Original performance might not be delivered if any part of the transmitter is deteriorated. Perform regular maintenance checks to assure continued safe operation. If the maintenance checks is not performed, degradation or loss of function may go unnoticed and lead to misdiagnosis. To use the transmitter in safe and optimum condition, perform maintenance check every six months.

The following units are necessary for some checking items.

- AX-410G medical instrument checker
- AX-300T SpO₂ checker
- Receiving monitor

CAUTION

Never disassemble or repair the transmitter. If there is any problem with the transmitter, contact your Nihon Kohden representative.

NOTE

- The measurement accuracy of the above units must be managed to perform accurate maintenance check.
- For details on the operation of the above units, refer to the manuals provided with these units.

A maintenance check sheet is provided at the end of this section. Make a copy of this check sheet before performing maintenance check.

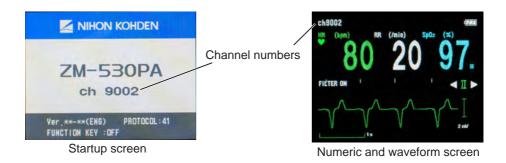
1. External Check

- There is no damage or dirt on the outside of the transmitter.
- The battery case cover is not damaged, the spring is firmly attached and the battery case cover can be closed firmly.
- No keys are damaged.
- No electrode leads are damaged.
- There are no blood or chemicals on the transmitter.
- The springs in the battery compartment are not damaged or detached.
- Terminals in the battery case are not corroded.

2. Transmitter Channel

- The channel number label on the transmitter is not torn or removed.
- The channel of the transmitter matches the label.

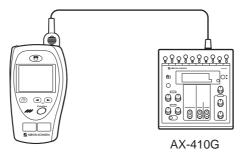
The transmitter channel is displayed in the upper left corner of the screen. The channel number also appears on the startup screen.



3. Transmitting/Receiving Signal

Use the AX-410G medical instrument checker and receiving monitor.

1. Connect the medical instrument checker to the transmitter only with the electrode leads.



- 2. Place the transmitter 2 to 3 m from the receiving monitor.
- 3. Set the channel on the receiving monitor to the channel of the transmitter.
- 4. Turn on the transmitter and medical instrument checker.
- 5. Check that the ECG of the transmitter appears on the receiving monitor.
- 6. Turn off the transmitter.
- 7. Check that the ECG disappears from the receiving monitor.

4. Display

Check that there are no dots missing on the screen.

1. Turn off the transmitter.

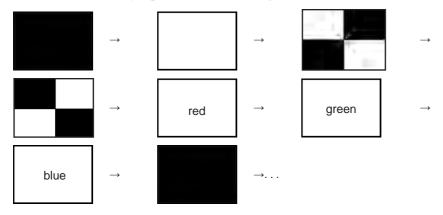
- 2. While pressing the Function key, turn on the transmitter. The MENU screen appears.
- 3. Press the ► key to move the cursor to "MANUAL CHECK" and press the Function key.



4. Press the \triangleleft or \triangleright key to move the cursor to "LCD TEST" and press the Function key.

MANUAL CHECK	
LCD TEST	
AD TEST	
KEY CHECK	
SP02 CONNECT	
IFDA COMMUNICATION TEST	
IP O DOWN	

5. Each time the ▶ key is pressed, the screen changes as below. Check that no dots are missing.



- 6. Press the Screen key to return to the MANUAL CHECK screen.
- 7. Press the Screen key again to return to the MENU screen.

5. Key Operation

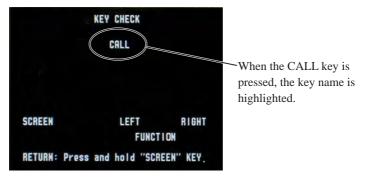
- 1. Turn off the transmitter.
- 2. While pressing the Function key, turn on the transmitter. The MENU screen appears.
- 3. Press the ► key to move the cursor to "MANUAL CHECK" and press the Function key.



4. Press the \triangleleft or \triangleright key to move the cursor to "KEY CHECK" and press the Function key.



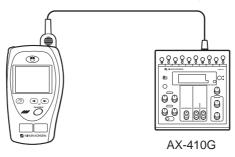
5. Press each key one at a time and check that the pressed key is highlighted on the screen.



6. After checking, press and hold the Screen key to return to the MANUAL CHECK screen.

6. ECG Check

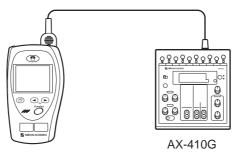
1. Connect the medical instrument checker to the transmitter only with the electrode leads.



- 2. Place the transmitter 1 m from the receiving monitor.
- 3. Turn on the transmitter and medical instrument checker.
- 4. Check that the ECG of the transmitter appears on the receiving monitor.

7. Respiration Check

1. Connect the medical instrument checker to the transmitter only with the electrode leads.



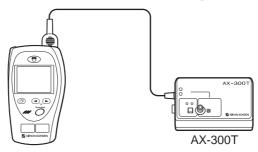
- 2. Place the transmitter 1 m from the receiving monitor.
- 3. Turn on the transmitter and medical instrument checker.
- 4. Check that the respiration waveform of the transmitter appears on the receiving monitor.

8. SpO₂ Check

SpO₂ can be checked with an SpO₂ checker or a medical instrument checker.

With SpO₂ Checker

1. Connect the SpO₂ checker to the transmitter only with the SpO₂ connection cable.



- 2. Place the transmitter 1 m from the receiving monitor.
- 3. Turn on the transmitter and SpO_2 checker.
- 4. Check that the pulse bar graph appears on the transmitter screen.

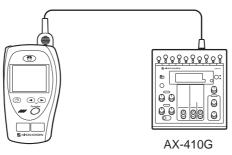
SpO ₂ on the SpO ₂ Checker		Range
SpO ₂ *	97%	95 to 99% SpO ₂ (±2 digits)
	80%	78 to 82%SpO ₂ (±2 digits)
	70%	66 to 74%SpO ₂ (±4 digits)
Pulse rate	60 beats/min	57 to 63 beats/min ($\pm 3\% \pm 1$ beat/min)
	120 beats/min	115 to 125 beats/min (±3% ±1 beat/min)

5. Check that SpO_2 and pulse rate on the transmitter is within the following range.

- * The SpO₂ check with the SpO₂ checker is affected by the checker's tolerance to the SpO₂ measuring accuracy of the transmitter. (The measurement accuracy is described in the "Specifications" section.) For details, refer to the SpO₂ checker manual.
- 6. Check that the SpO₂ and pulse waveform of the transmitter appear on the receiving monitor.

With Medical Instrument Checker

1. Connect the medical instrument checker to the transmitter only with the SpO₂ connection cable.



- 2. Place the transmitter 1 m from the receiving monitor.
- 3. Turn on the transmitter and medical instrument checker.
- 4. Check that the pulse bar graph appears on the transmitter screen.
- 5. Check that SpO_2 and pulse rate on the transmitter is within the following range.

Medical Instrument Checker		Range
SpO ₂ *	97%	95 to 99% SpO ₂ (±2 digits)
	80%	78 to 82%SpO ₂ (±2 digits)
	70%	66 to 74%SpO ₂ (±4 digits)
ECG	NORMAL 80	76 to 84 beats/min (±4 beats/min)

- * The SpO₂ check with the medical instrument checker is affected by the simulator's tolerance to the SpO₂ measuring accuracy of the transmitter. (The measurement accuracy is described in the "Specifications" section.) For details, refer to the medical instrument checker manual.
- 6. Check that the SpO₂ and pulse waveform of the transmitter appear on the receiving monitor.

Maintenance Check Sheet

1.	External Check	Pass	Fail
2.	Transmitter Channel	Pass	Fail
3.	Transmitting/Receiving Signal	Pass	Fail
4.	Display	Pass	Fail
5.	Key Operation	Pass	Fail
6.	ECG Check	Pass	Fail
7.	Respiration Check	Pass	Fail
8.	SpO ₂ Check	Pass	Fail

Overall Judgement

- \Box OK
- $\hfill\square$ Can be used but needs maintenance.
- □ Maintenance required. Cannot be used.

Lifetime and Disposal

CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

Disposing of Used Batteries

Battery Lifetime

Replace the batteries when the battery replacement indication appears on the transmitter.

Disposal

NOTE

Remove the batteries before disposing of the transmitter.

Before disposing of the batteries, check with your local solid waste officials for details in your area for proper disposal. It may be illegal to dispose of these batteries in the municipal waste stream.

Disposing of Electrodes and SpO₂ Probes

Refer to the manual for each item.

Disposing of Transmitter

Remove the batteries from the transmitter and dispose of the transmitter following your local laws for disposal.

Cleaning, Disinfection and Sterilization

Transmitter and Electrode Leads

CAUTION

This transmitter is not waterproof. If detergent or liquid spills into the transmitter, stop cleaning or disinfecting it and contact your Nihon Kohden representative. The transmitter needs to be checked for safety and function before use.

NOTE

The transmitter cannot be sterilized. Sterilizing the transmitter may damage it.

Before cleaning or disinfecting, remove the batteries from the transmitter. Be careful not to let any liquid get inside the transmitter.

Cleaning

Wipe the transmitter and electrode leads with a soft cloth moistened with ethanol for disinfection (76.9 to 81.4% by vol) or neutral detergent diluted with water. After cleaning, dry them completely.

Use cotton swab moistened with neutral detergent diluted with water to clean inside the battery compartment.

Disinfection

CAUTION

Do not immerse the electrode lead connector in liquid.

Wipe the outside surface of the transmitter and electrode lead with a non-abrasive cloth moistened with any of the disinfectants listed below. For details on the disinfectants, refer to the instruction provided with the disinfectants. Use the recommended concentration.

Disinfectant	Concentration (%)
Glutaraldehyde solution	2.0
Alkyldiaminoethylglycine hydrochloride	0.5
Benzalkonium chloride	0.2
Benzethonium chloride solution	0.2
Chlorhexidine gluconate solution	0.5
Phtharal	0.55
Phenol	1.56

SpO₂ Probe

Refer to the probe manual.

Periodic Replacement Schedule

To maintain the performance of the instrument, the following part must be periodically replaced.

Name	Code No.	Expected Life Span
Silicon seal (for battery case cover)	6114-918705	1 year

Repair Parts Availability Policy

Nihon Kohden Corporation (NKC) shall stock repair parts (parts necessary to maintain the performance of the instrument) for a period of 8 years from the date of delivery. In that period NKC or its authorized agents will repair the instrument. This period may be shorter than 8 years if a board or part necessary for the faulty section is not available.

Specifications

ZM-520PA/ZM-530PA

Measured Parameters

Waveforms: Numeric data:

Transmitted Data

Waveforms: Numeric data: Status information: ECG, impedance method respiration, pulse Heart rate, respiration rate, SpO₂, pulse rate

ECG, respiration, pulse wave SpO₂, pulse rate Battery replacement, battery level*, alarm suspended, pause monitoring*, patient confirmed*, ECG lead, pacing detection, electrode detachment, electrode impedance*, ECG off*, respiration method (impedance)*, SpO₂ status, respiration status*, channel ID, time constant (3.2 s), type of transmitter, transmitter code number*, transmitter serial number*

* Transmitted only when the protocol is "51".

Display

Display size: Viewing area: Resolution:

Displayed Data

Numeric and waveform screen:

Waveform review screen: Numeric review screen:

Check electrodes screen:

ECG

ECG Measurement

Channels:	4
Input dynamic range:	$\pm 10 \text{ mV}$ or more
Electrode offset potential tolerance:	$\pm 500 \text{ mV}$ or more
Input impedance:	$5 \text{ M}\Omega$ or more

2.2 inch TFT color LCD 44.16 (H) × 33.12 (V) mm 320 (H) × 240 (V) dots

ECG (one waveform from lead I, II, III, Va or Vb), heart
rate, pulse rate, respiration rate, SpO ₂ , message, battery level,
QRS/pulse sync mark, pulse bar graph, ECG lead
ECG or pulse wave of past 10 minutes
Heart rate or pulse rate, respiration rate and SpO ₂ at 1 minute
interval for past 10 minutes
ECG for checking electrode attachment
-

Common mode rejection ratio:	95 dB or more	
	IEC 60601-2-27: 2005 50.102.10 complied	
Pacing pulse detection:	amplitude ± 2 to 700 mV, duration 0.1 to 2 ms	
	IEC 60601-2-27: 2005 complied	
	Based upon pacemaker pulse rejection capability	
Defibrillation-proof:	ECG input protected against 400 Ws/DC 5 kV	
ECC	IEC 60601-2-27 17.101 complied	
ECG recovery time after defibrillation Electrode condition:		
	Displays CHECK ELECTRODES message	
Tall T-wave rejection capability:	Complies with the heights of T-waves from 0 to 1.2 mV	
TT , , , ,	IEC 60601-2-27: 2005 50.102.17 complied	
Heart rate averaging:	Calculated by using the most recent 8 beats.	
Heart rate meter accuracy and respo		
	Ventricular bigeminy (Test waveform name: aami3a*):	
	80 bpm	
	Slow alternating ventricular bigeminy (Test waveform name: aami3b*): 60 bpm	
	Rapid alternating ventricular bigeminy (Test waveform	
	name: aami3c*): 108 bpm	
	Bidirectional systoles (Test waveform name: aami3d*):	
	88 bpm	
	* The test waveforms can be download at http://www.	
	physionet.org	
Response time of heart rate meter to change in heart rate:		
Response time of heart fate meter to	HR change from 80 to 120 bpm: 4 to 8 seconds	
	HR change from 80 to 40 bpm: 11 to 15 seconds	
Pacemaker pulse rejection capability		
i accinater puise rejection capability	Complies with the amplitudes of pacemaker pulses ± 2 to	
	$\pm 700 \text{ mV}$ and widths 0.1 to 2 ms (specified in IEC 60601-2-	
	27: 2005 50.102.13)	
Pacemaker pulse rejection capability, with overshoot:		
i accinator paíse rejection capacing	Overshoot amplitudes and time constants of $\pm 0.12 \text{ mV}/100$	
	ms to $\pm 2 \text{ mV}/4 \text{ ms}$ (As defined by method B of IEC 60601-	
	2-27: 2005 50.102.13, this corresponds to the pacemaker	
	pulses amplitudes and widths of $\pm 4 \text{ mV/2}$ ms to amplitudes	
	±80 mV/0.1 ms.)	
	·	
ECG Display and Heart Rate Count		

Frequency characteristic:	filter on: 1 to 18 Hz, filter off: 0.05 to 60 Hz
Heart rate detection method:	Average
QRS detection:	70 to 120 ms: amplitude \geq 0.5 mV, rate 30 to 200 beats/min
	40 to 120 ms: amplitude \geq 0.5 mV, rate 30 to 250 beats/min

Heart rate counting range:0, 15 to 300 beats/minHeart rate counting accuracy*:±2 beats/min, (0, 15 to 300 beats/min)* Essential performance of this transmitter

Respiration Measurement

Measuring method:	Impedance method	
Measuring lead:	Between R and F	
Impedance range:	220 to 2000 Ω	
Excitor current:	54 to 93 µAp-p, 48 kHz	
Respiration rate measuring accuracy*: ±2 counts/min (at 0 to 150 counts/min)		
Respiration rate counting range:	0 to 150 counts/min	
* Essential performance of this transmitter		

SpO₂ Measurement (ISO 9919: 2005 compliance)

Measuring range:	0 to 100%SpO ₂	
Declared range:	70 to 100% SpO ₂	
Minimum display range:	1%SpO ₂	
Display update cycle:	Every 3 seconds	
Measuring accuracy (rms)*:	Accuracy assurance temperature: 18 to 40°C	
Total accuracy including probe:	80% SpO ₂ $\le \%$ SpO ₂ $\le 100\%$ SpO ₂ : $\pm 2\%$ SpO ₂	
	70% SpO ₂ $\leq \%$ SpO ₂ $< 80\%$ SpO ₂ : $\pm 3\%$ SpO ₂	
	under 70% SpO ₂ : not specified	
Accuracy of the transmitter:	80% SpO ₂ $\le \%$ SpO ₂ $\le 100\%$ SpO ₂ : $\pm 1\%$ SpO ₂	
	$50\% SpO_2 \le \% SpO_2 < 80\% SpO_2: \pm 2\% SpO_2$	
	under 50% SpO ₂ : not specified	
Pulse rate declared range:	30 to 300 bpm	
Pulse rate display range:	30 to 300 bpm	
Pulse rate accuracy (rms)*:	$\pm 3\% \pm 1$ bpm	
* Essential performance of this transmitter		

* Essential performance of this transmitter

NOTE

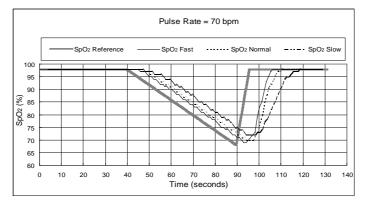
- The SpO₂ measuring accuracy was tested using the TL-201T, TL-260T, TL-271T and TL-631T SpO₂ probes. The testing was performed during induced hypoxia on healthy volunteers (Ethnicity: 10 Caucasians, 2 Africans, 1 Asian and 3 Indians), (Skin: 8 light, 4 medium, 4 dark), (Age: 21 to 34), (5 women and 11 men) under the condition of no motion. Arterial blood was sampled and measured by a CO-oximeter. The difference between SpO₂ measured by the SpO₂ probe and functional SaO₂ measured by a CO-oximeter was calculated using the root-mean-square (rms) method according to ISO 9919: 2005. This measurement accuracy figure represents 2/3 of all test measurements.
- A pulse oximeter tester that generates simulated signals can be used to check the difference from the design specification, but it cannot be used as a replacement for

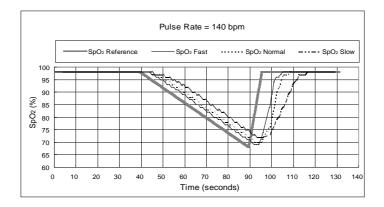
human signals for testing accuracy.

Response time:

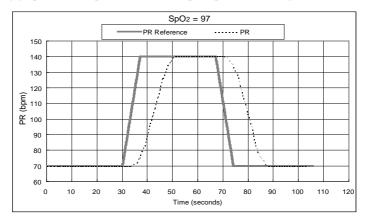
Selectable from "Slow", "Normal" and "Fast".

The following graphs show response time for 0.6%/s \mbox{SpO}_2 change.





The following graph shows response time for 10 bpm/s pulse rate change.



Transmitter

FCC regulation:	FCC part 95 Subpart H
	Wireless Medical Telemetry Service (WMTS)
Field strength limits:	$\leq 200 \text{ mV/m} (\text{at 3 m})$
Undesired emissions:	
FCC part 95 95.2379 (a), (b):	\leq 960 MHz: 200 μ V/m (at 3 m)
	\geq 960 MHz: 500 μ V/m (at 3 m)
Antenna:	Internal
Transmission channel:	Indicated on the transmitter
Transmission frequency range:	608.0250 to 613.9750 MHz
Channel spacing:	50 kHz or 37.5 kHz (12.5 kHz when interleaved)
Modulation:	FSK (frequency shift keying)
Type of emission:	F1D
Occupied bandwidth:	12 to 18 kHz
Effective radiated power:	1.0 mW

Power Requirements

Rated voltage:	3.0 V	
Shutdown voltage:	1.4 to 1.75 V	
Operating voltage:	Shutdown voltage to 3.2 V	
Battery type:	Two AA (LR6) type alkaline dry cell primary batteries	
Battery lifetime (with alkaline batteries, at room temperature):		
ZM-520PA:	approximately 3.5 days	
ZM-530PA:	approximately 2.5 days (measuring ECG, respiration and	
	SpO ₂)	
	approximately 3.5 days (measuring ECG and respiration)	

Dimension and Weight

Dimension:	78 W × 137 H × 36 D (mm)
Weight:	about 230 g (excluding batteries and other accessories)
	about 280 g (including batteries, excluding other accessories)

Environment

Operating e	environment
-------------	-------------

Temperature:	5 to 40°C (41 to 104°F)
Humidity:	30 to 85% (noncondensing)
Atmospheric pressure:	700 to 1060 hPa

Storage and transport environment

Temperature:	-20 to +65°C (-4 to +149°F)
Humidity:	10 to 95%
Atmospheric pressure:	700 to 1060 hPa

Water resistance

Water does not get inside the transmitter when immersed in water up to 30 cm deep for 3 minutes.

Safety Standards

Safety standard:

CAN/CSA-C22.2 No. 601-1 M90 CAN/CSA-C22.2 No. 601-1. 1S1-94 CAN/CSA-C22.2 No. 601-1. 1B-90 CAN/CSA-C22.2 No. 60601-2-49-04 CAN/CSA-C22.2 No. 60601-2-27-06 IEC 60601-1: 1988 IEC 60601-1: 1988 IEC 60601-1 Amendment 1: 1991 IEC 60601-1 Amendment 2: 1995 IEC 60601-2-27: 2005 IEC 60601-2-49: 2001 ISO 9919: 2005 UL 60601-1: 2003 Type of protection against electrical shock:

INTERNALLY POWERED EQUIPMENT

Degree of protection against electrical shock:

ECG and impedance method respiration:

SpO₂:

DEFIBRILLATION-PROOF TYPE CF APPLIED PART DEFIBRILLATION-PROOF TYPE BF APPLIED PART

Degree of protection against harmful ingress of water:

IPX0 (non-protected)

Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE:

	Equipment not suitable for use in the presence of
	FLAMMABLE ANAESTHETIC MIXTURE WITH
	AIR, OR WITH OXYGEN OR NITROUS OXIDE
Mode of operation:	CONTINUOUS OPERATION
ME EQUIPMENT type:	HAND-HELD and PORTABLE

Electromagnetic Compatibility

IEC 60601-1-2: 2001 IEC 60601-1-2 Amendment 1: 2004

Electromagnetic Emissions

This model (ZM-520PA/ZM-530PA) is intended for use in the electromagnetic environment specified below. The customer or the user of ZM-520PA or ZM-530PA should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	ZM-520PA/ZM-530PA uses RF energy only for its
CISPR 11		internal function. Therefore, its RF emissions are
		very low and are not likely to cause any interference
		in nearby electronic equipment.
RF emissions	Class B	ZM-520PA/ZM-530PA is suitable for use in all
CISPR 11		establishments, including domestic establishments.
Harmonic emissions	Not applicable	
IEC 61000-3-2		
Voltage fluctuations/	Not applicable	
flicker emissions		
IEC 61000-3-3		

Electromagnetic Immunity

This model ZM-520PA/ZM-530PA is intended for use in the electromagnetic environment specified below. The customer or the user of ZM-520PA or ZM-530PA 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	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	_
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	 Uτ) for 0.5 cycles 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles <5% Uτ (>95% dip in Uτ) for 5 s 	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m C mains voltage prior to	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Avoiding Electromagnetic Interference (Impedance Respiration)

Impedance respiration measurement is very sensitive and affected by electromagnetic interference. Technological limitations do not allow immunity levels higher than 1 V/m for radiated RF electromagnetic fields. Electromagnetic fields with field strengths above 1 V/m may cause measurement error. Do not use electrically radiating equipment near the impedance respiration measurements.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of ZM-520PA/ZM-530PA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
		(1 V/m 80 MHz to 2.5 GHz for respiration)	$(d = 3.5\sqrt{P} \ 80 \text{ MHz}$ to 800 MHz for respiration $d = 7.0\sqrt{P} \ 800 \text{ MHz}$ to 2.5 GHz for respiration)
			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 deter mined by an electromagnetic site survey ^{*1} , should be less than the compliance level in each frequency range ^{*2} .
			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.

*1 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 ZM-520PA/ZM-530PA is used exceeds the applicable RF compliance level above, ZM-520PA/ ZM-530PA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating ZM-520PA/ZM-530PA.

 *2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m for respiration and 3 V/m for all other functions.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment

The ZM-520PA/ZM-530PA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ZM-520PA/ZM-530PA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ZM-520PA/ZM-530PA as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz d = $1.2\sqrt{P}$	80 MHz to 800 MHz d = $1.2\sqrt{P}$	800 MHz to 2.5 GHz d = $2.3\sqrt{P}$
(**)	u = 1.27 P	(For respiration: d = 3.5√P)	(For respiration: d = 7.0√P)
0.01	0.12	0.12 (0.35*)	0.23 (0.7*)
0.1	0.38	0.38 (1.1*)	0.73 (2.2*)
1	1.2	1.2 (3.5*)	2.3 (7.0*)
10	3.8	3.8 (11*)	7.3 (22*)
100	12	12 (35*)	23 (70*)

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) according to the transmitter manufacturer.

(* For respiration)

- 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.

Recovery Time after Defibrillation

The transmitter returns to the normal operating mode within 10 seconds after defibrillation. The stored settings are not affected.

System Composition for EMC Test

The ZM-520PA/ZM-530PA transmitter is tested to comply with IEC 60601-1-2: 2001 and Amendment 1: 2004 with the following composition.

Units	Cable Length
ZM-520PA/ZM-530PA transmitter	
BR-906P ECG electrode lead	0.8 m
TL-201T finger probe	1.6 m

ZM-521PA/ZM-531PA Measured Parameters

Waveforms: Numeric data:

Transmitted Data

Waveforms: Numeric data: Status information: ECG, impedance method respiration, pulse Heart rate, respiration rate, SpO₂, pulse rate

ECG, respiration, pulse wave SpO₂, pulse rate Battery replacement, battery level*, alarm suspended, pause monitoring*, patient confirmed*, ECG lead, pacing detection, electrode detachment, electrode impedance*, ECG off*, respiration method (impedance)*, SpO₂ status, respiration status*, channel ID, time constant (3.2 s), type of transmitter, transmitter code number*, transmitter serial number*

* Transmitted only when the protocol is "51".

Display

Display size:	2.2 inch TFT color LCD
Viewing area:	44.16 (H) × 33.12 (V) mm
Resolution:	$320 (H) \times 240 (V) dots$

Displayed Data

Numeric and waveform screen:	ECG (one waveform from lead I, II, III, Va or Vb), heart rate, pulse rate, respiration rate, SpO ₂ , message, battery level, QRS/pulse sync mark, pulse bar graph, ECG lead
Waveform review screen:	ECG or pulse wave of past 10 minutes
Numeric review screen:	Heart rate or pulse rate, respiration rate and SpO ₂ at 1 minute
	interval for past 10 minutes
Check electrodes screen:	ECG for checking electrode attachment

ECG

ECG Measurement

Channels:	4
Input dynamic range:	±10 mV or more
Electrode offset potential tolerance:	$\pm 500 \text{ mV}$ or more
Input impedance:	5 M Ω or more
Common mode rejection ratio:	95 dB or more
	IEC 60601-2-27: 2005 50.102.10 complied
Pacing pulse detection:	amplitude ± 2 to 700 mV, duration 0.1 to 2 ms
	IEC 60601-2-27: 2005 complied
	Based upon pacemaker pulse rejection capability

Defibrillation-proof:	ECG input protected against 400 Ws/DC 5 kV	
	IEC 60601-2-27 17.101 complied	
ECG recovery time after defibrillation	on: within 10 s	
Electrode condition:	Displays CHECK ELECTRODES message	
Tall T-wave rejection capability:	Complies with the heights of T-waves from 0 to 1.2 mV	
	IEC 60601-2-27: 2005 50.102.17 complied	
Heart rate averaging:	Calculated by using the most recent 8 beats.	
Heart rate meter accuracy and respon	nse to irregular rhythm:	
	Ventricular bigeminy (Test waveform name: aami3a*):	
	80 bpm	
	Slow alternating ventricular bigeminy (Test waveform name: aami3b*): 60 bpm	
	Rapid alternating ventricular bigeminy (Test waveform	
	name: aami3c*): 108 bpm	
	Bidirectional systoles (Test waveform name: aami3d*):	
	88 bpm	
	* The test waveforms can be download at http://www.	
	physionet.org	
Response time of heart rate meter to	change in heart rate:	
	HR change from 80 to 120 bpm: 4 to 8 seconds	
	HR change from 80 to 40 bpm: 11 to 15 seconds	
Pacemaker pulse rejection capability, without overshoot:		
	Complies with the amplitudes of pacemaker pulses ± 2 to	
	\pm 700 mV and widths 0.1 to 2 ms (specified in IEC 60601-2-	
	27: 2005 50.102.13)	
Pacemaker pulse rejection capability, with overshoot:		
	Overshoot amplitudes and time constants of $\pm 0.12 \text{ mV}/100$	
	ms to ± 2 mV/4 ms (As defined by method B of IEC 60601-	
	2-27: 2005 50.102.13, this corresponds to the pacemaker	
	pulses amplitudes and widths of $\pm 4 \text{ mV}/2 \text{ ms}$ to amplitudes	
	±80 mV/0.1 ms.)	

ECG Display and Heart Rate Count

Frequency characteristic:	filter on: 1 to 18 Hz, filter off: 0.05 to 60 Hz	
Heart rate detection method:	Average	
QRS detection:	70 to 120 ms: amplitude \geq 0.5 mV, rate 30 to 200 beats/min	
	40 to 120 ms: amplitude \geq 0.5 mV, rate 30 to 250 beats/min	
Heart rate counting range:	0, 15 to 300 beats/min	
Heart rate counting accuracy*:	± 2 beats/min, (0, 15 to 300 beats/min)	
* Essential performance of this transmitter		

* Essential performance of this transmitter

Respiration Measurement

Measuring method:	Impedance method	
Measuring lead:	Between R and F	
Impedance range:	220 to 2000 Ω	
Excitor current:	54 to 93 µAp-p, 48 kHz	
Respiration rate measuring accuracy*: ±2 counts/min (at 0 to 150 counts/min)		
Respiration rate counting range:	0 to 150 counts/min	
* Essential performance of this transmitter		

SpO₂ Measurement (ISO 9919: 2005 compliance)

Measuring range:	0 to 100%SpO ₂	
Declared range:	70 to 100% SpO ₂	
Minimum display range:	1%SpO ₂	
Display update cycle:	Every 3 seconds	
Measuring accuracy (rms)*:	Accuracy assurance temperature: 18 to 40°C	
Total accuracy including probe:	80% SpO ₂ $\le \%$ SpO ₂ $\le 100\%$ SpO ₂ : $\pm 2\%$ SpO ₂	
	70% SpO ₂ $\leq \%$ SpO ₂ $< 80\%$ SpO ₂ : $\pm 3\%$ SpO ₂	
	under 70% SpO ₂ : not specified	
Accuracy of the transmitter:	80% SpO ₂ $\le \%$ SpO ₂ $\le 100\%$ SpO ₂ : $\pm 1\%$ SpO ₂	
	50% SpO ₂ $\leq \%$ SpO ₂ $< 80\%$ SpO ₂ : $\pm 2\%$ SpO ₂	
	under 50% SpO ₂ : not specified	
Pulse rate measuring range:	30 to 300 bpm	
Pulse rate display range:	30 to 300 bpm	
Pulse rate accuracy (rms)*:	$\pm 3\% \pm 1$ bpm	
* Essential performance of this transmitter		

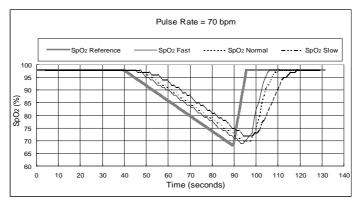
* Essential performance of this transmitter

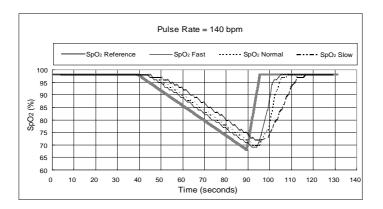
NOTE

- The SpO₂ measuring accuracy was tested using the TL-201T, TL-260T, TL-271T and TL-631T SpO₂ probes. The testing was performed during induced hypoxia on healthy volunteers (Ethnicity: 10 Caucasians, 2 Africans, 1 Asian and 3 Indians), (Skin: 8 light, 4 medium, 4 dark), (Age: 21 to 34), (5 women and 11 men) under the condition of no motion. Arterial blood was sampled and measured by a CO-oximeter. The difference between SpO₂ measured by the SpO₂ probe and functional SaO₂ measured by a CO-oximeter was calculated using the root-mean-square (rms) method according to ISO 9919: 2005. This measurement accuracy figure represents 2/3 of all test measurements.
- A pulse oximeter tester that generates simulated signals can be used to check the difference from the design specification, but it cannot be used as a replacement for human signals for testing accuracy.

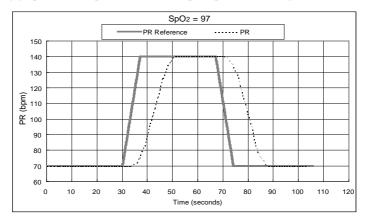
Response time:

Selectable from "Slow", "Normal" and "Fast". The following graphs show response time for 0.6%/s \mbox{SpO}_2 change.





The following graph shows response time for 10 bpm/s pulse rate change.



Transmitter

FCC regulation:	FCC part 95 Subpart H
Field strength limits:	Wireless Medical Telemetry Service (WMTS) ≤ 740 mV/m (at 3 m)
Undesired emissions:	
FCC part 95 95.2379 (a), (b):	\leq 960 MHz: \leq 200 μ V/m (at 3 m)
	$\ge 960 \text{ MHz} \le 500 \ \mu\text{V/m} \text{ (at 3 m)}$
Antenna:	Internal
Transmission channel:	Indicated on the transmitter
Transmission frequency range:	1395.0250 to 1399.9750 MHz
	1427.0250 to 1431.9750 MHz
Channel spacing:	50 kHz or 37.5 kHz (12.5 kHz when interleaved)
Modulation:	FSK (frequency shift keying)
Type of emission:	F1D
Occupied bandwidth:	12 to 18 kHz
Effective radiated power:	5.0 mW
	Can be changed to 1.0 mW if required

Power Requirements

Rated voltage:	3.0 V
Shutdown voltage:	1.4 to 1.75 V
Operating voltage:	Shutdown voltage to 3.2 V
Battery type:	Two AA (LR6) type alkaline dry cell primary batteries
Battery lifetime (with alkaline batter	ies, at room temperature):
ZM-521PA:	approximately 2.5 days
ZM-531PA:	approximately 2 days (measuring ECG, respiration and
	SpO ₂)
	approximately 2.5 days (measuring ECG and respiration)

Dimension and Weight

Dimension:	78 W × 137 H × 36 D (mm)
Weight:	about 230 g (excluding batteries and other accessories)
	about 280 g (including batteries, excluding other accessories)

Environment

Operating environment

Temperature:	5 to 40°C (41 to 104°F)
Humidity:	30 to 85% (noncondensing)
Atmospheric pressure:	700 to 1060 hPa

Storage and transport environment

Temperature:	-20 to +65°C (-4 to +149°F)
Humidity:	10 to 95%
Atmospheric pressure:	700 to 1060 hPa

Water resistance

Water does not get inside the transmitter when immersed in water up to 30 cm deep for 3 minutes.

Safety Standards

Safety standard:

CAN/CSA-C22.2 No. 601-1 M90 CAN/CSA-C22.2 No. 601-1. 1S1-94 CAN/CSA-C22.2 No. 601-1. 1B-90 CAN/CSA-C22.2 No. 60601-2-49-04 CAN/CSA-C22.2 No. 60601-2-27-06 IEC 60601-1: 1988 IEC 60601-1 Amendment 1: 1991 IEC 60601-1 Amendment 2: 1995 IEC 60601-2-27: 2005 IEC 60601-2-49: 2001 ISO 9919: 2005 UL 60601-1: 2003 Type of protection against electrical shock:

INTERNALLY POWERED EQUIPMENT

Degree of protection against electrical shock:

ECG and impedance method respiration:

SpO2:DEFIBRILLATION-PROOF TYPE CF APPLIED PARTDegree of protection against harmful ingress of water:

IPX0 (non-protected)

Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE:

	Equipment not suitable for use in the presence of
	FLAMMABLE ANAESTHETIC MIXTURE WITH
	AIR, OR WITH OXYGEN OR NITROUS OXIDE
Mode of operation:	CONTINUOUS OPERATION
ME EQUIPMENT type:	HAND-HELD and PORTABLE

Electromagnetic Compatibility

IEC 60601-1-2: 2001 IEC 60601-1-2 Amendment 1: 2004

Electromagnetic Emissions

This Model ZM-521PA/ZM-531PA is intended for use in the electromagnetic environment specified below. The customer or the user of ZM-521PA/ZM-531PA should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	ZM-521PA/ZM-531PA uses RF energy only for its
CISPR 11		internal function. Therefore, its RF emissions are very
		low and are not likely to cause any interference in
		nearby electronic equipment.
RF emissions	Class B	ZM-521PA/ZM-531PA is suitable for use in all
CISPR 11		establishments, including domestic establishments.
Harmonic emissions	Not applicable	
IEC 61000-3-2		
Voltage fluctuations/	Not applicable	
flicker emissions		
IEC 61000-3-3		

Electromagnetic Immunity

This model ZM-521PA/ZM-531PA is intended for use in the electromagnetic environment specified below. The customer or the user of ZM-521PA/ZM-531PA 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	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	_
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	 Uτ) for 0.5 cycles 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles <5% Uτ (>95% dip in Uτ) for 5 s 	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m C mains voltage prior to	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Avoiding Electromagnetic Interference (Impedance Respiration)

Impedance respiration measurement is very sensitive and affected by electromagnetic interference. Technological limitations do not allow immunity levels higher than 1 V/m for radiated RF electromagnetic fields. Electromagnetic fields with field strengths above 1 V/m may cause measurement error. Do not use electrically radiating equipment near the impedance respiration measurements.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of ZM-521PA/ZM-531PA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz		
		(1 V/m 80 MHz to 2.5 GHz for respiration)	$(d = 3.5\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz for}$ respiration $d = 7.0\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz for}$ respiration)	
			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 deter mined by an electromagnetic site survey ^{*1} , should be less than the compliance level in each frequency range ^{*2} .	
			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. 				

- *1 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 ZM-521PA/ZM-531PA is used exceeds the applicable RF compliance level above, ZM-521PA/ZM-531PA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating ZM-521PA/ZM-531PA.
- *2 Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m for respiration and 3 V/m for all other functions.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment

ZM-521PA/ZM-531PA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ZM-521PA/ZM-531PA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ZM-521PA/ZM-531PA as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = $2.3\sqrt{P}$		
	d = 1.2√P	(For respiration: d = $3.5\sqrt{P}$)	(For respiration: d = $7.0\sqrt{P}$)		
0.01	0.12	0.12 (0.35*)	0.23 (0.7*)		
0.1	0.38	0.38 (1.1*)	0.73 (2.2*)		
1	1.2	1.2 (3.5*)	2.3 (7.0*)		
10	3.8	3.8 (11*)	7.3 (22*)		
100	12	12 (35*)	23 (70*)		

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) according to the transmitter manufacturer.

(* For respiration)

- 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.

Recovery Time after Defibrillation

The transmitter returns to the normal operating mode within 10 seconds after defibrillation. The stored settings are not affected.

System Composition for EMC Test

The ZM-521PA/ZM-531PA transmitter is tested to comply with IEC 60601-1-2: 2001 and Amendment 1: 2004 with the following composition.

Units	Cable Length
ZM-521PA/ZM-531PA transmitter	
BR-906P ECG electrode lead	0.8 m
TL-201T finger probe	1.6 m

Standard Accessories

Name	Model	Q'ty	Supply Code
Strap		1	Y233

Options

CAUTION

Only use Nihon Kohden specified electrodes, electrode leads and SpO_2 probes. Otherwise, the maximum performance from the transmitter cannot be guaranteed.

Transmitter

QI-901PK channel writer

ECG/RESP

Name	Туре	Length (m)	Model	Qty	Supply Code
	3 electrodes, AHA, clip type	0.8	BR-903PA	1	K911A
	3 electrodes, AHA, clip type	0.8	BR-933PA	1	K903B
Electrode	3 electrodes, AHA, hook type	0.8	BR-943PA	1	K904B
lead	6 electrodes, AHA, clip type	0.8	BR-936PA	1	K903D
	6 electrodes, AHA, hook type	0.8	BR-946PA	1	K904D

\mathbf{SpO}_{2}

Name	Cable Length (m)	Model	Qty	Supply Code
Finger probe (reusable)	0.6	TL-201T	1	P225H
Finger probe (reusable)	1.6	1L-2011	1	P225F
Multi-site probe (reusable)	1.6	TL-220T	1	P225G
Eingen muche (neurophie)	0.6	TL-631T1	1	P311A
Finger probe (reusable)	1.6	TL-631T3	1	P311C
SaO analy (for a halt disease his)	0.8	TL-271T	24	P203A
SpO ₂ probe (for adult, disposable)	1.6	TL-271T3	24	P203E
SaO anala (fan abild dianaachta)	0.8	TL-272T	24	P203B
SpO ₂ probe (for child, disposable)	1.6	TL-272T3	24	P203F
SpO ₂ probe (for neonate/adult,	0.8	TL-273T	24	P203C
disposable)	1.6	TL-273T3	24	P203G
SpO ₂ probe (for child/infant,	0.8	TL-274T	24	P203D
disposable)	1.6	TL-274T3	24	P203H
SpO ₂ probe (for adult/neonate,	0.8	TL-051S	5	P228A
disposable)	1.6	TL-052S	5	P228B
SpO ₂ probe (for child/infant,	0.8	TL-061S	5	P229A
disposable)	1.6	TL-062S	5	P229B
COTTONY tape		_	20	P259
Foam tape for TL-051S/052S/ 061S/062S	_	_	4 × 25 packages	P260
Attachment tape for TL-220T/631T		_	3×30 packages	P263
Probe fastener		YS-093P2	30	P267

Transmission Frequencies

Channel: 9002 to 9478

Transmission Frequency (MHz)	Channel No.
608.0250	9002
608.0375	9003
608.0500	9004
608.0625	9005
608.0750	9006
608.0875	9007
608.1000	9008
608.1125	9009
608.1250	9010
608.1375	9011
608.1500	9012
608.1625	9013
608.1750	9014
608.1875	9015
608.2000	9016
608.2125	9017
608.2250	9018
608.2375	9019
608.2500	9020
608.2625	9021
608.2750	9022
608.2875	9023
608.3000	9024
608.3125	9025
608.3250	9026
608.3375	9027
608.3500	9028
608.3625	9029

Transmission Frequency (MHz)	Channel No.
608.3750	9030
608.3875	9031
608.4000	9032
608.4125	9033
608.4250	9034
608.4375	9035
608.4500	9036
608.4625	9037
608.4750	9038
608.4875	9039
608.5000	9040
608.5125	9041
608.5250	9042
608.5375	9043
608.5500	9044
608.5625	9045
608.5750	9046
608.5875	9047
608.6000	9048
608.6125	9049
608.6250	9050
608.6375	9051
608.6500	9052
608.6625	9053
608.6750	9054
608.6875	9055
608.7000	9056
608.7125	9057

Transmission Frequency (MHz)	Channel No.
608.7250	9058
608.7375	9059
608.7500	9060
608.7625	9061
608.7750	9062
608.7875	9063
608.8000	9064
608.8125	9065
608.8250	9066
608.8375	9067
608.8500	9068
608.8625	9069
608.8750	9070
608.8875	9071
608.9000	9072
608.9125	9073
608.9250	9074
608.9375	9075
608.9500	9076
608.9625	9077
608.9750	9078
608.9875	9079
609.0000	9080
609.0125	9081
609.0250	9082
609.0375	9083
609.0500	9084
609.0625	9085

Transmission Frequency (MHz)	Channel No.
609.0750	9086
609.0875	9087
609.1000	9088
609.1125	9089
609.1250	9090
609.1375	9091
609.1500	9092
609.1625	9093
609.1750	9094
609.1875	9095
609.2000	9096
609.2125	9097
609.2250	9098
609.2375	9099
609.2500	9100
609.2625	9101
609.2750	9102
609.2875	9103
609.3000	9104
609.3125	9105
609.3250	9106
609.3375	9107
609.3500	9108
609.3625	9109
609.3750	9110
609.3875	9111
609.4000	9112
609.4125	9113
609.4250	9114
609.4375	9115
609.4500	9116
609.4625	9117
609.4750	9118

Transmission Frequency (MHz)	Channel No.
609.4875	9119
609.5000	9120
609.5125	9121
609.5250	9122
609.5375	9123
609.5500	9124
609.5625	9125
609.5750	9126
609.5875	9127
609.6000	9128
609.6125	9129
609.6250	9130
609.6375	9131
609.6500	9132
609.6625	9133
609.6750	9134
609.6875	9135
609.7000	9136
609.7125	9137
609.7250	9138
609.7375	9139
609.7500	9140
609.7625	9141
609.7750	9142
609.7875	9143
609.8000	9144
609.8125	9145
609.8250	9146
609.8375	9147
609.8500	9148
609.8625	9149
609.8750	9150
609.8875	9151

Transmission	Channel
Frequency (MHz)	No.
609.9000	9152
609.9125	9153
609.9250	9154
609.9375	9155
609.9500	9156
609.9625	9157
609.9750	9158
609.9875	9159
610.0000	9160
610.0125	9161
610.0250	9162
610.0375	9163
610.0500	9164
610.0625	9165
610.0750	9166
610.0875	9167
610.1000	9168
610.1125	9169
610.1250	9170
610.1375	9171
610.1500	9172
610.1625	9173
610.1750	9174
610.1875	9175
610.2000	9176
610.2125	9177
610.2250	9178
610.2375	9179
610.2500	9180
610.2625	9181
610.2750	9182
610.2875	9183
610.3000	9184

Transmission Frequency (MHz)	Channel No.
610.3125	9185
610.3250	9186
610.3375	9187
610.3500	9188
610.3625	9189
610.3750	9190
610.3875	9191
610.4000	9192
610.4125	9193
610.4250	9194
610.4375	9195
610.4500	9196
610.4625	9197
610.4750	9198
610.4875	9199
610.5000	9200
610.5125	9201
610.5250	9202
610.5375	9203
610.5500	9204
610.5625	9205
610.5750	9206
610.5875	9207
610.6000	9208
610.6125	9209
610.6250	9210
610.6375	9211
610.6500	9212
610.6625	9213
610.6750	9214
610.6875	9215
610.7000	9216
610.7125	9217

Transmission Frequency (MHz)	Channel No.
610.7250	9218
610.7375	9219
610.7500	9220
610.7625	9221
610.7750	9222
610.7875	9223
610.8000	9224
610.8125	9225
610.8250	9226
610.8375	9227
610.8500	9228
610.8625	9229
610.8750	9230
610.8875	9231
610.9000	9232
610.9125	9233
610.9250	9234
610.9375	9235
610.9500	9236
610.9625	9237
610.9750	9238
610.9875	9239
611.0000	9240
611.0125	9241
611.0250	9242
611.0375	9243
611.0500	9244
611.0625	9245
611.0750	9246
611.0875	9247
611.1000	9248
611.1125	9249
611.1250	9250

Transmission Frequency (MHz)	Channel No.
611.1375	9251
611.1500	9252
611.1625	9253
611.1750	9254
611.1875	9255
611.2000	9256
611.2125	9257
611.2250	9258
611.2375	9259
611.2500	9260
611.2625	9261
611.2750	9262
611.2875	9263
611.3000	9264
611.3125	9265
611.3250	9266
611.3375	9267
611.3500	9268
611.3625	9269
611.3750	9270
611.3875	9271
611.4000	9272
611.4125	9273
611.4250	9274
611.4375	9275
611.4500	9276
611.4625	9277
611.4750	9278
611.4875	9279
611.5000	9280
611.5125	9281
611.5250	9282
611.5375	9283

Transmission Frequency (MHz)	Channel No.
611.5500	9284
611.5625	9285
611.5750	9286
611.5875	9287
611.6000	9288
611.6125	9289
611.6250	9290
611.6375	9291
611.6500	9292
611.6625	9293
611.6750	9294
611.6875	9295
611.7000	9296
611.7125	9297
611.7250	9298
611.7375	9299
611.7500	9300
611.7625	9301
611.7750	9302
611.7875	9303
611.8000	9304
611.8125	9305
611.8250	9306
611.8375	9307
611.8500	9308
611.8625	9309
611.8750	9310
611.8875	9311
611.9000	9312
611.9125	9313
611.9250	9314
611.9375	9315
611.9500	9316

Transmission Frequency (MHz)	Channel No.
611.9625	9317
611.9750	9318
611.9875	9319
612.0000	9320
612.0125	9321
612.0250	9322
612.0375	9323
612.0500	9324
612.0625	9325
612.0750	9326
612.0875	9327
612.1000	9328
612.1125	9329
612.1250	9330
612.1375	9331
612.1500	9332
612.1625	9333
612.1750	9334
612.1875	9335
612.2000	9336
612.2125	9337
612.2250	9338
612.2375	9339
612.2500	9340
612.2625	9341
612.2750	9342
612.2875	9343
612.3000	9344
612.3125	9345
612.3250	9346
612.3375	9347
612.3500	9348
612.3625	9349

Transmission Frequency (MHz)	Channel No.
612.3750	9350
612.3875	9351
612.4000	9352
612.4125	9353
612.4250	9354
612.4375	9355
612.4500	9356
612.4625	9357
612.4750	9358
612.4875	9359
612.5000	9360
612.5125	9361
612.5250	9362
612.5375	9363
612.5500	9364
612.5625	9365
612.5750	9366
612.5875	9367
612.6000	9368
612.6125	9369
612.6250	9370
612.6375	9371
612.6500	9372
612.6625	9373
612.6750	9374
612.6875	9375
612.7000	9376
612.7125	9377
612.7250	9378
612.7375	9379
612.7500	9380
612.7625	9381
612.7750	9382

Transmission Frequency (MHz)	Channel No.
612.7875	9383
612.8000	9384
612.8125	9385
612.8250	9386
612.8375	9387
612.8500	9388
612.8625	9389
612.8750	9390
612.8875	9391
612.9000	9392
612.9125	9393
612.9250	9394
612.9375	9395
612.9500	9396
612.9625	9397
612.9750	9398
612.9875	9399
613.0000	9400
613.0125	9401
613.0250	9402
613.0375	9403
613.0500	9404
613.0625	9405
613.0750	9406
613.0875	9407
613.1000	9408
613.1125	9409
613.1250	9410
613.1375	9411
613.1500	9412
613.1625	9413
613.1750	9414
613.1875	9415

Transmission Frequency (MHz)	Channel No.
613.2000	9416
613.2125	9417
613.2250	9418
613.2375	9419
613.2500	9420
613.2625	9421
613.2750	9422
613.2875	9423
613.3000	9424
613.3125	9425
613.3250	9426
613.3375	9427
613.3500	9428
613.3625	9429
613.3750	9430
613.3875	9431
613.4000	9432
613.4125	9433
613.4250	9434
613.4375	9435
613.4500	9436
613.4625	9437
613.4750	9438
613.4875	9439
613.5000	9440
613.5125	9441
613.5250	9442
613.5375	9443
613.5500	9444
613.5625	9445
613.5750	9446
613.5875	9447
613.6000	9448

Transmission Frequency (MHz)	Channel No.
613.6125	9449
613.6250	9450
613.6375	9451
613.6500	9452
613.6625	9453
613.6750	9454
613.6875	9455
613.7000	9456
613.7125	9457
613.7250	9458
613.7375	9459
613.7500	9460
613.7625	9461
613.7750	9462
613.7875	9463
613.8000	9464
613.8125	9465
613.8250	9466
613.8375	9467
613.8500	9468
613.8625	9469
613.8750	9470
613.8875	9471
613.9000	9472
613.9125	9473
613.9250	9474
613.9375	9475
613.9500	9476
613.9625	9477
613.9750	9478

Transmission Frequency (MHz)	Channel No.
1395.0250	E002
1395.0375	E003
1395.0500	E004
1395.0625	E005
1395.0750	E006
1395.0875	E007
1395.1000	E008
1395.1125	E009
1395.1250	E010
1395.1375	E011
1395.1500	E012
1395.1625	E013
1395.1750	E014
1395.1875	E015
1395.2000	E016
1395.2125	E017
1395.2250	E018
1395.2375	E019
1395.2500	E020
1395.2625	E021
1395.2750	E022
1395.2875	E023
1395.3000	E024
1395.3125	E025
1395.3250	E026
1395.3375	E027
1395.3500	E028
1395.3625	E029
1395.3750	E030
1395.3875	E031
1395.4000	E032
1395.4125	E033

Transmission Frequency (MHz)	Channel No.
1395.4250	E034
1395.4375	E035
1395.4500	E036
1395.4625	E037
1395.4750	E038
1395.4875	E039
1395.5000	E040
1395.5125	E041
1395.5250	E042
1395.5375	E043
1395.5500	E044
1395.5625	E045
1395.5750	E046
1395.5875	E047
1395.6000	E048
1395.6125	E049
1395.6250	E050
1395.6375	E051
1395.6500	E052
1395.6625	E053
1395.6750	E054
1395.6875	E055
1395.7000	E056
1395.7125	E057
1395.7250	E058
1395.7375	E059
1395.7500	E060
1395.7625	E061
1395.7750	E062
1395.7875	E063
1395.8000	E064
1395.8125	E065

Transmission	
Frequency	Channel
(MHz)	No.
1395.8250	E066
1395.8375	E067
1395.8500	E068
1395.8625	E069
1395.8750	E070
1395.8875	E071
1395.9000	E072
1395.9125	E073
1395.9250	E074
1395.9375	E075
1395.9500	E076
1395.9625	E077
1395.9750	E078
1395.9875	E079
1396.0000	E080
1396.0125	E081
1396.0250	E082
1396.0375	E083
1396.0500	E084
1396.0625	E085
1396.0750	E086
1396.0875	E087
1396.1000	E088
1396.1125	E089
1396.1250	E090
1396.1375	E091
1396.1500	E092
1396.1625	E093
1396.1750	E094
1396.1875	E095
1396.2000	E096
1396.2125	E097

Transmission Frequency (MHz)	Channel No.
1396.2250	E098
1396.2375	E099
1396.2500	E100
1396.2625	E101
1396.2750	E102
1396.2875	E103
1396.3000	E104
1396.3125	E105
1396.3250	E106
1396.3375	E107
1396.3500	E108
1396.3625	E109
1396.3750	E110
1396.3875	E111
1396.4000	E112
1396.4125	E113
1396.4250	E114
1396.4375	E115
1396.4500	E116
1396.4625	E117
1396.4750	E118
1396.4875	E119
1396.5000	E120
1396.5125	E121
1396.5250	E122
1396.5375	E123
1396.5500	E124
1396.5625	E125
1396.5750	E126
1396.5875	E127
1396.6000	E128
1396.6125	E129
1396.6250	E130
1396.6375	E131

Transmission	
Frequency	Channel
(MHz)	No.
1396.6500	E132
1396.6625	E133
1396.6750	E134
1396.6875	E135
1396.7000	E136
1396.7125	E137
1396.7250	E138
1396.7375	E139
1396.7500	E140
1396.7625	E141
1396.7750	E142
1396.7875	E143
1396.8000	E144
1396.8125	E145
1396.8250	E146
1396.8375	E147
1396.8500	E148
1396.8625	E149
1396.8750	E150
1396.8875	E151
1396.9000	E152
1396.9125	E153
1396.9250	E154
1396.9375	E155
1396.9500	E156
1396.9625	E157
1396.9750	E158
1396.9875	E159
1397.0000	E160
1397.0125	E161
1397.0250	E162
1397.0375	E163
1397.0500	E164
1397.0625	E165

Transmission Frequency (MHz)	Channel No.
1397.0750	E166
1397.0875	E167
1397.1000	E168
1397.1125	E169
1397.1250	E170
1397.1375	E171
1397.1500	E172
1397.1625	E173
1397.1750	E174
1397.1875	E175
1397.2000	E176
1397.2125	E177
1397.2250	E178
1397.2375	E179
1397.2500	E180
1397.2625	E181
1397.2750	E182
1397.2875	E183
1397.3000	E184
1397.3125	E185
1397.3250	E186
1397.3375	E187
1397.3500	E188
1397.3625	E189
1397.3750	E190
1397.3875	E191
1397.4000	E192
1397.4125	E193
1397.4250	E194
1397.4375	E195
1397.4500	E196
1397.4625	E197
1397.4750	E198
1397.4875	E199

Transmission Frequency (MHz)	Channel No.
1397.5000	E200
1397.5125	E201
1397.5250	E202
1397.5375	E203
1397.5500	E204
1397.5625	E205
1397.5750	E206
1397.5875	E207
1397.6000	E208
1397.6125	E209
1397.6250	E210
1397.6375	E211
1397.6500	E212
1397.6625	E213
1397.6750	E214
1397.6875	E215
1397.7000	E216
1397.7125	E217
1397.7250	E218
1397.7375	E219
1397.7500	E220
1397.7625	E221
1397.7750	E222
1397.7875	E223
1397.8000	E224
1397.8125	E225
1397.8250	E226
1397.8375	E227
1397.8500	E228
1397.8625	E229
1397.8750	E230
1397.8875	E231
1397.9000	E232
1397.9125	E233

Transmission Frequency (MHz)	Channel No.
1397.9250	E234
1397.9375	E235
1397.9500	E236
1397.9625	E237
1397.9750	E238
1397.9875	E239
1398.0000	E240
1398.0125	E241
1398.0250	E242
1398.0375	E243
1398.0500	E244
1398.0625	E245
1398.0750	E246
1398.0875	E247
1398.1000	E248
1398.1125	E249
1398.1250	E250
1398.1375	E251
1398.1500	E252
1398.1625	E253
1398.1750	E254
1398.1875	E255
1398.2000	E256
1398.2125	E257
1398.2250	E258
1398.2375	E259
1398.2500	E260
1398.2625	E261
1398.2750	E262
1398.2875	E263
1398.3000	E264
1398.3125	E265
1398.3250	E266
1398.3375	E267

Transmission Frequency	Channel
(MHz)	No.
1398.3500	E268
1398.3625	E269
1398.3750	E270
1398.3875	E271
1398.4000	E272
1398.4125	E273
1398.4250	E274
1398.4375	E275
1398.4500	E276
1398.4625	E277
1398.4750	E278
1398.4875	E279
1398.5000	E280
1398.5125	E281
1398.5250	E282
1398.5375	E283
1398.5500	E284
1398.5625	E285
1398.5750	E286
1398.5875	E287
1398.6000	E288
1398.6125	E289
1398.6250	E290
1398.6375	E291
1398.6500	E292
1398.6625	E293
1398.6750	E294
1398.6875	E295
1398.7000	E296
1398.7125	E297
1398.7250	E298
1398.7375	E299
1398.7500	E300
1398.7625	E301

Transmission Frequency (MHz)	Channel No.
1398.7750	E302
1398.7875	E303
1398.8000	E304
1398.8125	E305
1398.8250	E306
1398.8375	E307
1398.8500	E308
1398.8625	E309
1398.8750	E310
1398.8875	E311
1398.9000	E312
1398.9125	E313
1398.9250	E314
1398.9375	E315
1398.9500	E316
1398.9625	E317
1398.9750	E318
1398.9875	E319
1399.0000	E320
1399.0125	E321
1399.0250	E322
1399.0375	E323
1399.0500	E324
1399.0625	E325
1399.0750	E326
1399.0875	E327
1399.1000	E328
1399.1125	E329
1399.1250	E330
1399.1375	E331
1399.1500	E332
1399.1625	E333
1399.1750	E334
1399.1875	E335

Transmission Frequency	Channel
(MHz)	No.
1399.2000	E336
1399.2125	E337
1399.2250	E338
1399.2375	E339
1399.2500	E340
1399.2625	E341
1399.2750	E342
1399.2875	E343
1399.3000	E344
1399.3125	E345
1399.3250	E346
1399.3375	E347
1399.3500	E348
1399.3625	E349
1399.3750	E350
1399.3875	E351
1399.4000	E352
1399.4125	E353
1399.4250	E354
1399.4375	E355
1399.4500	E356
1399.4625	E357
1399.4750	E358
1399.4875	E359
1399.5000	E360
1399.5125	E361
1399.5250	E362
1399.5375	E363
1399.5500	E364
1399.5625	E365
1399.5750	E366
1399.5875	E367
1399.6000	E368
1399.6125	E369

Transmission Frequency (MHz)	Channel No.
1399.6250	E370
1399.6375	E371
1399.6500	E372
1399.6625	E373
1399.6750	E374
1399.6875	E375
1399.7000	E376
1399.7125	E377
1399.7250	E378
1399.7375	E379
1399.7500	E380
1399.7625	E381
1399.7750	E382
1399.7875	E383
1399.8000	E384
1399.8125	E385
1399.8250	E386
1399.8375	E387
1399.8500	E388
1399.8625	E389
1399.8750	E390
1399.8875	E391
1399.9000	E392
1399.9125	E393
1399.9250	E394
1399.9375	E395
1399.9500	E396
1399.9625	E397
1399.9750	E398

Transmission Frequency (MHz)	Channel No.
1427.0250	E502
1427.0375	E503
1427.0500	E504
1427.0625	E505
1427.0750	E506
1427.0875	E507
1427.1000	E508
1427.1125	E509
1427.1250	E510
1427.1375	E511
1427.1500	E512
1427.1625	E513
1427.1750	E514
1427.1875	E515
1427.2000	E516
1427.2125	E517
1427.2250	E518
1427.2375	E519
1427.2500	E520
1427.2625	E521
1427.2750	E522
1427.2875	E523
1427.3000	E524
1427.3125	E525
1427.3250	E526
1427.3375	E527
1427.3500	E528
1427.3625	E529
1427.3750	E530
1427.3875	E531
1427.4000	E532
1427.4125	E533

Transmission	Channel
Frequency	No.
(MHz)	E534
1427.4250	
1427.4375	E535
1427.4500	E536
1427.4625	E537
1427.4750	E538
1427.4875	E539
1427.5000	E540
1427.5125	E541
1427.5250	E542
1427.5375	E543
1427.5500	E544
1427.5625	E545
1427.5750	E546
1427.5875	E547
1427.6000	E548
1427.6125	E549
1427.6250	E550
1427.6375	E551
1427.6500	E552
1427.6625	E553
1427.6750	E554
1427.6875	E555
1427.7000	E556
1427.7125	E557
1427.7250	E558
1427.7375	E559
1427.7500	E560
1427.7625	E561
1427.7750	E562
1427.7875	E563
1427.8000	E564
1427.8125	E565

Transmission	
Frequency	Channel
(MHz)	No.
1427.8250	E566
1427.8375	E567
1427.8500	E568
1427.8625	E569
1427.8750	E570
1427.8875	E571
1427.9000	E572
1427.9125	E573
1427.9250	E574
1427.9375	E575
1427.9500	E576
1427.9625	E577
1427.9750	E578
1427.9875	E579
1428.0000	E580
1428.0125	E581
1428.0250	E582
1428.0375	E583
1428.0500	E584
1428.0625	E585
1428.0750	E586
1428.0875	E587
1428.1000	E588
1428.1125	E589
1428.1250	E590
1428.1375	E591
1428.1500	E592
1428.1625	E593
1428.1750	E594
1428.1875	E595
1428.2000	E596
1428.2125	E597

Transmission Frequency (MHz)	Channel No.
1428.2250	E598
1428.2375	E599
1428.2500	E600
1428.2625	E601
1428.2750	E602
1428.2875	E603
1428.3000	E604
1428.3125	E605
1428.3250	E606
1428.3375	E607
1428.3500	E608
1428.3625	E609
1428.3750	E610
1428.3875	E611
1428.4000	E612
1428.4125	E613
1428.4250	E614
1428.4375	E615
1428.4500	E616
1428.4625	E617
1428.4750	E618
1428.4875	E619
1428.5000	E620
1428.5125	E621
1428.5250	E622
1428.5375	E623
1428.5500	E624
1428.5625	E625
1428.5750	E626
1428.5875	E627
1428.6000	E628
1428.6125	E629
1428.6250	E630
1428.6375	E631

Transmission Frequency (MHz)	Channel No.
1428.6500	E632
1428.6625	E633
1428.6750	E634
1428.6875	E635
1428.7000	E636
1428.7125	E637
1428.7250	E638
1428.7375	E639
1428.7500	E640
1428.7625	E641
1428.7750	E642
1428.7875	E643
1428.8000	E644
1428.8125	E645
1428.8250	E646
1428.8375	E647
1428.8500	E648
1428.8625	E649
1428.8750	E650
1428.8875	E651
1428.9000	E652
1428.9125	E653
1428.9250	E654
1428.9375	E655
1428.9500	E656
1428.9625	E657
1428.9750	E658
1428.9875	E659
1429.0000	E660
1429.0125	E661
1429.0250	E662
1429.0375	E663
1429.0500	E664
1429.0625	E665

Transmission Frequency (MHz)	Channel No.
1429.0750	E666
1429.0875	E667
1429.1000	E668
1429.1125	E669
1429.1250	E670
1429.1375	E671
1429.1500	E672
1429.1625	E673
1429.1750	E674
1429.1875	E675
1429.2000	E676
1429.2125	E677
1429.2250	E678
1429.2375	E679
1429.2500	E680
1429.2625	E681
1429.2750	E682
1429.2875	E683
1429.3000	E684
1429.3125	E685
1429.3250	E686
1429.3375	E687
1429.3500	E688
1429.3625	E689
1429.3750	E690
1429.3875	E691
1429.4000	E692
1429.4125	E693
1429.4250	E694
1429.4375	E695
1429.4500	E696
1429.4625	E697
1429.4750	E698
1429.4875	E699

Transmission Frequency (MHz)	Channel No.
1429.5000	E700
1429.5125	E701
1429.5250	E702
1429.5375	E703
1429.5500	E704
1429.5625	E705
1429.5750	E706
1429.5875	E707
1429.6000	E708
1429.6125	E709
1429.6250	E710
1429.6375	E711
1429.6500	E712
1429.6625	E713
1429.6750	E714
1429.6875	E715
1429.7000	E716
1429.7125	E717
1429.7250	E718
1429.7375	E719
1429.7500	E720
1429.7625	E721
1429.7750	E722
1429.7875	E723
1429.8000	E724
1429.8125	E725
1429.8250	E726
1429.8375	E727
1429.8500	E728
1429.8625	E729
1429.8750	E730
1429.8875	E731
1429.9000	E732
1429.9125	E733

Transmission Frequency (MHz)	Channel No.
1429.9250	E734
1429.9375	E735
1429.9500	E736
1429.9625	E737
1429.9750	E738
1429.9875	E739
1430.0000	E740
1430.0125	E741
1430.0250	E742
1430.0375	E743
1430.0500	E744
1430.0625	E745
1430.0750	E746
1430.0875	E747
1430.1000	E748
1430.1125	E749
1430.1250	E750
1430.1375	E751
1430.1500	E752
1430.1625	E753
1430.1750	E754
1430.1875	E755
1430.2000	E756
1430.2125	E757
1430.2250	E758
1430.2375	E759
1430.2500	E760
1430.2625	E761
1430.2750	E762
1430.2875	E763
1430.3000	E764
1430.3125	E765
1430.3250	E766
1430.3375	E767

Transmission Frequency (MHz)	Channel No.
1430.3500	E768
1430.3625	E769
1430.3750	E770
1430.3875	E771
1430.4000	E772
1430.4125	E773
1430.4250	E774
1430.4375	E775
1430.4500	E776
1430.4625	E777
1430.4750	E778
1430.4875	E779
1430.5000	E780
1430.5125	E781
1430.5250	E782
1430.5375	E783
1430.5500	E784
1430.5625	E785
1430.5750	E786
1430.5875	E787
1430.6000	E788
1430.6125	E789
1430.6250	E790
1430.6375	E791
1430.6500	E792
1430.6625	E793
1430.6750	E794
1430.6875	E795
1430.7000	E796
1430.7125	E797
1430.7250	E798
1430.7375	E799
1430.7500	E800
1430.7625	E801

Transmission Frequency (MHz)	Channel No.
1430.7750	E802
1430.7875	E803
1430.8000	E804
1430.8125	E805
1430.8250	E806
1430.8375	E807
1430.8500	E808
1430.8625	E809
1430.8750	E810
1430.8875	E811
1430.9000	E812
1430.9125	E813
1430.9250	E814
1430.9375	E815
1430.9500	E816
1430.9625	E817
1430.9750	E818
1430.9875	E819
1431.0000	E820
1431.0125	E821
1431.0250	E822
1431.0375	E823
1431.0500	E824
1431.0625	E825
1431.0750	E826
1431.0875	E827
1431.1000	E828
1431.1125	E829
1431.1250	E830
1431.1375	E831
1431.1500	E832
1431.1625	E833
1431.1750	E834
1431.1875	E835

Transmission Frequency (MHz)	Channel No.
1431.2000	E836
1431.2125	E837
1431.2250	E838
1431.2375	E839
1431.2500	E840
1431.2625	E841
1431.2750	E842
1431.2875	E843
1431.3000	E844
1431.3125	E845
1431.3250	E846
1431.3375	E847
1431.3500	E848
1431.3625	E849
1431.3750	E850
1431.3875	E851
1431.4000	E852
1431.4125	E853
1431.4250	E854
1431.4375	E855
1431.4500	E856
1431.4625	E857
1431.4750	E858
1431.4875	E859
1431.5000	E860
1431.5125	E861
1431.5250	E862
1431.5375	E863
1431.5500	E864
1431.5625	E865
1431.5750	E866
1431.5875	E867
1431.6000	E868
1431.6125	E869

Transmission Frequency (MHz)	Channel No.
1431.6250	E870
1431.6375	E871
1431.6500	E872
1431.6625	E873
1431.6750	E874
1431.6875	E875
1431.7000	E876
1431.7125	E877
1431.7250	E878
1431.7375	E879
1431.7500	E880
1431.7625	E881
1431.7750	E882
1431.7875	E883
1431.8000	E884
1431.8125	E885
1431.8250	E886
1431.8375	E887
1431.8500	E888
1431.8625	E889
1431.8750	E890
1431.8875	E891
1431.9000	E892
1431.9125	E893
1431.9250	E894
1431.9375	E895
1431.9500	E896
1431.9625	E897
1431.9750	E898

Manufacturer

NIHON KOHDEN CORPORATION

1-31-4 Nishiochiai, Shinjuku-ku Tokyo 161-8560, Japan Phone +81 3-5996-8041

North and South America

NIHON KOHDEN AMERICA, INC.

15353 Barranca Parkway, Irvine, CA 92618, U.S.A. Toll-free +1-800-325-0283 Phone +1 949-580-1555 Fax +1 949-580-1550

NIHON KOHDEN MEXICO S.A. DE C.V.

Insurgentes Sur 730, Piso 9 Oriente, Col. Del Valle C.P. 03100, Delegacion Benito Juarez, Ciudad de Mexico Phone +52 55-8851-5550 Fax +52 55-8851-5580

NIHON KOHDEN DO BRASIL LTDA.

Rua Diadema, 89, 1º andar, conjuntos 11 a 17, bairro Mauá no Município de São Caetano do Sul, Estado de São Paulo CEP 09580-670, Brasil Phone +55 11-3044-1700 Fax +55 11-3044-0463

Europe

ECTREP European Representative NIHON KOHDEN EUROPE GmbH Raiffeisenstrasse 10, 61191 Rosbach, Germany Phone +49 6003-827-0 Fax +49 6003-827-599

NIHON KOHDEN DEUTSCHLAND GmbH

Raiffeisenstrasse 10, 61191 Rosbach, Germany Phone +49 6003-827-0 Fax +49 6003-827-599

NIHON KOHDEN FRANCE SARL

Centre d'Affaires La Boursidière, Bât C – RDC, 92357 Le Plessis Robinson, France Phone +33 1-49-08-05-50 Fax +33 1-49-08-93-32

NIHON KOHDEN IBERICA S.L.

Calle Toronga 23, Oficina 1 28043 Madrid, Spain Phone +34 917-161-080 Fax +34 913-004-676

NIHON KOHDEN ITALIA S.r.I.

Via Fratelli Bronzetti 28, 24124 Bergamo, Italy Phone + 39 035-219543 Fax + 39 035-232546

UK Responsible Person

NIHON KOHDEN UK LTD.

Unit 3, Heyworth Business Park, Old Portsmouth Road, Peasmarsh, Guildford, Surrey, GU3 1AF, UK Phone +44 14-8333-1328

Asia

SHANGHAI KOHDEN

MEDICAL ELECTRONIC INSTRUMENT CORP.

No. 567 Huancheng Bei Road Shanghai Comprehensive Industrial Development Zone Fengxian District, Shanghai 201401, China Phone + 86 21-5743-6998

NIHON KOHDEN SINGAPORE PTE LTD

1 Maritime Square, #10-34 HarbourFront Centre Singapore 099253 Phone +65 6376-2210 Fax +65 6376-2264

NIHON KOHDEN INDIA PVT. LTD.

308, Tower A, Spazedge, Sector 47, Sohna Road Gurgaon-122 002 Haryana, India Toll-free +91 1800-103-8182 Phone +91 124-493-1000 Fax +91 124-493-1029

NIHON KOHDEN MIDDLE EAST FZE

JAFZA One Tower A, 19th floor, Office No. 1912 P.O. Box 261516, Jebel Ali Free Zone, Dubai, U.A.E. Phone +971 4-884-0080 Fax +971 4-880-0122

NIHON KOHDEN KOREA, INC.

3F, Cheongok Bldg., 88, Dongmak-ro, Mapo-gu, Seoul, 04075, Republic of Korea Phone +82 2-3273-2310 Fax +82 2-3273-2352

Contact information is accurate as of Sep 2022. Visit https://www.nihonkohden.com/ for the latest information.

The model and serial number of your device are identified on the rear or bottom of the unit. Write the model and serial number in the spaces provided below. Whenever you call your representative concerning this device, mention these two pieces of information for quick and accurate service.

Model -

Serial Number .

Your Representative

Note for users in the territory of the EEA and Switzerland:

Any serious incident that has occurred in relation to the device should be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

ZM-520PA, ZM-521PA, ZM-530PA, ZM-531PA_0614-904743G

NIHON KOHDEN

-

NIHON KOHDEN CORPORATION

1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan Phone +81 3-5996-8041 https://www.nihonkohden.com/