

Service Manual

Tentative

Life Scope **TR**

Bedside Monitor

BSM-6301/BSM-6501/BSM-6701

BSM-6000 series
BSM-6301A
BSM-6301K
BSM-6501A
BSM-6501K
BSM-6701A
BSM-6701K

If you have any comments or suggestions on this manual, please contact us at: www.nihonkohden.com

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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 non-approved 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.
 - (2) Check that the instrument is grounded properly.
 - (3) Check that all cords are connected properly.
 - (4) Pay extra attention when the instrument is combined 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 battery-operated 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.
- 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 least every 6 months.
 - (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 distributor.

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 product to sale by or on the order of a physician.

EMC RELATED CAUTION

This equipment and/or system complies with IEC 60601-1-2 International Standard for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in 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:

1. 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. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.
2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:
Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.
3. 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. A humid room can help lessen this problem.
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. 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. 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.

Caution - continued

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.

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

In IEC 60601-1-2 Medical Electronic Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic compatibility-Requirements and test. Section 36. 202. 2 Radiated radio-frequency electromagnetic fields, PATIENT COUPLED EQUIPMENT and/or SYSTEMS applicable IMMUNITY test methods are under consideration at SC62A/WG13. The 3 V/m IMMUNITY level may be inappropriate especially when measuring SpO₂ because physiological signals can be much smaller than those induced by a 3 V/m electromagnetic field.

When measuring SpO₂, various interference may produce false waveforms which look like pulse waveforms. SpO₂ value and pulse rate may be measured from these false waveforms, causing the alarm to function improperly.

When installing the monitor, avoid locations where the monitor may receive strong electromagnetic interference such as radio or TV stations, cellular phone or mobile two-way radios.

BSM-6301 and BSM-6501 (when QE-910P is not connected) comply with International Standard IEC 60601-1-2 (2001) which requires CISPR11, Group 1, Class B. Class B EQUIPMENT is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

BSM-6301, BSM-6501 (when QE-910P is connected) and BSM-6701 comply with International Standard IEC 60601-1-2 (2001) which requires CISPR11, Group 1, Class A. Class A EQUIPMENT is equipment suitable for use in industrial or light industrial establishments and commercial environment.

BSM-6301 and BSM-6501 (when QE-910P and ZS-900P are connected) are CLASS A equipment if the equipment complies with IEC 60601-1-2: 2001 36 201.1.5 in the countries which do not have national wireless rule.

WARNING

Interaction Between Minute Ventilation Rate-Adaptive Pacemakers and Cardiac Monitoring and Diagnostic Equipment*

The bioelectric impedance measurement sensor of a minute ventilation rate-adaptive implantable pacemaker may be affected by cardiac monitoring and diagnostic equipment which is connected to the same patient. If this occurs, the pacemaker may pace at its maximum rate and give incorrect data to the monitor or diagnostic equipment. If this occurs, disconnect the monitor or diagnostic equipment 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.

- * Minute ventilation is sensed in rate-adaptive pacemakers by a technology known as bioelectric impedance measurement (BIM). Many medical devices in addition to pacemakers use this technology. When one of these devices is used on a patient with an active, minute ventilation rate-adaptive pacemaker, the pacemaker may erroneously interpret the mixture of BIM signals created in the patient, resulting in an elevated pacing rate.

For more information, see the FDA web site.

<http://www.fda.gov/cdrh/safety.html>

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 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, prerequisites, alternative methods or supplemental information.

Text Conventions in this Manual

- Names of hard keys on the main unit are enclosed in square brackets: [Menu]
- Messages that are displayed on the screen are enclosed in quotation marks: "CHECK ELECTRODES"
- Names of items that are displayed on the screen are enclosed in angle brackets: <SENSITIVITY>

Related Documentation

The BSM-6301A/K, BSM-6501A/K and BSM-6701A/K bedside monitors come with the following manuals in addition to the operator's manual.

Administrator's Guide

Describes how to install the bedside monitor. It also explains about the password protected settings on the SYSTEM SETUP window and SYSTEM CONFIGURATION screen which only an administrator can change.

User's Guide, Part I

Gives supplemental information on the operation of the bedside monitor.

User's Guide, Part II

Describes the features and settings of the monitoring parameters.

Service Manual

Describes information on servicing the bedside monitor. Only qualified service personnel can service the bedside monitor.

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Introduction

This service manual provides useful information to qualified personnel to understand, troubleshoot, service, maintain and repair the BSM-6000A/K series Bedside Monitor (referred to as “the instrument” in this service manual).

The information in the operator’s manual is primarily for the user. However, it is important for service personnel to thoroughly read the operator’s manual and service manual before starting to troubleshoot, service, maintain or repair this instrument. This is because service personnel need to understand the operation of the instrument in order to effectively use the information in the service manual.

General Information on Servicing

Note the following information when servicing the instrument.

CAUTION

Safety

- There is the possibility that the outside surface of the instrument, such as the operation keys, could be contaminated by contagious germs, so disinfect and clean the instrument before servicing it. When servicing the instrument, wear rubber gloves to protect yourself from infection.
- There is the possibility that when the lithium battery is broken, a solvent or toxic substance inside the lithium battery could leak out. If the solvent or toxic substance touches your skin or gets into your eye or mouth, immediately wash it with a lot of water and see a physician.

Liquid ingress

The instrument is not drip-proof, so do not install the instrument where water or liquid can get into or fall on the instrument. If liquid accidentally gets into the instrument or the instrument accidentally drops into liquid, disassemble the instrument, clean it with clean water and dry it completely. After reassembling, use the patient safety checks and function/performance checks to verify that there is nothing wrong. If there is something wrong with the instrument, contact your Nihon Kohden representative for repair.

Environmental Safeguards

Depending on the local laws in your community, it may be illegal to dispose of the lithium battery and CRT unit in the regular waste collection. Check with your local officials for proper disposal procedures.

Disinfection and cleaning

To disinfect the outside surface of the instrument, wipe it with a nonabrasive cloth moistened with any of the disinfectants listed below. Do not use any other disinfectants or ultraviolet rays to disinfect the instrument.

- Chlorhexidine gluconate solution: 0.5%
- Benzethonium chloride solution: 0.2%
- Glutaraldehyde solution: 2.0%
- Benzalkonium chloride: 0.2%
- Hydrochloric alkyl diaminoethylglycine: 0.5%

Transport

- Use the specified shipment container and packing material to transport the instrument. If necessary, double pack the instrument.

Also, put the instrument into the shipment container after packing so that the buffer material does not get inside the instrument.

- When transporting a board or unit of the instrument, be sure to use a conductive bag. Never use an aluminum bag when transporting the power board, power unit or board on which a lithium battery is mounted. Also, never wrap the board or unit of the instrument with styrene foam or a plastic bag which generates static electricity.

Handling the instrument

- Because the outside surface of the instrument is made of resin, it can be easily damaged. When handling the instrument, remove clutter from around the instrument and be careful not to damage the instrument or get it dirty.
- Because most of the boards in the instrument are multilayer boards with surface mounted electrical devices (SMD), a special tool is required when removing and soldering the electrical devices. To avoid damaging other electrical components, do not remove and solder SMD components yourself.

Measuring and Test Equipment

Maintain the accuracy of the measuring and test equipment by checking and calibrating it according to the check and calibration procedures.

Service Policy and Patient Safety Checks

Service Policy

Our technical service policy for this instrument is to replace the faulty unit, board or part or damaged mechanical part with a new one. Do not perform electrical device or component level repair of the multilayer board or unit. We do not support component level repair outside the factory for the following reasons:

- Most of the boards are multilayer boards with surface mounted electrical devices, so the mounting density of the board is too high.
- A special tool and special repair skill is required to repair the multilayer boards with surface mounted electrical devices.

Disassemble the instrument or replace a board or unit in an environment where the instrument is protected against static electricity.

As background knowledge for repair, pay special attention to the following:

- You can reduce the repair time by considering the problem before starting repair.
- You can clarify the source of most of the troubles using the information from the diagnostic check function of the instrument.

Patient Safety Checks

Periodic maintenance procedures and diagnostic check procedures are provided in this manual to ensure that the instrument is operating in accordance with its design and production specifications. To verify that the instrument is working in a safe manner with regard to patient safety, patient safety checks should be performed on the instrument before it is first installed, periodically after installation, and after any repair is made on the instrument.

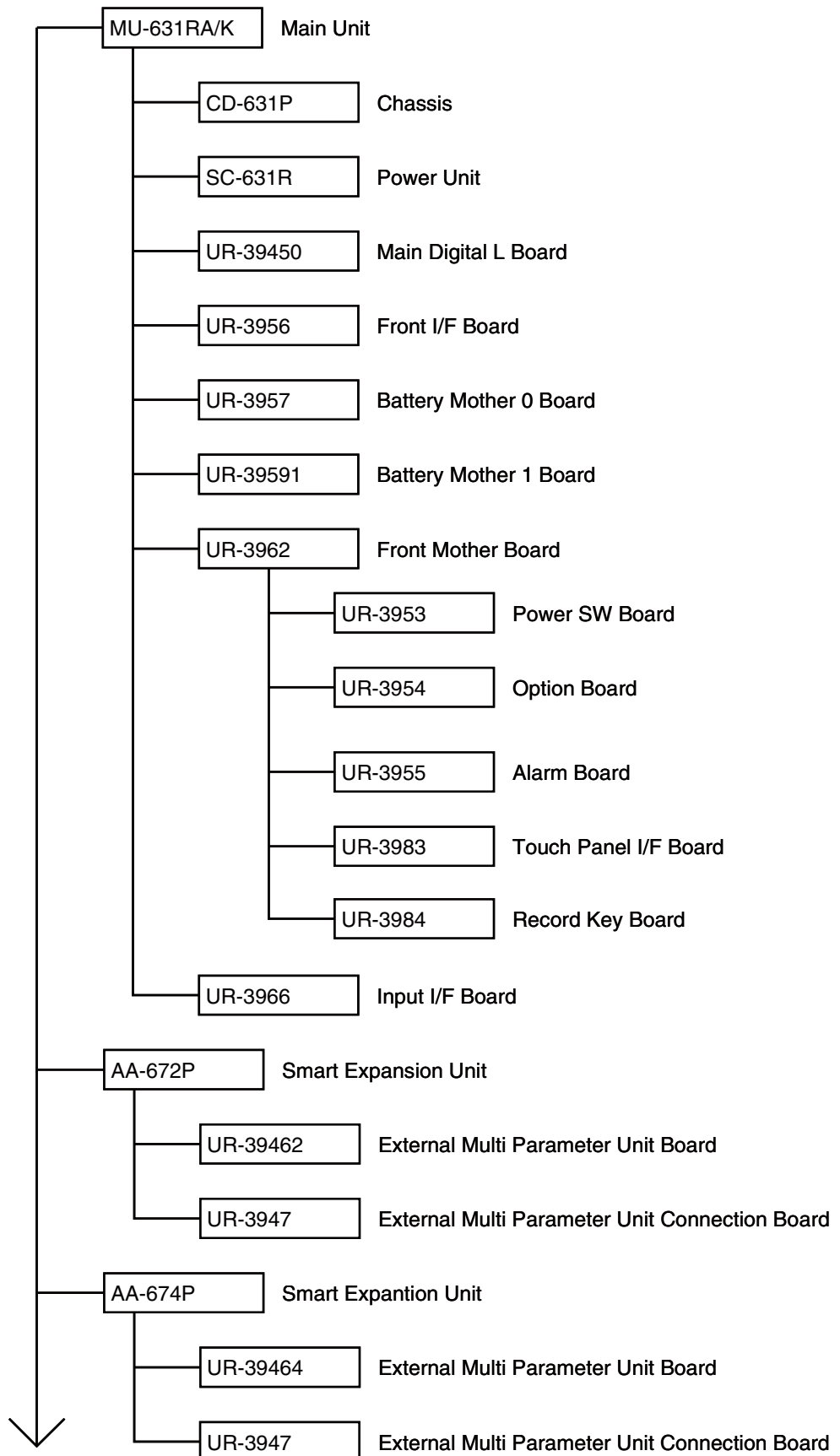
For patient safety checks, perform the following checks as described in the International Electrotechnical Commission's standard, IEC60601-1: 1988:

- Protective earth resistance check
- Earth leakage current check
- Enclosure leakage current check
- Patient leakage current check
- Withstanding voltage check

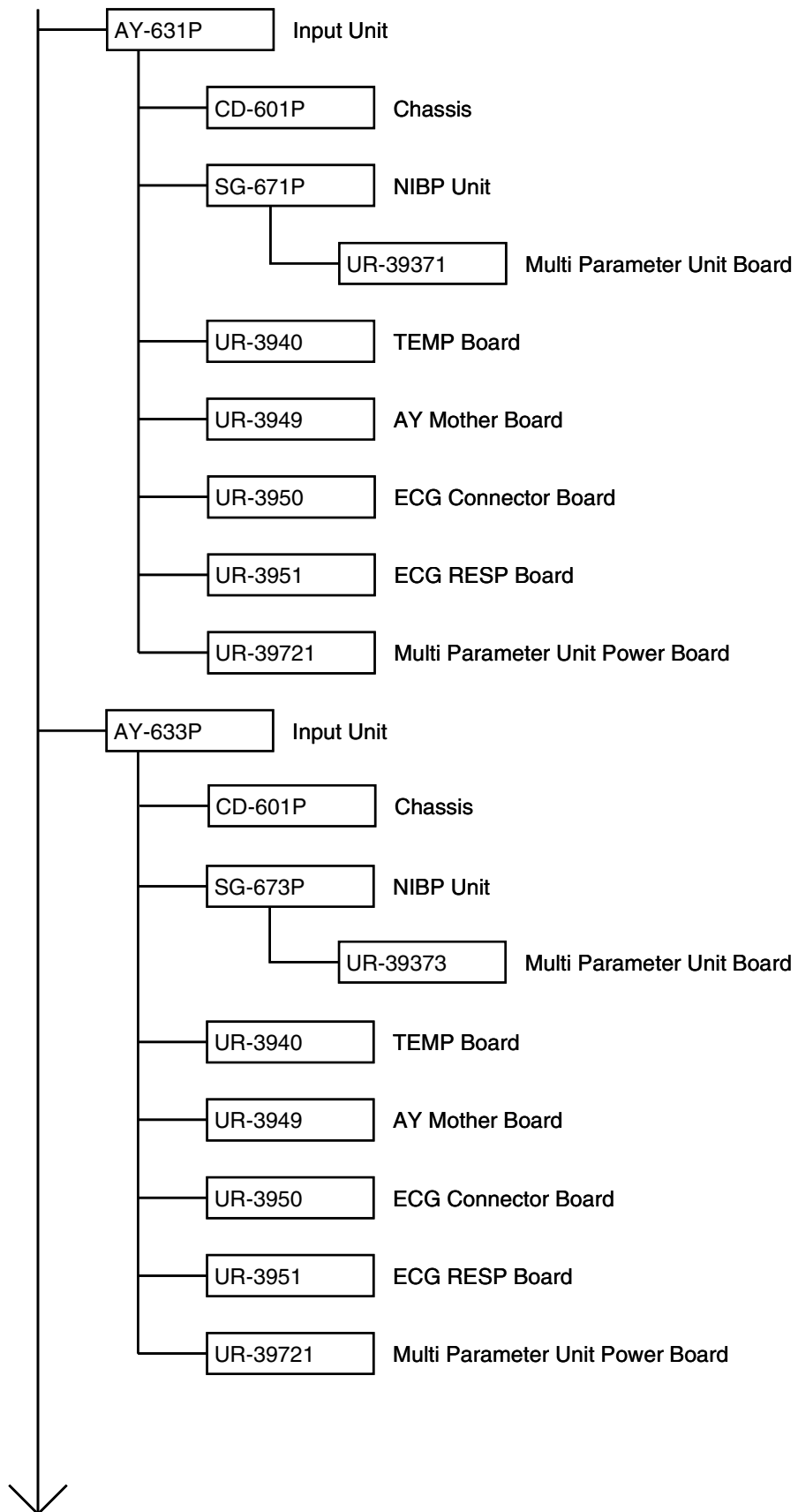
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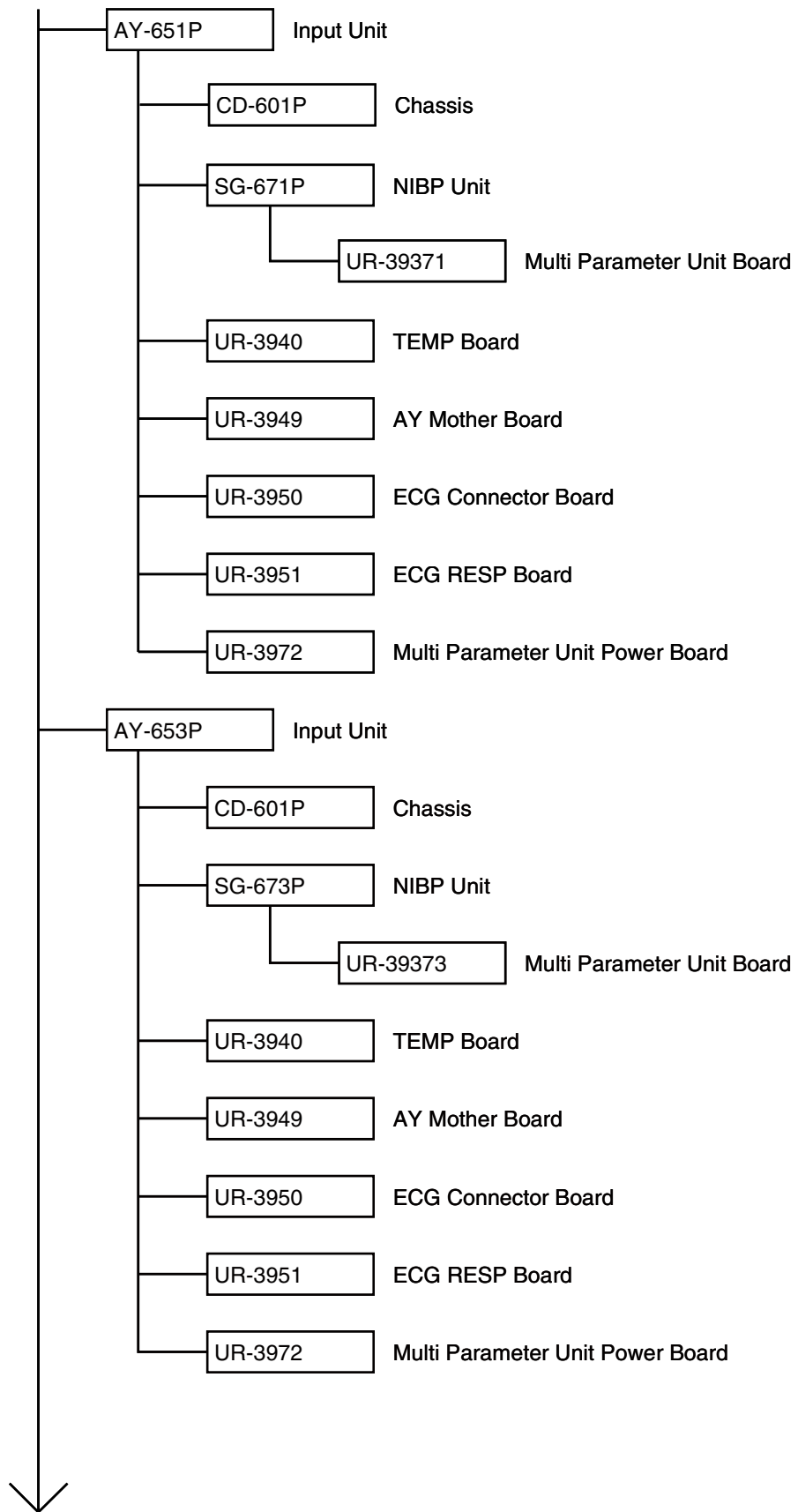
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BSM-6301A/K

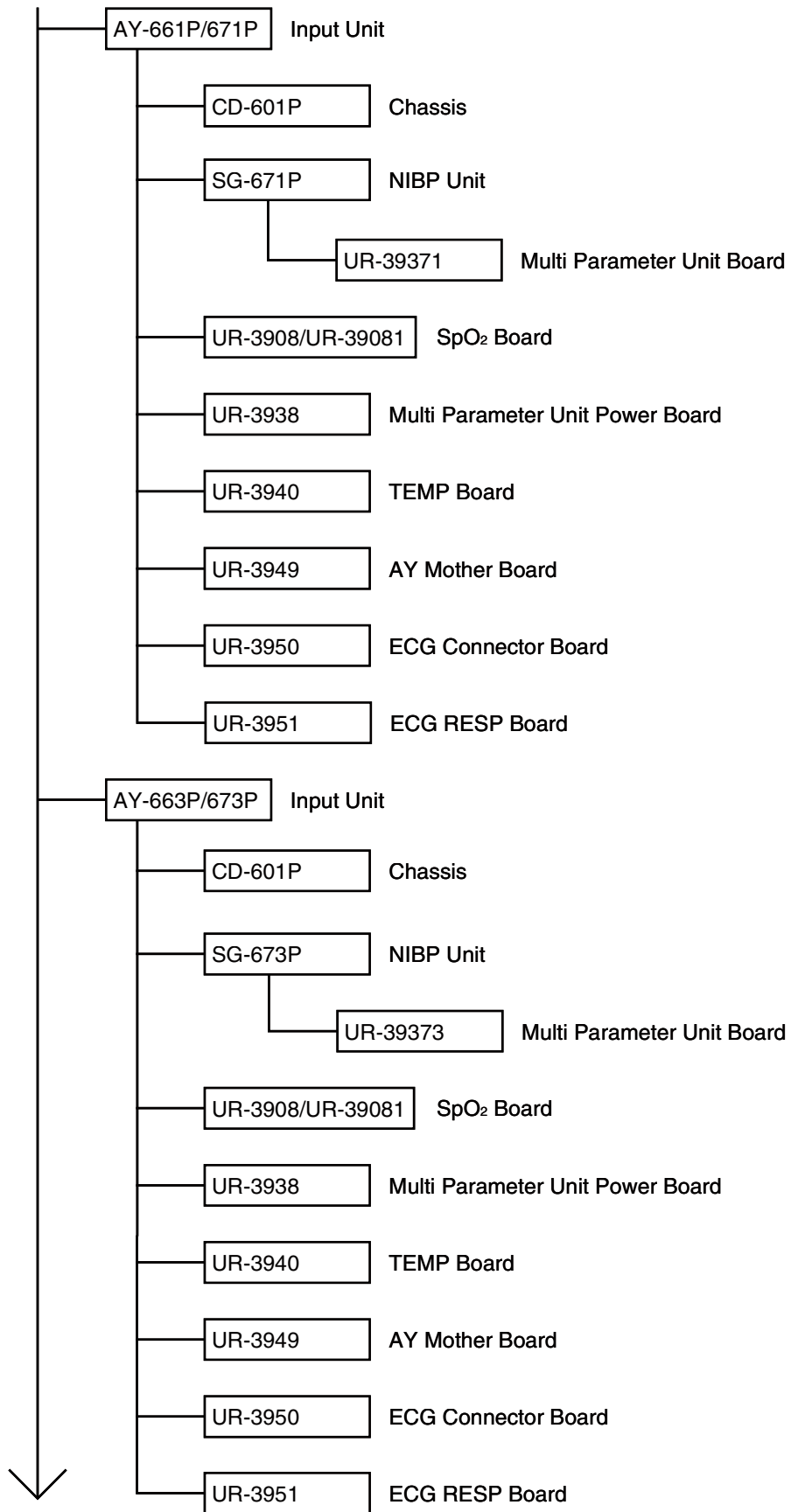


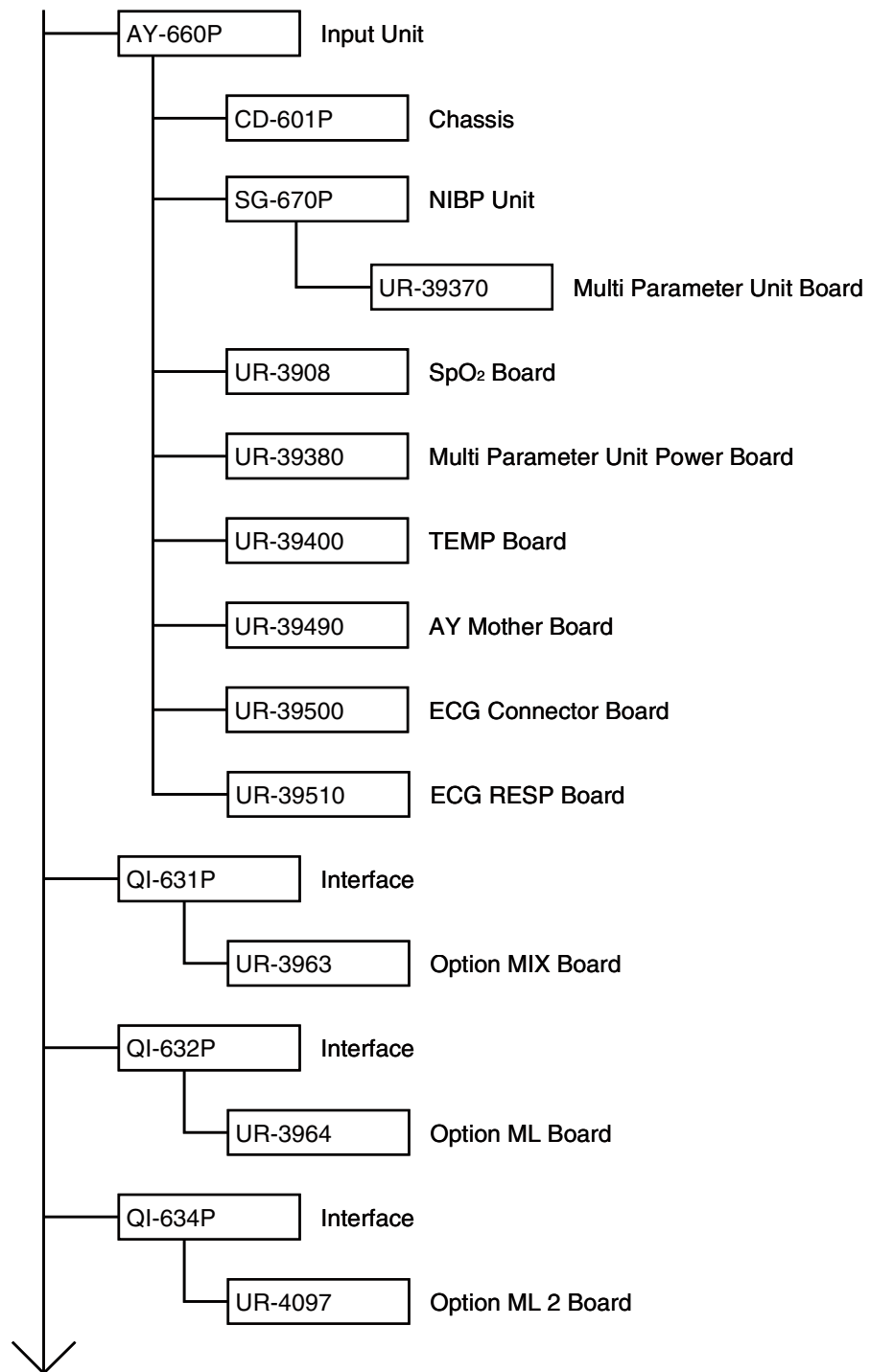
1. GENERAL



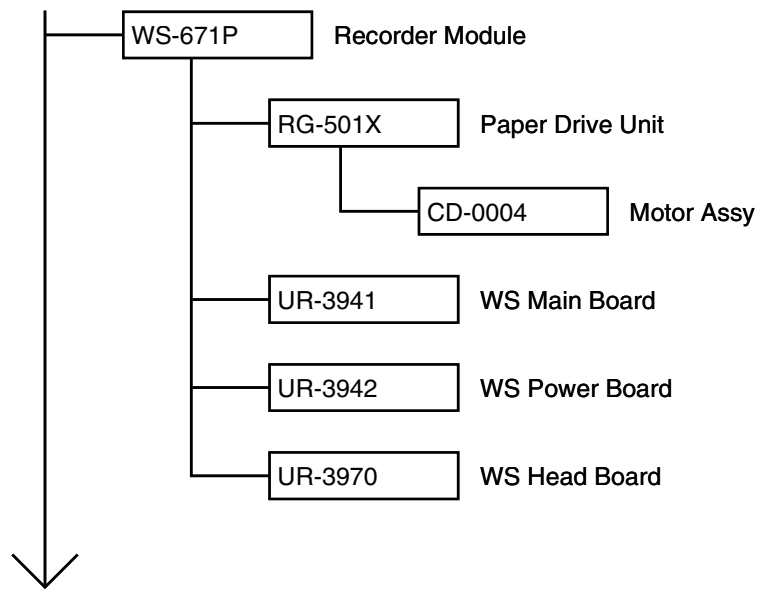


1. GENERAL

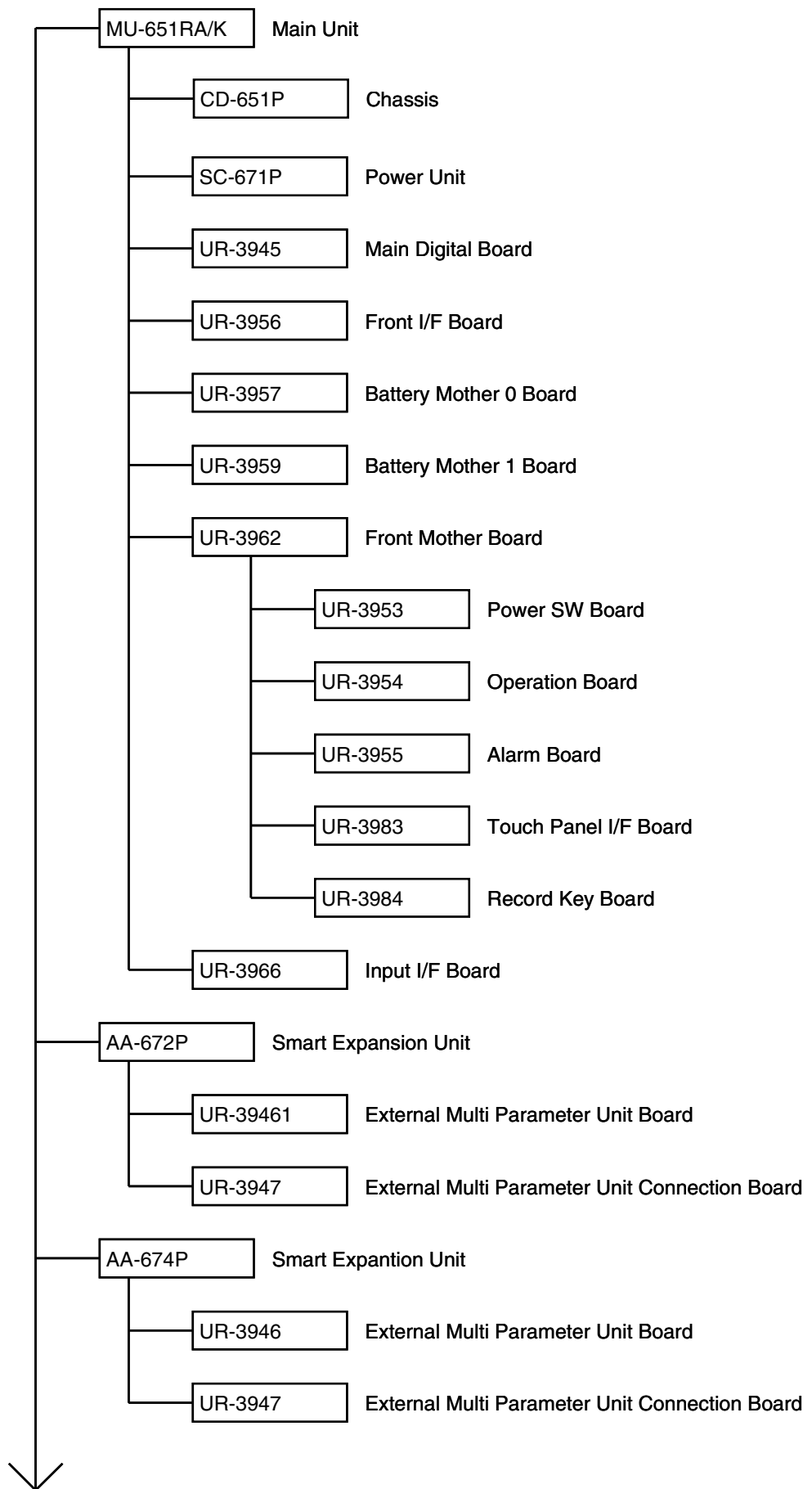




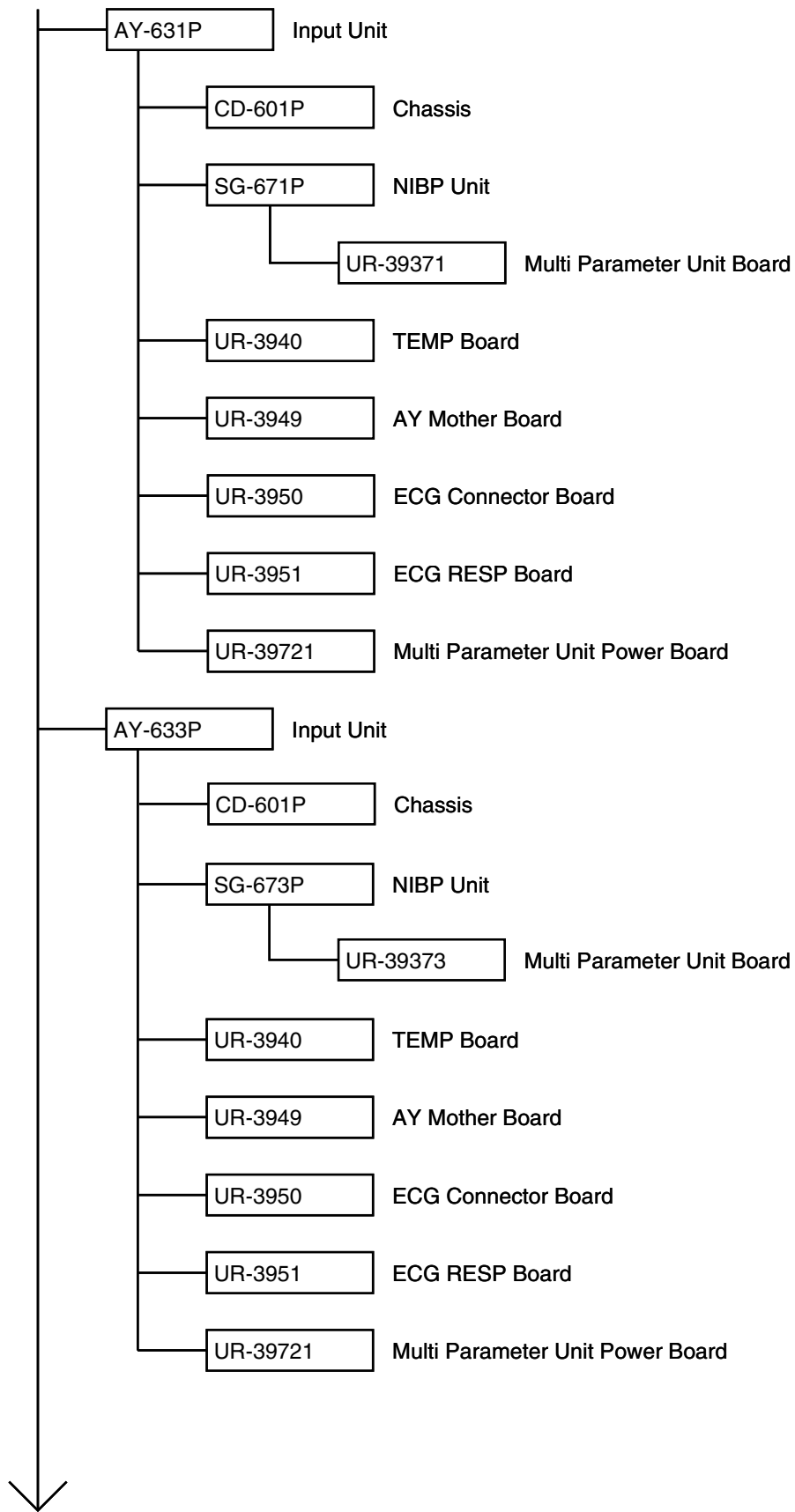
1. GENERAL

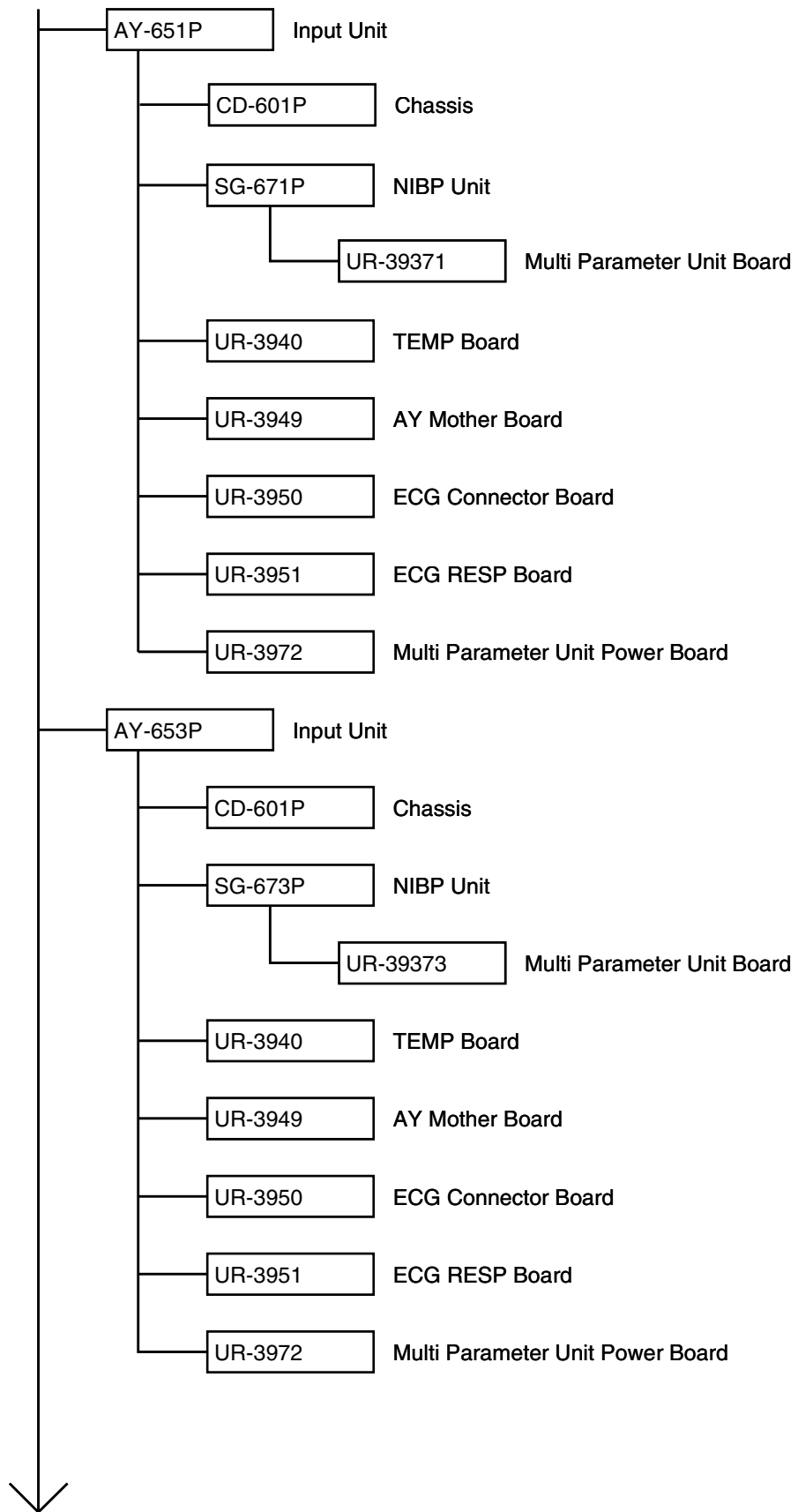


BSM-6501A/K

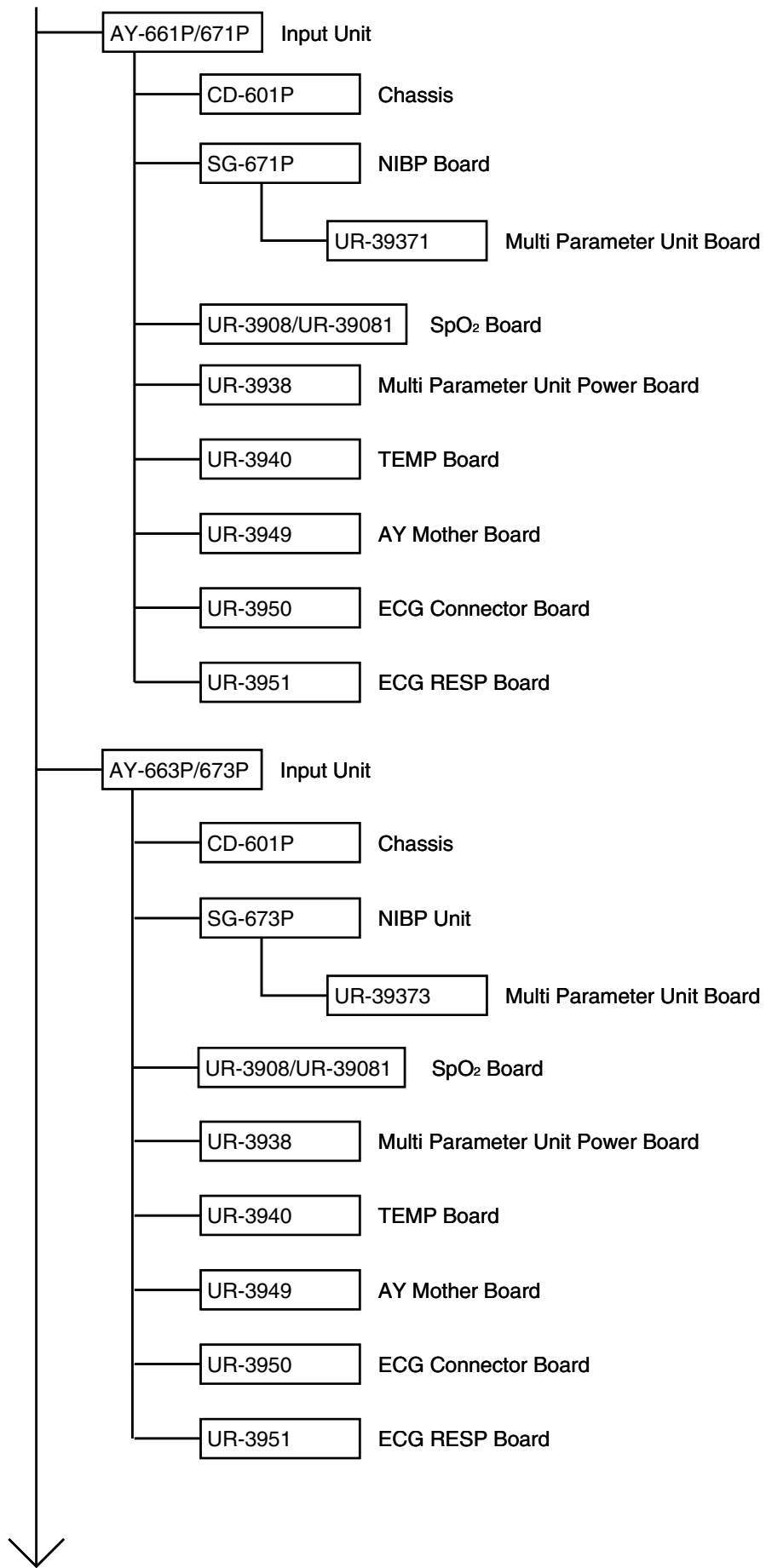


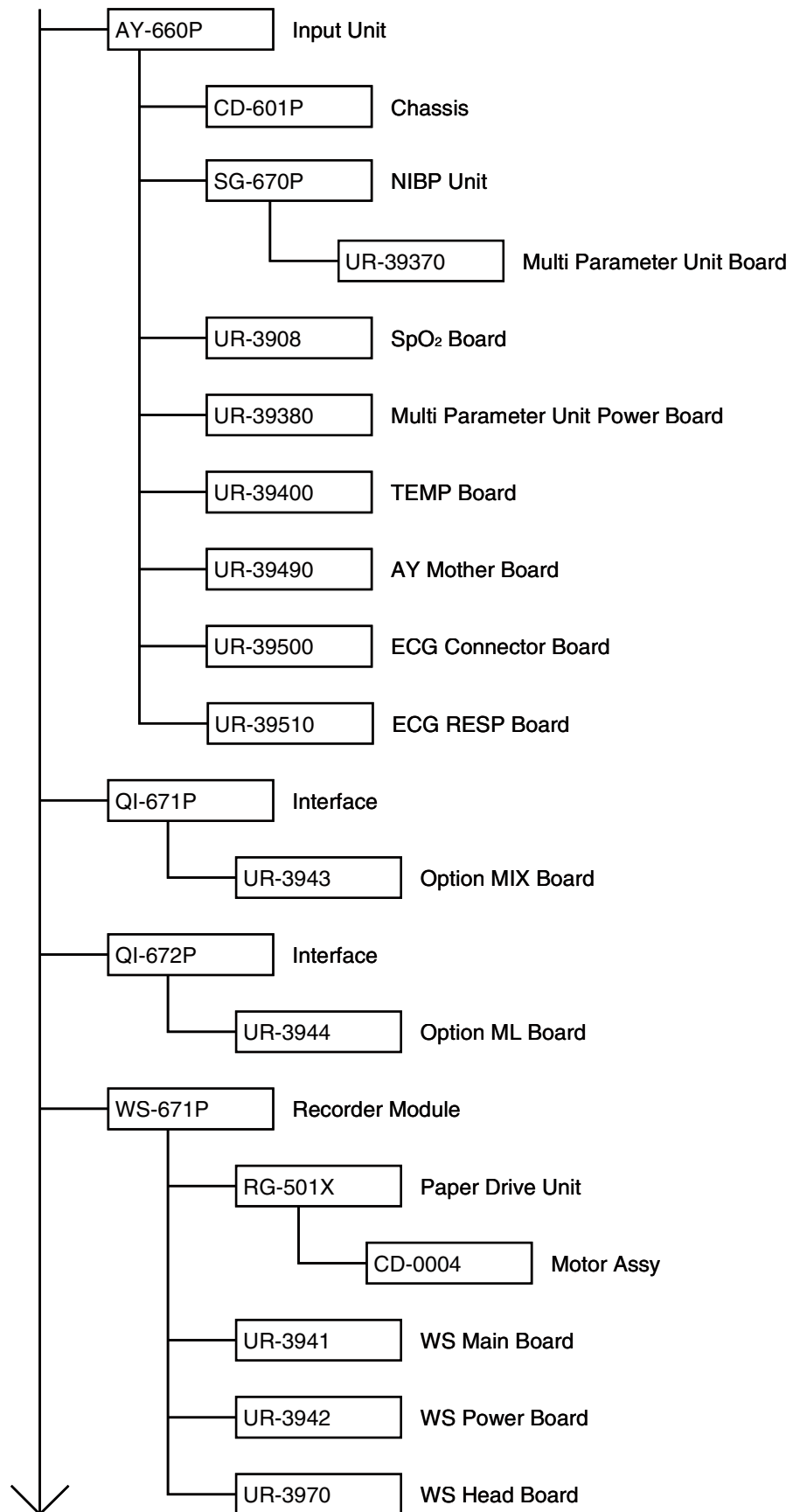
1. GENERAL



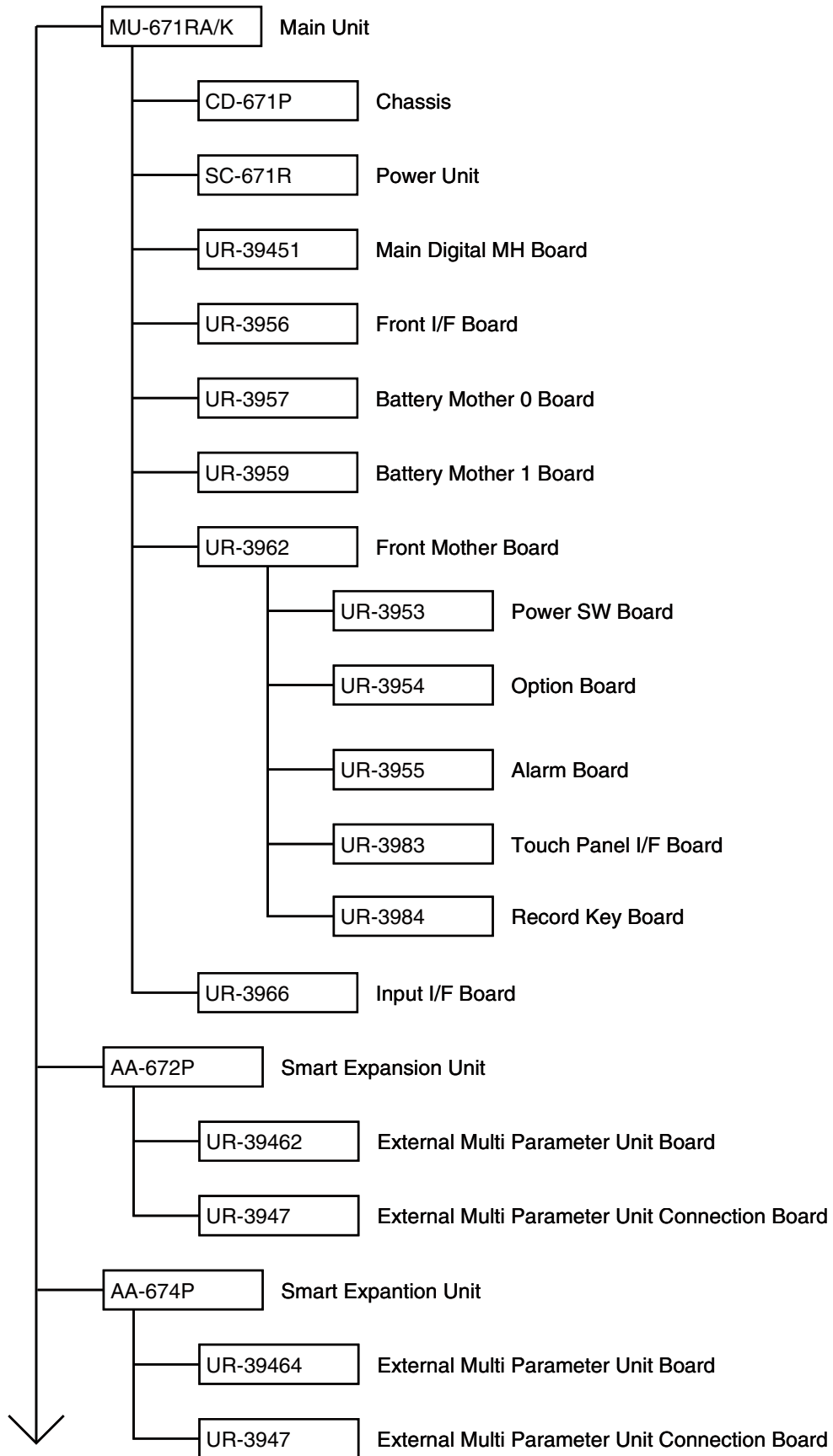


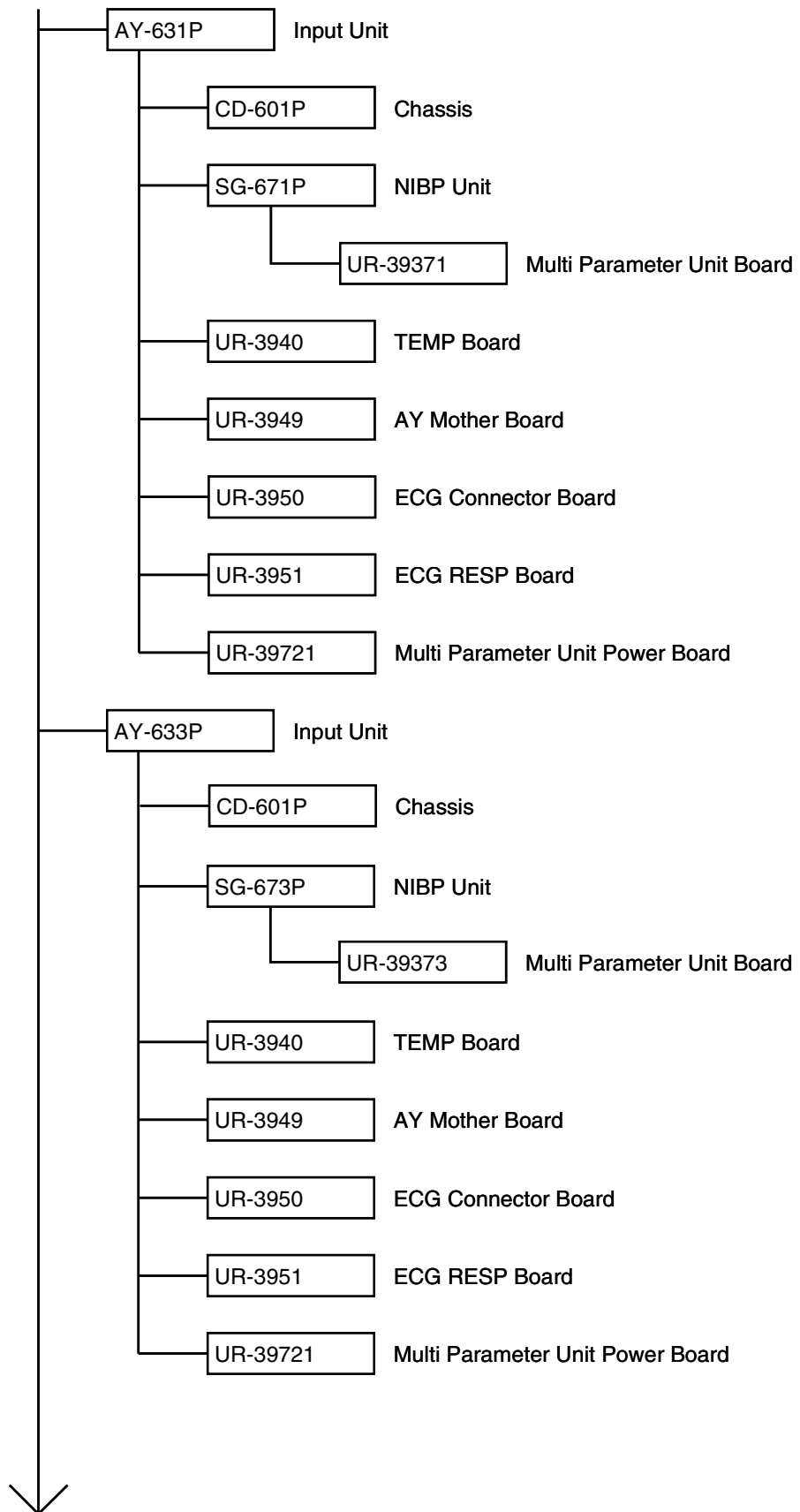
1. GENERAL



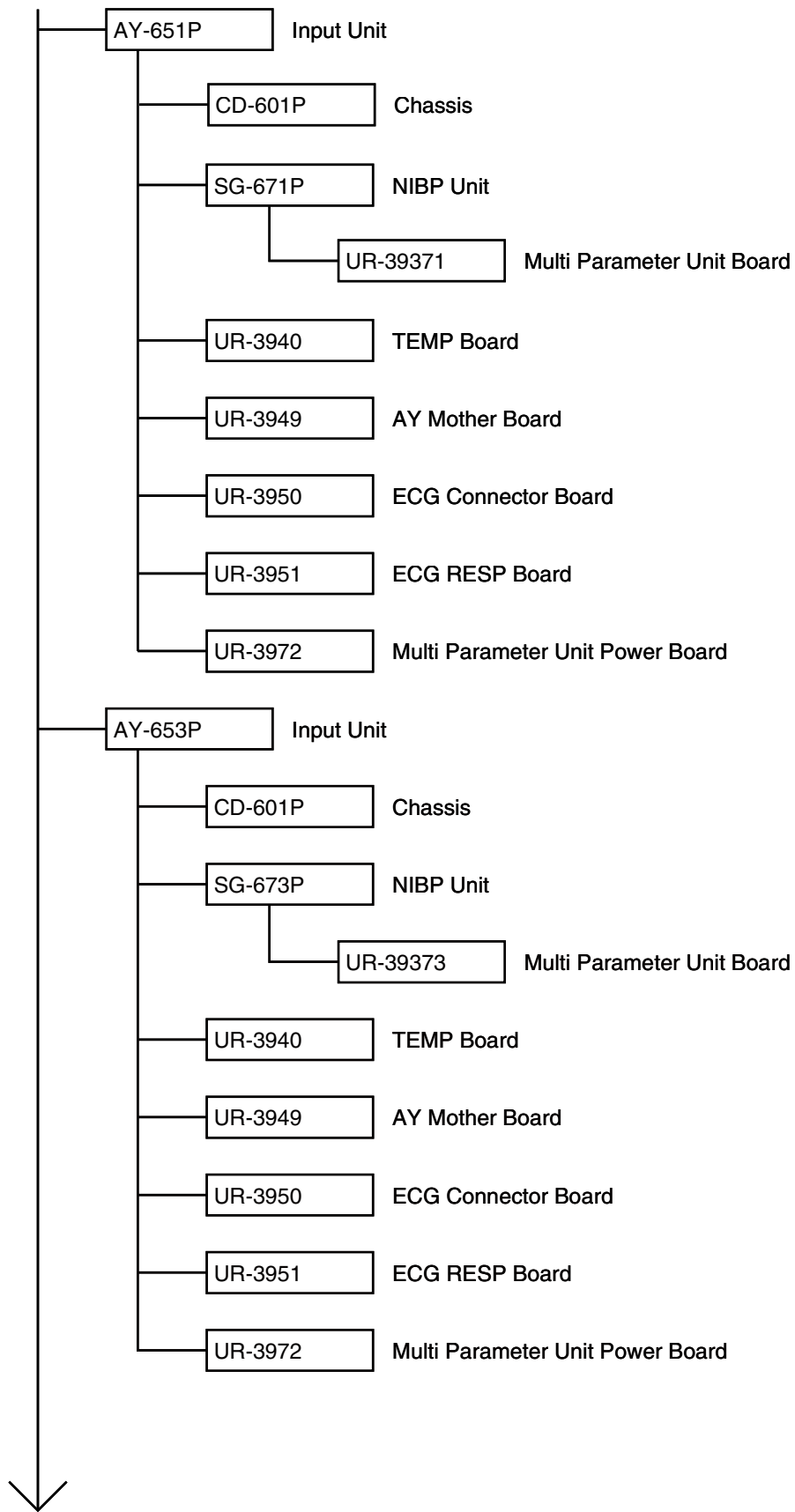


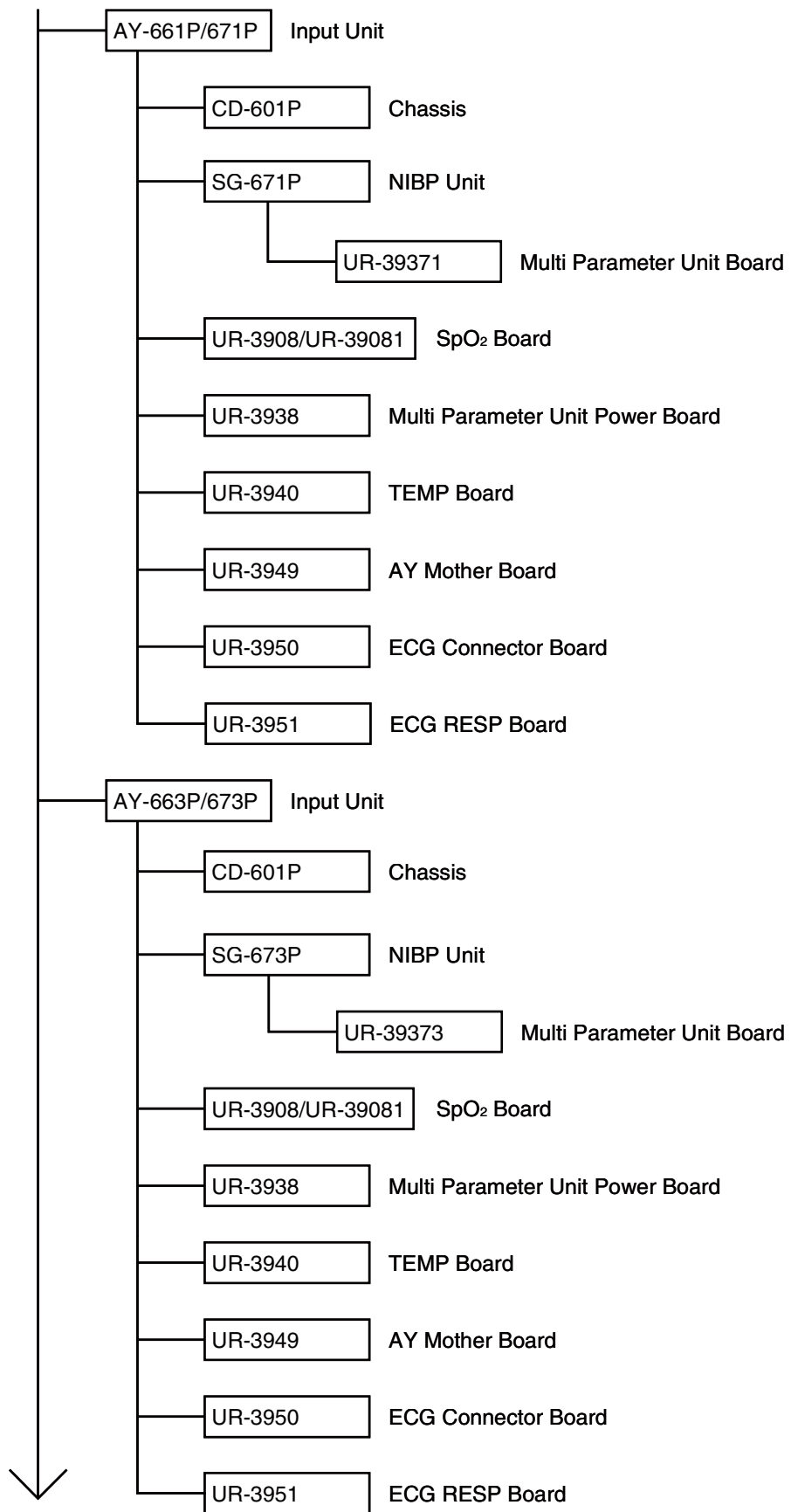
BSM-6701A/K



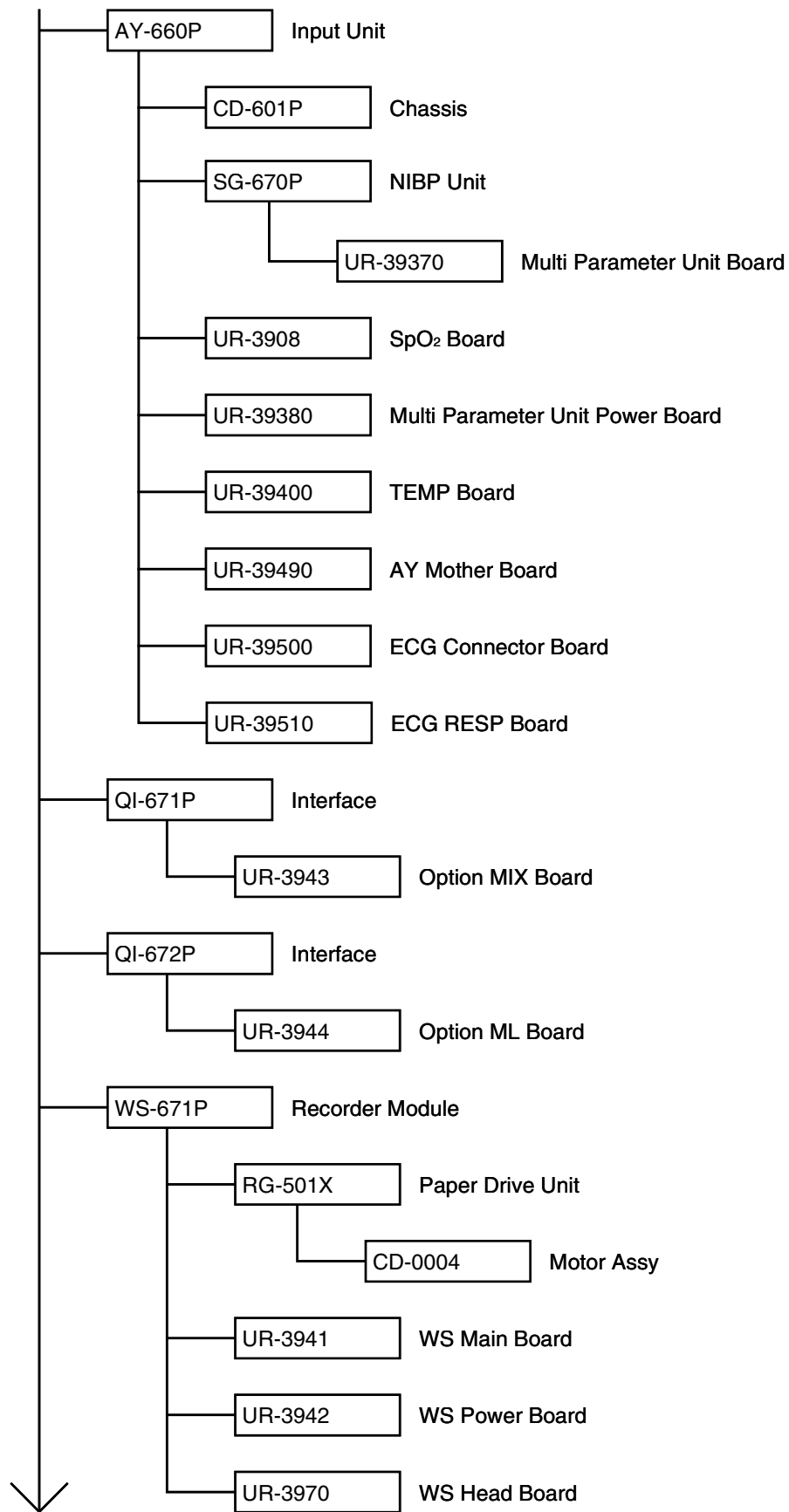


1. GENERAL





1. GENERAL



Specifications

Measuring Parameters

ECG, respiration in impedance and thermistor method, SpO₂, second SpO₂, NIBP, IBP, temperature, cardiac output, O₂, CO₂ in mainstream method and sidestream method, BIS, anesthetic gas (CO₂, O₂, N₂O, agent), TOF, ventilation, CCO, PCCO

Influence on Measuring Accuracy by Electrosurgery/Defibrillation/Electrostatic Discharge

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. When performing defibrillation, the <FILTERS> setting on the equipment must be set to MONITOR to return to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electro-surgery or defibrillation. This does not affect patient or equipment safety.

Display

Display size:

BSM-6301:	10.4 inch, color TFT type LCD
BSM-6501:	12.1 inch, color TFT type LCD
BSM-6701:	15 inch, color TFT type LCD

Resolution:

BSM-6301/6501:	800 × 600 dots
BSM-6701:	1024 × 768 dots

Viewing area:

BSM-6301:	212.2 mm × 159.4 mm
BSM-6501:	246.0 mm × 184.5 mm
BSM-6701:	304.1 mm × 228.1 mm

Waveform display:

ECG (maximum 12 traces), respiration, IBP (maximum 7 traces), SpO₂ pulse wave, CO₂ and CO thermodilution curve, EEG, N₂O concentration, O₂ concentration, anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane)

Waveform display mode:

Non-fade moving or non-fade fixed

Maximum number of waveform trace:

15 traces

Sweep speed:

6.25, 12.5, 25 or 50 mm/s

Respiration sweep speed:

1.56, 6.25, 12.5 or 25 mm/s

Aspect ratio (ECG display sensitivity ratio to sweep speed):

Standard:	0.4 s/mV
Setting range:	0.05 to 6.4 s/mV

Sweep time (at 25 mm/s sweep speed):

BSM-6301:	6.0 s
BSM-6501:	6.5 s
BSM-6701:	9.5 s

Display delay time:

DIAG and MONITOR mode: ≤ 250 ms

MAXIMUM mode:

≤ 1 s

Waveform display color:

12 colors

Numeric data display:

Heart rate, VPC rate, ST level, respiration rate, NIBP (systolic, diastolic, MAP), PWTT, delta PWTT, IBP (systolic, diastolic, mean), SpO₂, second SpO₂, pulse rate, temperature, CO, cardiac index, injectate temperature, blood temperature, O₂ concentration, EtCO₂, FiCO₂, BIS, Pmean, MV, PEEP, inspired O₂, Ppeak, inspired setO₂, TV, CCO, SVRI, SvO₂, Tb, EF, ScvO₂, CCI, EDV, SVR, EDVI, PCCO, PCCI

When gas is monitored, EtN₂O, FiN₂O, EtO₂, FiO₂ and inspired/expired

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	anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane)
Synchronization mark:	Heart rate sync mark, pulse rate sync mark, respiratory sync mark
Numeric display color:	12 colors
Recovery time after defibrillation:	10 s (at MONITOR mode)

Alarm

Alarm items:	Upper/lower limit alarms, arrhythmia alarms, parameter alarm, technical alarms (connector disconnection alarm, noise alarm, electrode off alarm, waveform detecting alarm, probe off alarm, cuff/hose check alarm, sensor check alarm, low battery alarm)
--------------	---

Alarm indication*: Alarm sound, blinking/lighting alarm indicator, highlighted numeric data/message. Displays the alarmed item at the upper part of the screen.*

* Essential performance in EMC standard

Alarm indicator indication:

Crisis:	red blinking: approx. 1.6 Hz (approx. 640 ms), duty 50%
Warning:	yellow blinking: approx. 0.8 Hz (approx. 1280 ms), duty 50%
Advisory:	yellow or blue lighting

Alarm sound:

Crisis:	pips or IEC standard
Warning:	bing bongs or IEC standard
Advisory:	bong for 20 or 120 s or IEC standard

Alarm silence: 1, 2 or 3 min

Alarm suspend: 1, 2, 3 min or OFF

Alarm signal delay in central monitor network: ≤ 4 s

ECG

Complies with IEC 60601-2-27 1st edition: 1994, 2nd edition: 2005, ANSI/AAMI EC13: 2002, ANSI/AAMI EC57: 1998.

Leads:

3-electrode cable:	I, II, III
6-electrode cable:	I, II, III, aVR, aVL, aVF, 2 from V1 to V6
10-electrode cable (when an AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P or AY-673P input unit is used):	I, II, III, aVR, aVL, aVF, V1 to V6
Defibrillation-proof:	ECG input protected against 400 Ws/DC 5 kV IEC 60601-2-27 17.101 compatible

Electrode offset potential tolerance: $\geq \pm 500$ mV

Input dynamic range: $\geq \pm 5$ mV

Internal noise: ≤ 30 μ Vp-p (Referred to input)

Noise suppression:

RL driving gain:	maximum 40 dB
Maximum voltage:	1.23 Vrms

Common mode rejection ratio: ≥ 95 dB

Input bias current: ≤ 100 nA

Frequency response:

DIAG mode:	0.05 to 150 Hz (-3 dB)
MONITOR mode:	0.3 to 40 Hz (-3 dB)
MAXIMUM mode:	1 to 18 Hz (-3 dB)

Input impedance: ≥ 5 M Ω (at 10 Hz)

≥ 2.5 M Ω (at 0.67 to 40 Hz)

ESU protection: Provided

	Recovers within 10 seconds after ESU and acquired data is not lost.
	IEC 60601-2-27: 2005 compatible
Leads-off sensing:	Each leads has own sensing
Active electrode:	< 100 nA
Reference electrode:	< 900 nA
12 lead ECG interpretation:	ECAPS 12C (BSM)
	Available when monitoring 12 leads
Time constant (at 10 Hz):	3.2 s
	0.05 to 150 Hz \pm 10 Hz (\geq -3 dB)
AC hum filter:	\leq -40 dB (at 50 or 60 Hz)
Interpretation items:	Normal sinus rhythm, TACHYCARDIA, BRADYCARDIA, VPC RUN, COUPLET, EARLY VPC
Display and output:	Screen, recorder module, network printer, printer connected to the central monitor
File storage:	6 files
Waveform display:	
Display sensitivity:	10 mm/mV \pm 5% (at \times 1 sensitivity)
Number of channels:	3 (maximum, with 6 or 10 electrodes at home screen) 12 (maximum, with 10 electrodes at 12 LEAD window)
Sensitivity control:	\times 1/4, \times 1/2, \times 1, \times 2, \times 4, or AUTO
Pacing mark display:	Available
Recording sensitivity:	10 mm/mV \pm 5% (same as the display sensitivity)
Heart rate count:	
Calculation method:	Moving average/Instantaneous beat to beat
QRS detection (at \times 1 sensitivity):	Adult: Width: 70 to 120 ms Amplitude: \geq 0.5 mV, rate: 30 to 200 beats/min Child and neonate: Width: 40 to 120 ms Amplitude: \geq 0.5 mV, rate: 30 to 250 beats/min
Counting range:	0, 15 to 300 beats/min (\pm 2 beats/min)
Counting accuracy*:	\pm 2 beats/min (0, 15 to 300 beats/min) * Essential performance in EMC standard
Heart rate display:	
	Heart rate sync mark delay time: within 100 to 200 ms (when QRS is detected)
	Heart rate display update cycle: Every 3 s or when alarm is generated
Tall T-wave rejection capability:	Complies with the heights of T-waves from 0 mV to 1.2 mV specified in ANSI/AAMI EC13 Sect. 4.1.2.1(c)
Heart rate averaging:	Calculated by using the most recent 4 or 12 beats.
Heart rate meter accuracy and response 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*): 120 bpm
	Bidirectional systoles (Test waveform name: aami3d*): 90 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: 9 to 12 seconds
	HR change from 80 to 40 bpm: 9 to 13 seconds
Time to alarm for tachycardia:	Ventricular tachycardia (amplitude 1 mV p-v, heart rate 206 bpm): at \times 1 gain (Test waveform name: aami4a*): 4 to 10 seconds

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at $\times 0.5$ gain (Test waveform name: aami4a_h*): 4 to 10 seconds
at $\times 2$ gain (Test waveform name: aami4a_d*): 4 to 10 seconds
Ventricular tachycardia (amplitude 2 mV p-v, heart rate 195 bpm):
at $\times 1$ gain (Test waveform name: aami4b*): 4 to 10 seconds
at $\times 0.5$ gain (Test waveform name: aami4b_h*): 4 to 10 seconds
at $\times 2$ gain (Test waveform name: aami4b_d*): 4 to 10 seconds
* The test waveforms can be download at <http://www.physionet.org>

Pacemaker pulse detector rejection of fast ECG signals:

Slew rate at which the pacemaker pulse detector responds: 6 to 8 V/s
Tested as specified in ANSI/AAMI EC13 Sect. 4.1.4.3

Pacemaker pulse rejection capability, without overshoot:

Complies with the amplitudes of pacemaker pulses ± 2 to ± 700 mV and widths 0.1 to 2 ms specified in ANSI/AAMI EC13 Sect. 4.1.4.1

Pacemaker pulse rejection capability, with overshoot:

Overshoot amplitudes and time constants of ± 0.12 mV/100 ms to ± 2 mV/4 ms
(As defined by method B of ANSI/AAMI EC13 Sect. 4.1.4.2, this corresponds to the pacemaker pulses amplitudes and widths of ± 4 mV/2 ms to amplitudes ± 80 mV/0.1 ms.)

Heart rate alarm:

Upper limit range: 16 to 300 beats/min, OFF in 1 beat/min steps
Lower limit range: OFF, 15 to 299 beats/min in 1 beat/min steps
Alarm items: TACHYCARDIA, BRADYCARDIA

Arrhythmia analysis:

Analysis method: Multi-template matching method
Number of channels: 2
VPC counting rate: 0 to 99 VPCs/min
Arrhythmia message: ASYSTOLE, VF, VT, V BRADY, EXT TACHY, EXT BRADY, SV TACHY, VPC RUN, TACHYCARDIA, BRADYCARDIA, COUPLET, EARLY VPC, MULTIFORM, V RHYTHM, PAUSE, BIGEMINY, TRIGEMINY, VPC, IRREGULAR RR, PACER NON-CAPTURE, PROLONGED RR, NO PACER PULSE
Other messages: NOISE, CHECK ELECTRODE, LEARNING
Arrhythmia alarm: Upper limit range: OFF, 1 to 99 VPC/min
Arrhythmia recall: Number of recall files: 8,192 (24 hours)
Storage time per file: 8 s

ST level measurement:

Number of measurement channels: 3-electrodes: 1 ch
6-electrodes: 8 ch
10-electrodes (when an AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P or AY-673P input unit is used): 12 ch
Measuring range: ± 2.5 mV
ST level alarm: Upper limit range: -1.99 to 2.00 mV, OFF in 0.01 mV steps
Lower limit range: OFF, -2.00 to 1.99 mV in 0.01 mV steps
Measurement point: Manual
Number of ST files: 1,440

Respiration (impedance method)

Measuring method: Transthoracic impedance pneumography
Number of channels: Selectable from R-F and R-L

Measuring impedance available range:	220 Ω to 4 k Ω
Excitator current:	45 \pm 10 μ Arms at 40 kHz (sine wave)
Internal noise:	\leq 0.2 Ω (Referred to input)
Respiration rate counting range:	0 to 150 counts/min
Respiration rate counting accuracy*:	\pm 2 counts/min (0 to 150 counts/min) * Essential performance in EMC standard
Frequency response (high frequency cut-off):	3 Hz \pm 1 Hz (–3 dB)
Defibrillation proof:	Respiration input protected against 400 Ws/DC 5 kV
Impedance respiration:	On/Off
Heart beat rejection:	Available
Waveform display:	
Display sensitivity:	10 mm/1 Ω \pm 25% (at \times 1 sensitivity)
Sensitivity control:	\times 1/4, \times 1/2, \times 1, \times 2, \times 4
Respiration rate display update cycle:	Every 3 s or when alarm is generated
Alarm:	
Upper limit range:	2 to 150 counts/min in 2 counts/min steps, OFF
Lower limit range:	OFF, 0 to 148 counts/min in 2 counts/min steps
Apnea alarm:	Setting range: OFF, 5 to 40 s in 5 s steps Displayed message: APNEA

SpO₂

Complies with ISO 9919: 2005.

SpO ₂ display:	
Display update cycle:	Every 3 s or when alarm is generated
Sync tone modulation:	Changes tone depending on SpO ₂ value
Sweep speed:	6.25, 12.5, 25, 50 mm/s
Waveform sensitivity:	\times 1/8, \times 1/4, \times 1/2, \times 1, \times 2, \times 4, \times 8 or AUTO
Measuring method:	Two wavelength light absorption method
Wavelength range:	
AY-631P/633P:	660/905 nm (LNOF tip clip and LNCS tip clip)
AY-631P/633P:	663/880 nm (Other clips)
AY-651P/653P:	660/900 nm
Emitted light energy:	
AY-631P/633P:	0.13 mW minimum, 0.79 mW maximum
AY-651P/653P:	< 15 mW
Data delay time:	\leq 10 s
Averaging time:	
AY-651P/653P:	6 to 7 s (approximately 3 seconds in Fast Mode) (If the dynamic averaging time exceeds 20 seconds for SpO ₂ , the SpO ₂ and pulse rate will continue to be updated every second.)
Display range:	
AY-631P/633P/651P/653P:	1 to 100%SpO ₂
AY-660P/661P/663P/671P/673P:	0 to 100%SpO ₂
Declared range:	
AY-631P/633P/651P/653P:	Depends on probe. Refer to the probe manual.
AY-660P/661P/663P/671P/673P:	70 to 100%SpO ₂

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Measuring accuracy*:

AY-631P/633P/651P/653P:	Depends on probe. Refer to the probe manual.
AY-660P/661P/663P/671P/673P:	$\pm 3\% \text{SpO}_2$ ($70\% \text{SpO}_2 \leq \% \text{SpO}_2 \leq 100\% \text{SpO}_2$) $\pm 2\% \text{SpO}_2$ ($80\% \text{SpO}_2 \leq \% \text{SpO}_2 \leq 100\% \text{SpO}_2$) Accuracy at surrounding temperature: 18 to 40°C (64.4 to 104°F) * Essential performance in EMC standard

NOTE for SpO₂ Accuracy of AY-660P/661P/663P/671P/673P:

- The SpO₂ measuring accuracy was tested on OLV-3100 pulse oximeter 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) 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.

NOTE for SpO₂ Accuracy of AY-631P/633P/651P/653P:

The SpO₂ accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

NOTE for AY-631P/633P

The plethysmographic waveform is scaled to a fixed size for signal strengths above 10% or 0.5%.

NOTE for AY-651P/653P

Nellcor OEM modules communicate a non-normalized depiction of the plethysmographic waveform.

Alarm:

Upper limit range:	51 to 100%SpO ₂ in 1%SpO ₂ steps, OFF
Lower limit range:	OFF, 50 to 99%SpO ₂ in 1%SpO ₂ steps
Alarm delay time:	approx. 5 seconds

Pulse rate:

Display range:	
AY-631P/633P:	25 to 240 beats/min
AY-651P/653P:	20 to 300 beats/min
AY-660P/661P/663P/671P/673P:	30 to 300 beats/min

Declared range:

AY-631P/633P:	25 to 240 beats/min
AY-651P/653P:	20 to 300 beats/min

AY-660P/661P/663P/671P/673P: 30 to 300 beats/min

Counting accuracy (rms)*:

- AY-631P/633P: ±3 beats/min (No motion)
- AY-631P/633P: ±5 beats/min (Motion)
- AY-651P/653P: ±3 beats/min
- AY-660P/661P/663P/671P/673P: ±3% ±1 beat/min

* Essential performance in EMC standard

Alarm:

Upper limit range:

When <SYNC SOURCE> is set to ECG:
16 to 300 beats/min in 1 beat/min steps, OFF
When <SYNC SOURCE> is set to PRESS or SpO₂:
31 to 300 beats/min in 1 beat/min steps, OFF

Lower limit range:

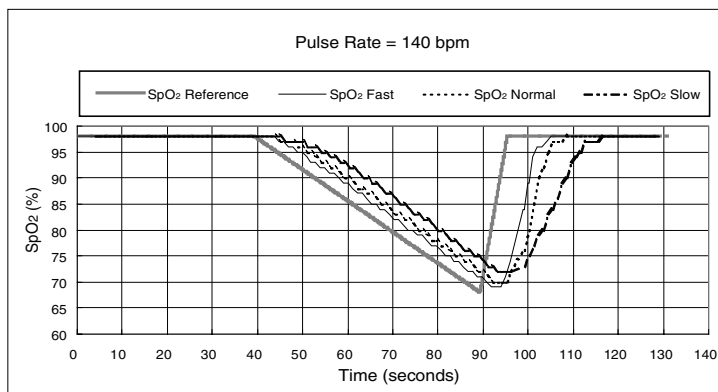
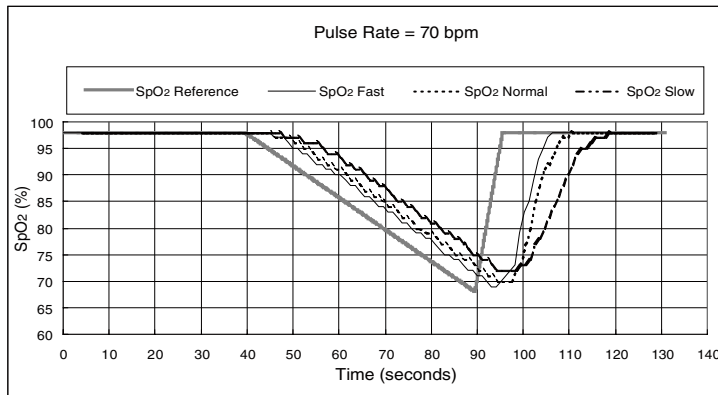
When <SYNC SOURCE> is set to ECG:
OFF, 15 to 299 beats/min in 1 beat/min steps
When <SYNC SOURCE> is set to PRESS or SpO₂:
OFF, 30 to 299 beats/min in 1 beat/min steps

Alarm delay time:

approx. 5 seconds

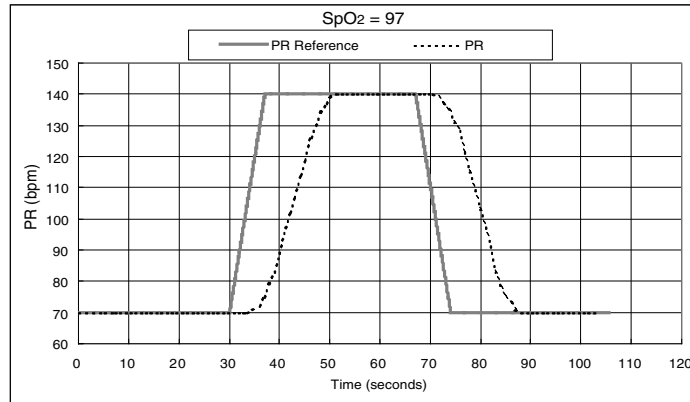
Response time:

Selectable from “SLOW”, “NORMAL” and “FAST”.
The following graphs show the response time example when SpO₂ changes 0.6%/s.



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The following graph shows the response time example when pulse rate changes 10 bpm/s.



Non Invasive Blood Pressure, NIBP

Complies with IEC 60601-2-30: 1999.

Measuring method:	Oscillometric
Measuring range:	0 to 300 mmHg
Cuff pressure display range:	0 to 300 mmHg
Accuracy:	± 3 mmHg ($0 \text{ mmHg} \leq \text{NIBP} < 200 \text{ mmHg}$) ± 4 mmHg ($200 \text{ mmHg} \leq \text{NIBP} \leq 300 \text{ mmHg}$)
Cuff inflation time:	
Adult/Child:	≤ 7 s (700 cc)
Neonate:	≤ 5 s (72 cc)
Measurement mode:	Adult, child or neonate is recognized by connected air hose
Maximum measurement time:	
Adult/Child:	≤ 160 s
Neonate:	≤ 80 s
Operation mode:	Manual, STAT (≤ 15 min), Periodic, PWTT and SIM (depends on the SITE setting)
Cuff pressure settings:	Manual or Auto
Auto remeasurement:	1 time
Air leakage:	≤ 3 mmHg/min
Measurement accuracy with a simulator*:	± 10 mmHg * Essential performance in EMC standard
Initial pressurization value:	
Adult:	180 mmHg
Child:	140 mmHg
Neonate:	100 mmHg
Maximum pressurization value:	
Adult/Child:	300 mmHg
Neonate:	150 mmHg
Display items:	Systolic (SYS), diastolic (DIA), mean (MAP), cuff pressure during NIBP measurement, delta PWTT
NIBP data display update cycle:	Updated every measurement
Measurement completion sound:	Generated at measurement completion (depends on the setting)
Alarm	
Upper limit range:	15 to 260 mmHg in 5 mmHg steps, OFF

Lower limit range:	OFF, 10 to 255 mmHg in 5 mmHg steps
Safety	
Maximum pressurization value cuff inflation limiter:	Adult/Child: 300 to 330 mmHg Neonate: 150 to 165 mmHg
Cuff inflation time limiter:	Adult/Child: 161 to 165 s Neonate: 81 to 84 s
Interval time limiter:	25 to 29 s
Power discontinuity:	Deflate immediately after power down

Multi Socket

Input impedance:	$\geq 900 \text{ k}\Omega$
Excitor output impedance:	$\leq 2 \Omega$
Excitor overcurrent protection:	100 mA
+5 V maximum power output from the socket:	500 mA

Invasive Blood Pressure, IBP

Complies with IEC 60601-2-34: 2000 except for clauses 44.6, 45.101 a) and 45.101 b).

Complied transducer:	P23XL-1 and P10EZ-1 Becton Dickinson disposable transducers Becton Dickinson disposable transducers DX series 5 $\mu\text{V/V/mmHg}$, bridge resistor: 200 Ω to 20 k Ω , defibrillation-proof or the equivalents
Volume displacement:	0.04 mm ³ /100 mmHg
Measuring range:	-50 to 300 mmHg
Auto zero balancing range:	$\pm 200 \text{ mmHg}$
Auto zero balancing accuracy:	$\pm 1 \text{ mmHg}$
Measuring accuracy:	$\pm 1 \text{ mmHg} \pm 1 \text{ digit}$ (-50 mmHg \leq IBP < 100 mmHg) $\pm 1\% \pm 1 \text{ digit}$ (100 mmHg \leq IBP \leq 300 mmHg)
Total measuring accuracy*:	$\pm 4\%$ or $\pm 4 \text{ mmHg}$ (whichever is greater)** * Essential performance in EMC standard ** When used with ANSI/AAMI BP-22-1994 complied equipments
Internal noise:	within $\pm 1 \text{ mmHg}$
Temperature zero drift:	$\pm 0.1 \text{ mmHg}/1^\circ\text{C}$
Frequency response:	DC to 12 Hz or 20 Hz (selectable)
Display items:	Systolic (SYS), diastolic (DIA), mean (MEAN)
Display update cycle:	Every 3 s or when alarm is generated
BP sync sound:	Systolic value 20 to 120 mmHg, changes in 20 steps every 5 mmHg
Alarm:	
Upper limit range:	2 to 300 mmHg in 2 mmHg steps, OFF
Lower limit range:	OFF, 0 to 298 mmHg steps in 2 mmHg steps
Alarm inactivation:	Alarm is inactivated in certain period when zero balancing is performed.

Pulse rate

Counting range:	0, 30 to 300 beats/min
Display range:	0 to 300 beats/min
Counting accuracy (rms):	$\pm 2 \text{ beats/min}$ (30 beats/min \leq PR \leq 300 beats/min)
Alarm:	Upper limit range: When <SYNC SOURCE> is set to ECG: 16 to 300 beats/min in 1 beat/min steps, OFF When <SYNC SOURCE> is set to PRESS or SpO ₂ : 31 to 300 beats/min in 1 beat/min steps, OFF Lower limit range: When <SYNC SOURCE> is set to ECG: OFF, 15 to 299 beats/min in 1 beat/min steps

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When <SYNC SOURCE> is set to PRESS or SpO₂:
OFF, 30 to 299 beats/min in 1 beat/min steps

System alarm delay time: Approx. 5 seconds

Temperature

Complies with EN 12470-4: 2000 only for clauses 6.2, 6.3 a), 6.5, 6.6, 6.7, 6.8, 6.9, 6.10 and 8.

Number of channels:

AY-660P: 1 maximum (1 TEMP socket)

AY-631P/633P/651P/653P/661P/663P/671P/673P: 4 maximum (2 TEMP sockets, 1 MULTI socket)

Measuring range: 0 to 45°C (32 to 113°F)

Measuring accuracy*: ±0.1°C (25°C ≤ TEMP ≤ 45°C)

±0.2°C (0°C ≤ TEMP < 25°C)

* Essential performance in EMC standard

Internal noise: ≤ 0.014°C (at 37°C)

Temperature drift: within ±0.005°C /°C

Display range: 0 to 45°C (32 to 113°F)

Display update cycle: Every 3 s or when alarm is generated

Time response delay from probe to monitor display:

≤ 6 seconds (sensor time constant is not included)

Alarm

Upper limit range: 0.1 to 45°C (33 to 113°F) in 0.1°C (1°F) steps, OFF

Lower limit range: OFF, 0.0 to 44.9°C (32 to 112°F) in 0.1°C (1°F) steps

Carbon Dioxide, CO₂ (Mainstream method)

For the TG-900P/TG-920P/TG-950P* CO₂ sensor kit specifications, refer to the kit manual.

* TG-950P is not available in USA

Calculation method

TG-900P/920P: semi-quantitative

TG-950P: quantitative

CO₂ measuring range: 0 to 100 mmHg

CO₂ measuring accuracy**

TG-900P/920P: ±3 mmHg (0 ≤ CO₂ ≤ 10 mmHg)

±4 mmHg (10 < CO₂ ≤ 40 mmHg)

±10% reading (40 < CO₂ ≤ 100 mmHg)

(At 1 atmospheric pressure, air inspiration, no condensation)

TG-950P: ±2 mmHg (0 ≤ CO₂ ≤ 40 mmHg)

±5% reading (40 < CO₂ ≤ 70 mmHg)

±7% reading (70 < CO₂ ≤ 100 mmHg)

(When no condensation)

** Essential performance in EMC standard

Warm-up time:

TG-900P/920P: 5 s

TG-950P: 15 s

Response time

TG-900P: 160 ms (typical) for steps from 10 to 90%

TG-920P: 120 ms (typical) for steps from 10 to 90%

TG-950P: 120 ms (typical) for steps from 10 to 90%

Respiration rate counting range

TG-900P/920P: 3 to 150 counts/min

TG-950P: 0 to 150 counts/min

Respiration rate counting accuracy	
TG-900P/920P:	3 to 60 counts/min, $\pm 5\%$ 61 to 150 counts/min, $\pm 10\%$
TG-950P:	± 1 count/min
O ₂ gas effect:	
TG-900P/920P:	-10% rdg (at 100% O ₂)
TG-950P:	-8% rdg (at 100% O ₂)
N ₂ O anesthetic gas effect:	Accuracy in using N ₂ O anesthetic gas is not guaranteed
CO ₂ value display update cycle:	Every 3 s or when alarm is generated
EtCO ₂ and FiCO ₂ alarm:	
Upper limit:	FiCO ₂ : 1 to 5 mmHg in 1 mmHg steps, OFF EtCO ₂ : 2 to 99 mmHg in 1 mmHg steps, OFF
Lower limit:	EtCO ₂ : OFF, 1 to 98 mmHg in 1 mmHg steps
Respiration rate alarm:	
Upper limit range:	2 to 150 counts/min in 2 counts/min steps, OFF
Lower limit range:	OFF, 0 to 148 counts/min in 2 counts/min steps
Apnea alarm:	OFF, 5 to 40 s in 5 s steps Displayed message: APNEA
Total system response time:	≤ 1.0 second

Inspired Oxygen Fractional Concentration, O₂ (when AY-631P/633P/651P/653P/661P/663P/671P/673P is connected)

Measuring items:	Inspired oxygen fraction concentration
Number of channels:	1
Calibration condition:	21 or 100% O ₂
Measuring range:	10 to 100% O ₂
Accuracy*:	$\pm 3\%$ full scale (includes sensor, when calibrated with air) * Essential performance in EMC standard
Internal noise:	$\leq 0.12\%$ O ₂ RMS $\pm 0.72\%$ O ₂
Temperature drift:	$\pm 0.12\%$ O ₂ /°C
FiO ₂ display update cycle:	Every 3 s or when alarm is generated
Alarm	
Upper limit range:	19 to 100% in 1% steps, OFF
Lower limit range:	18 to 99% in 1% steps

Cardiac Output, CO (when AY-631P/633P/651P/653P/661P/663P/671P/673P is connected)

Measuring method:	Thermodilution method
Measuring items:	CO, Ti, Tb, Delta Tb
Number of channels:	1
Measuring range:	
Injectate temperature (Ti):	0°C to 27°C
Blood temperature (Tb):	15°C to 45°C
Thermodilution curve (delta Tb):	0°C to 2.5°C
Cardiac output (CO):	0.5 to 20 L/min
Measuring accuracy:	
Ti:	$\pm 0.2^\circ\text{C}$ (0°C to 27°C)
Tb:	$\pm 0.1^\circ\text{C}$ (25°C \leq TEMP \leq 45°C) $\pm 0.2^\circ\text{C}$ (15°C \leq TEMP $<$ 25°C)
CO:	$\pm 5\%$

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Internal noise:

Ti:	$\leq 0.025^{\circ}\text{C RMS}$
Tb:	$\leq 0.016^{\circ}\text{C RMS}$ (correspond to 37°C)
Delta Tb:	$\leq 0.005^{\circ}\text{C RMS}$

Temperature drift:

Ti:	$\pm 0.005^{\circ}\text{C /}^{\circ}\text{C}$
Tb:	$\pm 0.005^{\circ}\text{C /}^{\circ}\text{C}$

Frequency response (delta Tb): DC to 12 Hz (-3 dB)

Injectate volume range: 3, 5, 10 mL

Display update cycle: Updated every measurement

Tb Alarm

Upper limit range:	15.1 to 45°C (59.2 to 113°F) in 0.1°C (1°F) steps, OFF
Lower limit range:	OFF, 15.0 to 44.9°C (59 to 112°F) in 0.1°C (1°F) steps

Respiration (Thermistor method) (when AY-631P/633P/651P/653P/661P/663P/671P/673P is connected)

Complied sensor: TR-900P respiration pickup for nose and TR-910P respiration pickup for airway

Measuring items: Thermistor respiration curve, respiration rate

Number of channel: 1

APNEA detection: Available

Respiration rate counting range: 0 to 150 counts/min

Measurable temperature range: 10 to 40°C

Accuracy*: ± 2 counts/min

* Essential performance in EMC standard

Internal noise: $\leq 2.5 \Omega$ (Referred to input)

Frequency response: 0.1 to 3 Hz (-3 dB)

Waveform display:

Display sensitivity: 10 mm/100 $\Omega \pm 20\%$ (at $\times 1$ sensitivity)

Sensitivity control: $\times 1/4$, $\times 1/2$, $\times 1$, $\times 2$, $\times 4$

Respiration rate display update cycle: Every 3 s or when alarm is generated

Alarm:

Upper limit range: 2 to 150 counts/min in 2 counts/min steps, OFF

Lower limit range: OFF, 0 to 148 counts/min in 2 counts/min steps

Apnea: OFF, 5 to 40 s in 5 s steps

Displayed message: APNEA

Bispectral Index, BIS (when AY-631P/633P/651P/653P/661P/663P/671P/673P is connected)

For the BIS processor specifications, refer to the BIS processor manual.

Alarm:

Upper limit range: 2 to 100 in 1 steps, OFF

Lower limit range: OFF, 0 to 99% in 1 steps

ECG/BP Output (when AY-631P/633P/651P/653P/661P/663P/671P/673P is connected)

Outputs 100 mmHg/V IBP waveform of the IBP connection cord connected to the MULTI socket, first trace of 1 mV/V ECG waveform and heart rate trigger. The heart rate trigger signal is generated based on the ECG waveform on the first trace. When more than one IBP waveforms are acquired, the IBP waveform is output following the highest priority label.

Complied medical electrical equipments

Connecting medical electrical equipment must comply to the following standards:

IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995

CSA C22.2 No.601.1

Medical electrical equipment must be connected by specified method in following standards:

IEC 60601-1-1: 2000
CSA C22.2 No.60601-1-1-02

Output impedance:

ECG: $\leq 100 \Omega$
BP: $\leq 100 \Omega$

Output-waveform:

ECG: $\pm 5.0 \text{ V}$ (at $1 \text{ mV/V} \pm 5\%$ sensitivity)
BP: $-0.5 \text{ to } +3.0 \text{ V}$ (at $100 \text{ mmHg/V} \pm 1\%$ sensitivity)
HT: $5.0 \text{ to } 15.0 \text{ V}$ (Open collector output, $0.5 \text{ to } 100 \text{ mA}$)

Frequency response:

ECG: $\geq 0.5 \text{ to } 100 \text{ Hz}$ ($\geq -3 \text{ dB}$)
(No reproducibility of pace maker pulse)
BP: $\geq \text{DC to } 20 \text{ Hz} \pm 3 \text{ Hz}$ (-3 dB)

HT pulse width:

15 ms

Gain:

ECG: 1000

Offset:

ECG: $\leq \pm 50 \text{ mV}$
BP: $\leq \pm 10 \text{ mV}$

Sensitivity accuracy:

ECG: $\pm 5\%$
BP: $\pm 1\%$

Delay:

ECG: 20 ms max
BP: 40 ms max
HT: 20 ms max

RGB Socket (when QI-631P or QI-671P is connected)

Output signal: Analog RGB signal, $0.7 \text{ V}_{\text{p-p}}$

Resolution:

BSM-6501: 800×600 dots
BSM-6701: 1024×768 dots

RS-232C Socket (when QI-631P or QI-671P is connected)

Serial communication: RS-232C complies
Baud rate: 9600, 19200, 38400 bps

Alarm Socket (when QI-632P or QI-671P is connected)

Alarm pole output: Red, yellow, blue and green
Sound output: Alarm and synchronization
Nurse call output: Not available

When WS-671P Recorder Module is Connected

Recording method: Thermal array recording
Number of channels: 3 (maximum)
Recording width: $\geq 46 \text{ mm}$
Paper speed: 12.5, 25, 50 mm/s

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Recording density:

Amplitude direction:	8 dots/mm
Feeding direction:	40 dots/mm (≤ 25 mm/s)
	20 dots/mm (50 mm/s)

Recording paper: FQW-50-2-100

When ZS-900P Transmitter* is Connected

* Not available in USA

Frequency capacity deviation:	$\leq \pm 3$ ppm (15 to 35°C)
Transmission power:	1.0 mW +5%, -40% (15 to 35°C)
Spurious emission strength:	≤ 2.5 μ W (5 MHz to 1.5 GHz)
Occupied bandwidth:	5.0 to 8.5 kHz
Adjacent channel leaking power:	≥ 40 dBR
Transmission frequency range:	420.0500 to 449.6625 MHz
Modulation method:	Frequency shift keying

Gas (when AG-920R multigas unit is connected)

For the AG-920R multigas unit specifications, refer to the multigas unit manual.

Measurement method:	Sidestream gas sampling
Measured gases:	CO ₂ partial pressure, N ₂ O concentration, O ₂ concentration, anesthetic agent concentration (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), respiration rate
Warm-up time:	45 seconds to first measurement 10 minutes to measurement with guaranteed accuracy
Sampling rate:	70 to 200 mL/min
CO ₂ measurement	
Measurement method:	Non-dispersive infrared ray absorption
Measuring range:	0 to 76 mmHg
Measuring accuracy:	± 2 mmHg ($0 \leq \text{CO}_2 < 40$ mmHg) ± 3 mmHg ($40 \leq \text{CO}_2 < 55$ mmHg) ± 4 mmHg ($55 \leq \text{CO}_2 \leq 76$ mmHg)

NOTE: CO₂ accuracy is maintained up to a respiratory rate of 60 bpm with I:E ratio of 1:3, 1:2, 1:1 and 2:1.

Response time (10 to 90%):	≤ 250 ms (under the condition of sampling flow is 200 mL/min and sampling line for adult and dryline for adult is connected)
Alarm:	Upper limit: FiCO ₂ : 1 to 5 mmHg in 1 mmHg steps, OFF EtCO ₂ : 2 to 99 mmHg in 1 mmHg steps, OFF Lower limit: EtCO ₂ : OFF, 1 to 98 mmHg in 1 mmHg steps

N₂O measurement

Measurement method:	Non-dispersive infrared ray absorption
Measuring range:	0 to 100%
Measuring accuracy:	$\pm 3\%$

NOTE: N₂O accuracy is maintained up to a respiratory rate of 30 bpm with I:E ratio of 1:3, up to a respiratory rate of 40 bpm with I:E ratio of 1:2 and up to a respiratory rate of 60 bpm with I:E ratio of 1:1 and 2:1.

Response time (10 to 90%):	≤ 250 ms (under the condition of sampling flow is 200 mL/min and sampling line for adult and dryline for adult is connected)
Alarm (FiN ₂ O, EtN ₂ O):	Upper limit: 1 to 100% in 1% steps, OFF Lower limit: OFF, 0 to 99% in 1% steps

O₂ measurement:

Measurement method:	Paramagnetic
Measuring range:	0 to 100%

Measuring accuracy:	$\pm 2\%$ ($0 \leq O_2 < 55\%$) $\pm 3\%$ ($55 \leq O_2 \leq 100\%$)
Response time (10 to 90%):	≤ 500 ms (under the condition of sampling flow is 200 mL/min and sampling line for adult and dryline for adult is connected)
Alarm:	Upper limit: FiO_2 : 19 to 100% in 1% steps, OFF EtO_2 : 11 to 100% in 1% steps, OFF Lower limit: FiO_2 : 18 to 99% in 1% steps EtO_2 : OFF, 10 to 99% in 1% steps
Anesthetic agent measurement:	
Measurement method:	Non-dispersive infrared ray absorption
Measuring range:	Halothane 0 to 5% Isoflurane 0 to 5% Enflurane 0 to 5% Sevoflurane 0 to 8% Desflurane 0 to 18%
Measuring accuracy:	$\pm 0.2\%$ ($0 \leq GAS \leq 5\%$) $\pm 0.4\%$ ($5 < GAS \leq 10\%$) $\pm 0.6\%$ ($10 < GAS \leq 15\%$) $\pm 1.0\%$ ($15 < GAS \leq 18\%$)
NOTE:	
	<ul style="list-style-type: none"> Anesthetic agent accuracy is maintained up to a respiratory rate of 60 bpm with I:E ratio of 1:3, 1:2, 1:1 and 2:1. When alcohol or acetone is present in the respiration circuit, the unit gives inaccurate gas analysis data. <ul style="list-style-type: none"> Response time (10 to 90%) : under the condition of sampling flow is 200 mL/min and sampling line for adult and dryline for adult is connected ≤ 300 ms (Halothane, Isoflurane, Sevoflurane, Desflurane) ≤ 500 ms (Enflurane)
Uncorrected MAC =	$\%Et(AA1)/x(AA) + \%Et(AA2)/x(AA) + \%Et(N_2O)/x(N_2O)$
$\%Et(AA1)$:	End tidal concentration of the first anesthetic agent
$\%Et(AA2)$:	End tidal concentration of the second anesthetic agent
$\%Et(N_2O)$:	End tidal concentration of N_2O
$x(AA)$:	Uses the following values with the MAC of the first anesthetic agent HAL = 0.77%, ENF = 1.7%, ISO = 1.15%, SEV = 2.1%, DES = 7.3%
$x(N_2O)$:	Uses 105% with the MAC of N_2O
Alarm:	
Upper limit:	$FiAgent$, $EtAgent$ (HAL, ISO, SEV, ENF): 0.1 to 7.0% in 0.1% steps, OFF $FiDES$, $EtDES$: 0.1 to 20.0%, OFF
Lower limit:	$FiAgent$, $EtAgent$ (HAL, ISO, SEV, ENF): OFF, 0.0 to 6.9% in 0.1% steps, OFF $FiDES$, $EtDES$: OFF, 0.0 to 19.9%
Respiration rate:	
Measuring range:	0, 4 to 60 counts/min
Measuring accuracy:	± 1 count/min (4 to 60 counts/min)
Alarm:	Upper limit: 2 to 150 counts/min in 2 counts/min steps, OFF Lower limit: OFF, 0 to 148 counts/min in 2 counts/min steps
Apnea alarm:	OFF, 5 to 40 s in 5 s steps Displayed message: APNEA
Air leakage:	≤ 10 mmHg/min

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Total system response time: ≤ 5.0 seconds

Carbon Dioxide, CO₂ (Sidestream method) (when AG-400RK is connected)

For the AG-400RK CO₂ unit specifications, refer to the CO₂ unit manual.

Sampling flow:	50 mL/min +15/-7.5 mL/min
Warm up time:	30 s average (from power on to the measurable state)
Measuring range:	0 to 99 mmHg
Total measuring accuracy:	Whichever greater in following measuring accuracy
Measuring accuracy:	0 to 38 mmHg ± 2 mmHg 39 to 99 mmHg $\pm [5 + 0.08 \times (\chi - 39)]$ % of reading χ : CO ₂ partial pressure of a standard gas with a known CO ₂ partial pressure (mmHg)
EtCO ₂ and FiCO ₂ alarm:	
Upper limit:	FiCO ₂ : 1 to 5 mmHg in 1 mmHg steps, OFF EtCO ₂ : 2 to 99 mmHg in 1 mmHg steps, OFF
Lower limit:	EtCO ₂ : OFF, 1 to 98 mmHg in 1 mmHg steps
Respiration rate measuring range:	0 to 150 counts/min
Respiration rate measuring accuracy:	101 to 150 counts/min: $\pm 5\%$ 71 to 100 counts/min: $\pm 3\%$ 41 to 70 counts/min: ± 2 counts/min 0 to 40 counts/min: ± 1 count/min
Respiration rate alarm:	
Upper limit range:	2 to 150 counts/min in 2 counts/min steps, OFF
Lower limit range:	OFF, 0 to 148 counts/min in 2 counts/min steps
Apnea alarm:	OFF, 5 to 40 s in 5 s steps Displayed message: APNEA
Total system response time:	≤ 3.5 seconds

Battery (SB-671P Battery Pack)

Type of battery:	Nickel-metal hydride
Number of batteries:	2
Battery lifetime:	1 year or 200 cycles of full discharging/charging
Battery operation time:	
BSM-6301/6501:	90 minutes
BSM-6701:	60 minutes
	(new battery, fully charged and no options are used)
DC voltage:	9.6 V
Charging current:	360 mA ± 50 mA (normal use)
Charging time	
During monitoring:	10 hours
During non-monitoring:	6 hours (two battery at the same time)
Battery status indication:	Battery lamps on the front panel, screen message and alarm sound, alarm indicator
Operating environment	
Charging temperature:	10 to 55°C (50 to 131°F)
Discharging temperature:	5 to 50°C (41 to 122°F)
Humidity:	30 to 85% RH (noncondensing)
Atmospheric pressure:	700 to 1060 hPa
Transport and storage environment:	When the battery pack is stored more than 6 months, charge and discharge or charge the battery once every 6 months.

Temperature:	-20 to +60°C (-4 to +140°F) (within 30 days)
	-20 to +45°C (-4 to +113°F) (within 90 days)
	-20 to +35°C (-4 to +95°F) (more than 90 days)
Humidity:	20 to 85% RH (noncondensing)
Atmospheric pressure:	700 to 1060 hPa

Power Requirement

Line voltage:	
AC:	AC 100 to 240 V ±10%
DC (SB-671P):	8.5 to 12.6 V
Line frequency:	50 or 60 Hz
Power consumption:	
BSM-6301:	AC 140 VA
BSM-6501:	AC 90 VA
BSM-6701:	AC 100 VA

Clock Accuracy

At operating temperature 25°C:	approx. ±2 min 40 s/month maximum
At storage temperature -20 to +60°C:	approx. ±6 min/month maximum

Environment

Operating environment:	
Temperature:	10 to 40°C (50 to 104°F)
Humidity:	30 to 85% RH (10 to 40°C, noncondensing)
Atmospheric pressure:	700 to 1060 hPa
Transport and storage environment:	
Temperature:	-20 to +65°C (-4 to +149°F)
	-15 to +55°C (Recording paper)
Humidity:	10 to 95% RH
Atmospheric pressure:	700 to 1060 hPa

Mechanical Strength

Mechanical strength:	Indoor mobile type
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Safety Standard

Safety standard:	CAN/CSA C22.2 No.601-1 M90 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.601-1S1-94 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.601-1B-98 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.60601-1-1-02 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.601.2.27-98 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.60601-2-30-02 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.60601-2-34-02 (BSM-6501A, BSM-6701A)
	CAN/CSA C22.2 No.60601-2-49-04 (BSM-6501A, BSM-6701A)
	EN 12470-4: 2000* ¹
	IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
	IEC 60601-1-1: 2000
	IEC 60601-1-2: 2001, Amendment 1: 2004
	IEC 60601-2-27: 1994 - Particular requirements for the safety of electrocardiographic monitoring equipment

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IEC 60601-2-27: 2005 - Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

IEC 60601-2-30: 1999 - Particular requirements for the safety of automatic cycling in in-direct blood pressure monitoring equipment

IEC 60601-2-34: 2000 - Particular requirements for the safety of direct blood pressure monitoring equipment*²

IEC 60601-2-49: 2001 - Particular requirements for the safety of multifunction patient monitoring equipment

*¹This monitor complies with EN 12470-4: 2000 only for clauses 6.2, 6.3 a), 6.5, 6.6, 6.7, 6.8, 6.9, 6.10 and 8.

*²This monitor complies with IEC 60601-2-34: 2000 except for clauses 44.6, 45.101 a) and 45.101 b).

ISO 21647: 2004

ISO 9919: 2005

Type of protection against electrical shock:

CLASS I EQUIPMENT (AC Powered)

Internally Powered EQUIPMENT (BATTERY Powered)

Degree of protection against electrical shock

Defibrillator-proof type CF applied part:

AY-631P, AY-633P, AY-651P and AY-653P:

ECG, Respiration (Impedance and Thermistor method), IBP, Temperature, SpO₂, CO₂, O₂, BIS, NIBP

AY-660P:

ECG, Respiration (Impedance method), IBP, Temperature, SpO₂, CO₂, NIBP

AY-661P, AY-663P, AY-671P and AY-673P:

ECG, Respiration (Impedance and Thermistor method), IBP, Temperature, SpO₂, Second SpO₂, CO₂, O₂, BIS, NIBP

AA-672P and AA-674P:

Respiration (Thermistor method), IBP, Temperature, CO₂, O₂, BIS, Second SpO₂ (only when AY-661P, AY-663P, AY-671P or AY-673P is used)

CF applied part:

AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P, AY-673P, AA-672P and AA-674P:

CO

Degree of protection against harmful ingress of water:

IPX0 (ordinary EQUIPMENT)

Degree of safety of application in the presence of 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

Dimensions and Weight (approximate)

MU-631R main unit	Dimensions: 316 W × 325 H × 188 D mm (excluding protruding parts) Weight: 5.3 kg
MU-651R main unit	Dimensions: 342 W × 353 H × 183 D mm (excluding protruding parts) Weight: 7.0 kg
MU-671R main unit	Dimensions: 415 W × 392 H × 191 D mm (excluding protruding parts) Weight: 9.0 kg

AY-631P/633P/651P/653P/660P/661P/663P/671P/673P input unit	Dimensions: 83 W × 176 H × 145 D mm (excluding protruding parts) Weight: 1.3 kg
AA-672P/674P smart expansion unit	Dimensions: 38 W × 165 H × 145 D mm (excluding protruding parts) Weight: 0.5 kg
WS-671P recorder module	Dimensions: 77 W × 73 H × 120 D mm (excluding protruding parts) Weight: 0.35 kg
QI-631P interface	Dimensions: 28.5 W × 94 H × 106 D mm (excluding protruding parts) Weight: 0.1 kg
QI-632P/634P interface	Dimensions: 27 W × 94 H × 106 D mm (excluding protruding parts) Weight: 0.1 kg
QI-671P interface	Dimensions: 29 W × 173 H × 112 D mm (excluding protruding parts) Weight: 0.16 kg
QI-672P interface	Dimensions: 26 W × 173 H × 107 D mm (excluding protruding parts) Weight: 0.15 kg
RY-910PA remote control	Dimensions: 45 W × 35 H × 135 D mm Weight: 0.08 kg
Interface QF series:	Dimensions: 65 W × 23 H × 44 D mm (excluding cables) Weight: 0.13 kg
Communication cable IF series:	Dimensions: 65 W × 23 H × 44 D mm (excluding cables) Weight: 0.13 kg

1. GENERAL

Electromagnetic Emissions

The BSM-6000's essential performances in EMC standard satisfy the following criteria.

This Model BSM-6000 is intended for use in the electromagnetic environment specified below.

The customer or the user of the BSM-6000 should assure that it is used in such an environment.

BSM-6301 and BSM-6501 (QE-910P BIS processor is not connected)

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BSM-6301 and BSM-6501 (QE-910P is not connected) use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B* ¹	The BSM-6301 and BSM-6501 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A* ²	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

*¹ BSM-6301 and BSM-6501 (when QE-910P and ZS-900P are connected) are CLASS A equipment if the equipments comply with IEC 60601-1-2: 2001 36 201.1.5 in the countries which do not have national wireless rule.

*² BSM-6301 is not applicable.

BSM-6301, BSM-6501 (QE-910P BIS Processor is connected) and BSM-6701

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BSM-6301, BSM-6501 (QE-910P connected) and BSM-6701 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BSM-6301, BSM-6501 (QE-910P is connected) and BSM-6701 are suitable for use in all establishments, excluding domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A*	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

* BSM-6301 is not applicable.

Electromagnetic Immunity


The BSM-6000's essential performances in EMC standard satisfy the following criteria.

This Model BSM-6000 is intended for use in the electromagnetic environment specified below.

The customer or the user of the BSM-6000 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 tiles. 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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BSM-6000 requires continued operation during power mains interruptions, it is recommended that the BSM-6000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level			

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BSM-6000 including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*¹, should be less than the compliance level in each frequency range*².</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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 the BSM-6000 is used exceeds the applicable RF compliance level above, the BSM-6000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BSM-6000.			
* ² Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment

The BSM-6000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BSM-6000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BSM-6000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. GENERAL

System Composition for EMC Test

The BSM-6000 bedside monitor is tested to comply with IEC 60601-1-2: 2001, Amendment 1: 2004 with the following composition. If any part which is not specified by Nihon Kohden is used, the EMC specifications might not comply.

Units	Cable length
MU-631R/MU-651R/MU-671R main unit	—
AY-633P/AY-660P/AY-673P input unit	—
QM-600P memory unit	—
AA-674P smart expansion unit	—
QI-631P/QI-632P/QI-634P/QI-671P/QI-672P interface	—
BJ-900P ECG patient cable	3.8 m
JL-900P SpO ₂ connection cord	2.5 m
TL-201T finger probe	1.6 m
JL-650P SpO ₂ connection cord	3.0 m
JL-630P SpO ₂ connection cord	3.0 m
LNOP-DCI Masimo adult reusable sensor	—
YN-921P air hose for neonate	3.5 m
YP-821P disposable cuff for neonate	0.2 m
YN-901P air hose for adult/child	3.5 m
YP-963T cuff for adult	0.15 m
JP-900P IBP connection cord	3.5 m
DX-300 monitoring kit	—
JT-950P CO connection cord	2.0 m
TC-704MU Becton Dickinson catheter soft type	1.1 m
SP-5030 bath probe	1.5 m
JT-900P temperature connection cord	0.3 m
401J thermistor probe for adult	3.5 m
402J thermistor probe for child	3.5 m
TG-900P CO ₂ sensor kit	3.0 m
TG-920P CO ₂ sensor kit	3.5 m
TG-950P CO ₂ sensor kit	4.0 m
JO-900P FiO ₂ connection cord	3.0 m
074705 oxygen sensor	0.6 m
TR-900P respiration pickup for nose	3.0 m
YJ-671P BISx connection cord	0.3 m
QE-910P BIS processor	—
YJ-910P ECG/BP output cable	5.0 m
QF-901P interface (including a cable for Drager ventilator)	—
QF-902P interface (including a cable for A-2000 BIS monitor)	—
QF-903P interface (including a cable for Vigilance CCO monitor)	—
QF-904P interface (including a cable for AG-920R multi-gas unit)	—
QF-905P interface (including a cable for AG-400RK CO ₂ unit)	—
YS-080P3 RGB cable	10 m
YS-089P2 serial connection cable	10 m
Basic optical mouse	—

Units	Cable length
SB-671P battery pack	—
ZS-900P transmitter	—
YS-089P7 network connection cable	0.7 m
QW-100Y (HIT-100) hyper isolation transformer	—
RY-910PA remote controller	—
Power cord W	2.5 m
Power cord H	2.5 m
Power cord N	2.4 m
Power cord UL	2.5 m
Power cord GB	2.5 m
Grounding lead	—
QI-320PA wireless LAN station	—
QI-600P interface unit	—
JA-690PA/JA-694PA data acquisition unit	—
YS-096P2/YS-096P3 unit connection cable	2.5 m/5.0 m
YS-096P5 multi-link cable	0.27 m

NOTE

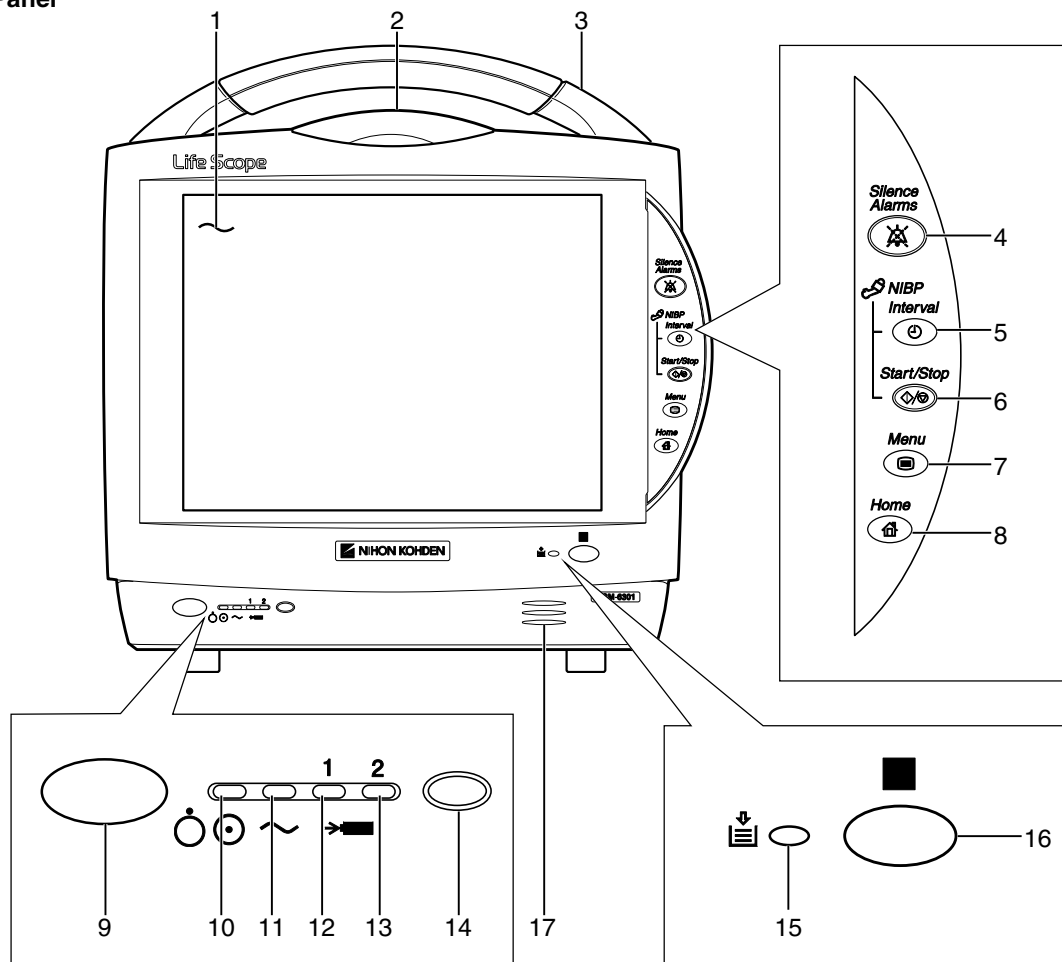
When the following units are used, IEC 60601-1-2: 1993 complies.

- Multigas unit AG-920R
- CO₂ unit AG-400RK

Panel Description

MU-631R Main Unit

Front Panel



1 Touch screen

Displays monitoring data. Touching a key or data on the screen changes the displayed screen and settings.

2 Alarm indicator

Red or yellow lamp blinks, or yellow or blue lamps lights according to the alarm settings. Green lamp blinks in synchronization with the patient's QRS or pulse.

3 Handle

For carrying the monitor.

4 Silence Alarms key

Silences the alarm sound.

5 NIBP Interval key

Selects NIBP measurement mode. Pressing this key changes the mode.

6 NIBP Start/Stop key

Starts NIBP measurement in selected mode. Pressing the key during measurement stops measurement.

7 Menu key

Displays the MENU window.

8 Home key

Closes all opened windows and displays the home screen.

9 Power switch

Press to turn the monitor power on. When turning the monitor power off, press and hold for more than three seconds.

10 Power lamp

Lights when the monitor power is turned on.

11 AC power lamp

Lights when the power cord is connected between the AC SOURCE socket and AC outlet.

12 Battery lamp 1

Indicates a battery status of the battery in the battery slot 1.

13 Battery lamp 2

Indicates a battery status of the battery in the battery slot 2.

14 Remote control sensor

Receives an infrared signal from the remote control.

15 ERROR lamp (option)

Blinks when out of paper. Lights when the recorder door is open.

16 RECORD/STOP key (option)

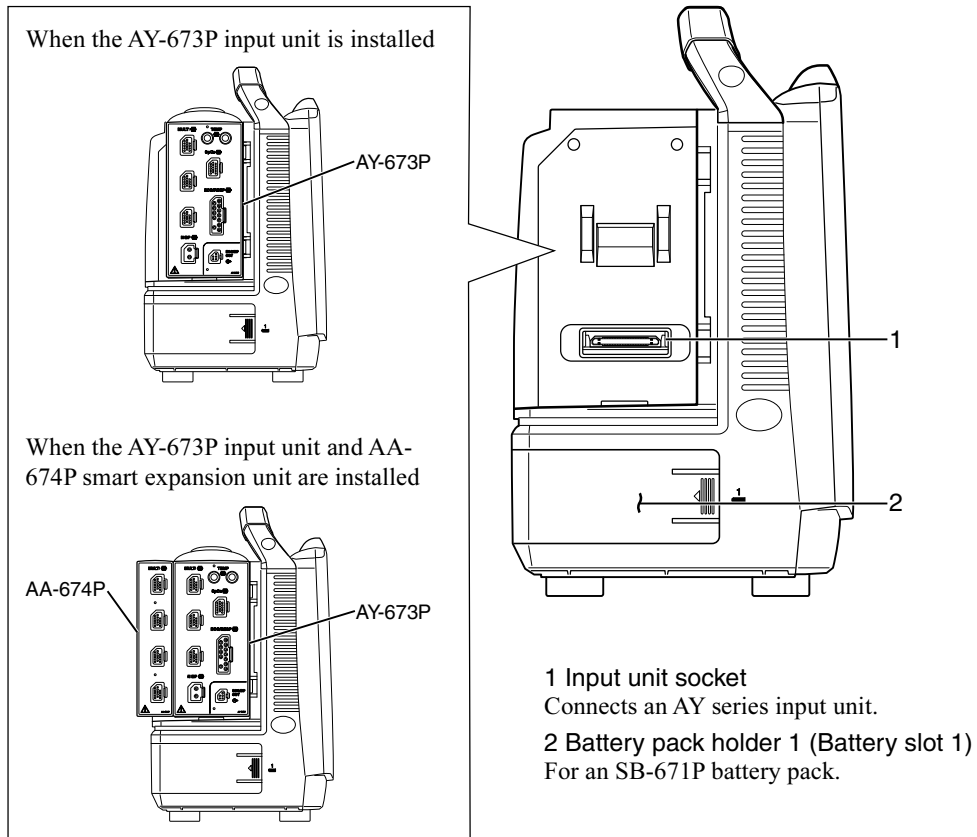
Press to start or stop recording.

17 Speaker

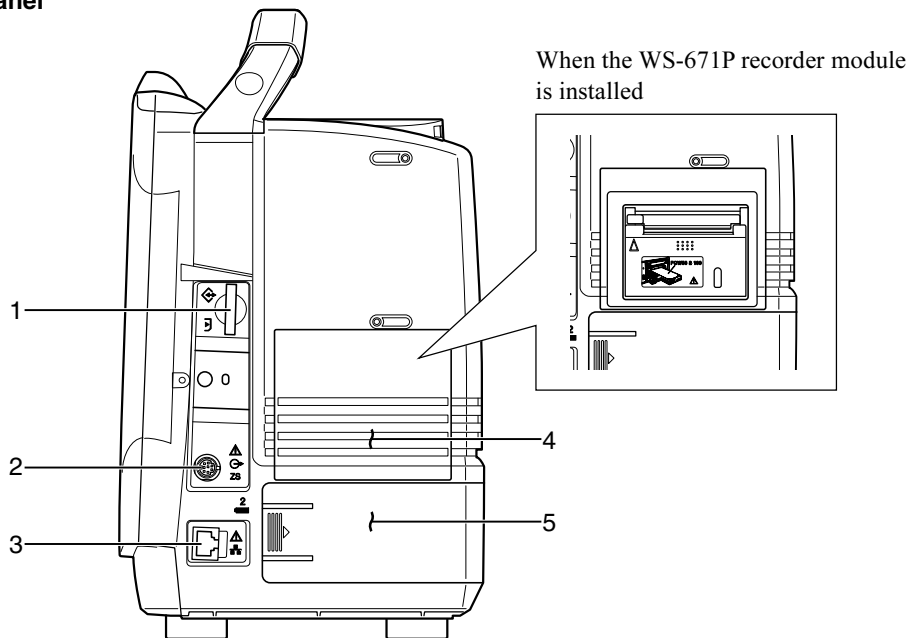
For alarms and sync sound.

1. GENERAL

Left Side Panel



Right Side Panel



1 SD card slot
For an SD card or program card.

2 ZS socket
For the ZS-900P* transmitter.
* ZS-900P transmitter is not available in USA

3 Network socket
Connects to monitor network system via the network separation unit.

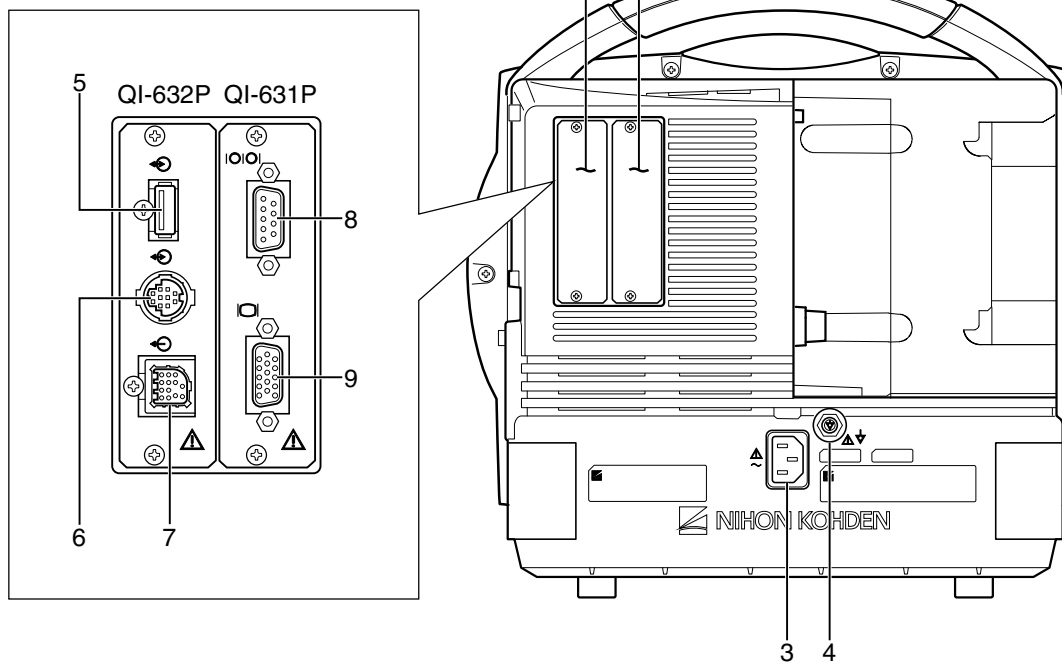
4 Recorder module holder
For the WS-671P recorder module.

5 Battery pack holder 2 (Battery slot 2)
For an SB-671P battery pack.

Rear Panel

Example shows the QI-631P and QI-632P interfaces installed.

When the optional interface is connected



1 QI-632P interface socket

Connects the QI-632P interface.

2 QI-631P interface socket

Connects the QI-631P interface.

3 AC SOURCE power cord socket

For the AC power cord.

4 Equipotential grounding terminal

For an equipotential grounding lead.

5 USB socket

Connects the mouse.

6 Multi-link socket (QI-632P/QI-634P)

Connects a QF series interface or IF series communication cable.

7 Alarm socket (QI-632P)

Not available.

8 RS-232C socket (QI-631P)

Not available.

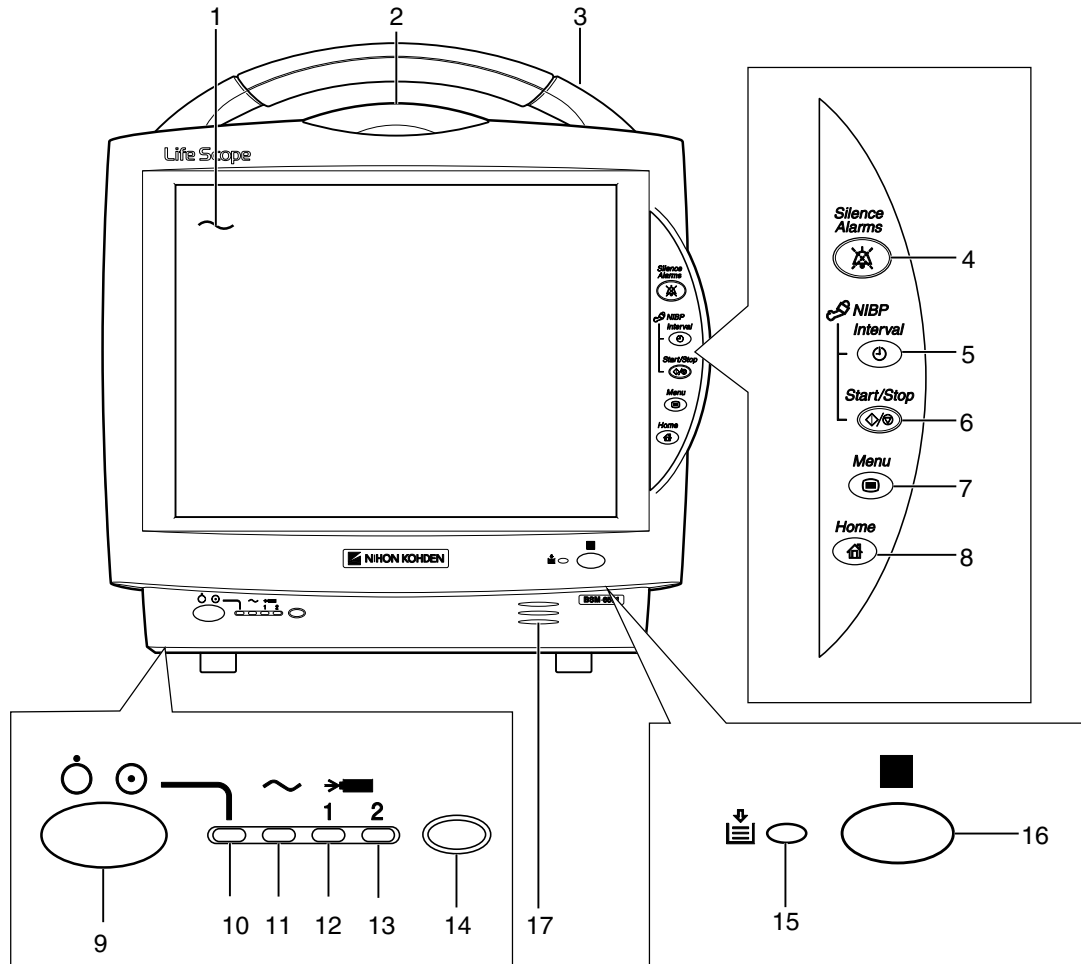
9 RGB socket (QI-631P)

Outputs the RGB video signal. Connects to the slave display.

1. GENERAL

MU-651R/MU-671R Main Unit

Front Panel



1 Touch screen

Displays monitoring data. Touching a key or data on the screen changes the displayed screen and settings.

2 Alarm indicator

Red or yellow lamp blinks, or yellow or blue lamps lights according to the alarm settings. Green lamp blinks in synchronization with the patient's QRS or pulse.

3 Handle

For carrying the monitor.

4 Silence Alarms key

Silences the alarm sound.

5 NIBP Interval key

Selects NIBP measurement mode. Pressing this key changes the mode.

6 NIBP Start/Stop key

Starts NIBP measurement in selected mode. Pressing the key during measurement stops measurement.

7 Menu key

Displays the MENU window.

8 Home key

Closes all opened windows and displays the home screen.

9 Power switch

Press to turn the monitor power on. When turning the monitor power off, press and hold for more than three seconds.

10 Power lamp

Lights when the monitor power is turned on.

11 AC power lamp

Lights when the power cord is connected between the AC SOURCE socket and AC outlet.

12 Battery lamp 1

Indicates a battery status of the battery in the battery slot 1.

13 Battery lamp 2

Indicates a battery status of the battery in the battery slot 2.

14 Remote control sensor

Receives an infrared signal from the remote control.

15 ERROR lamp (option)

Blinks when out of paper. Lights when the recorder door is open.

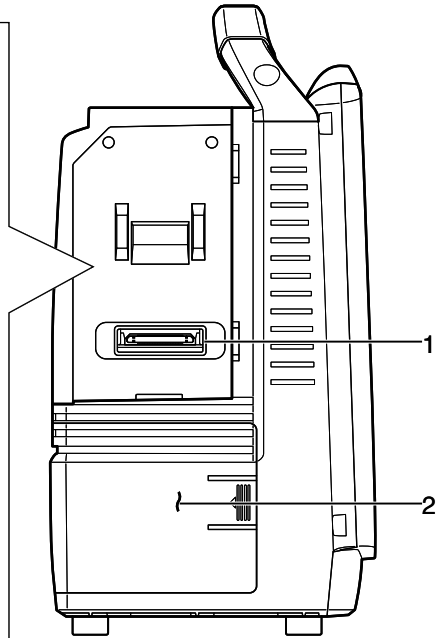
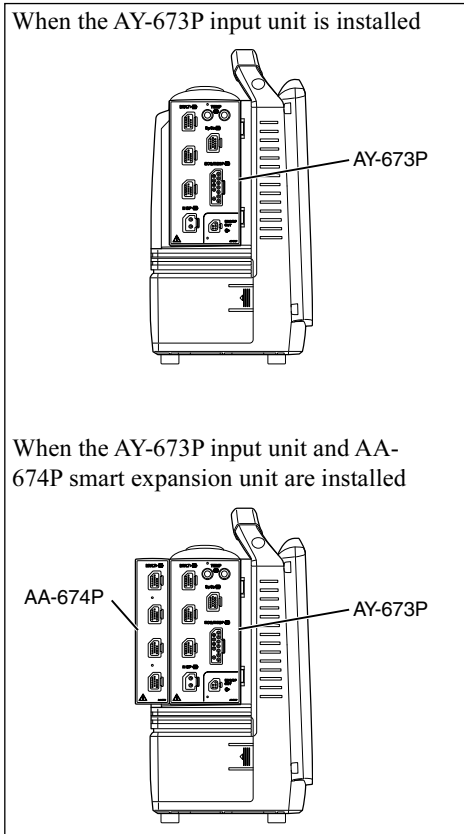
16 RECORD/STOP key (option)

Press to start or stop recording.

17 Speaker

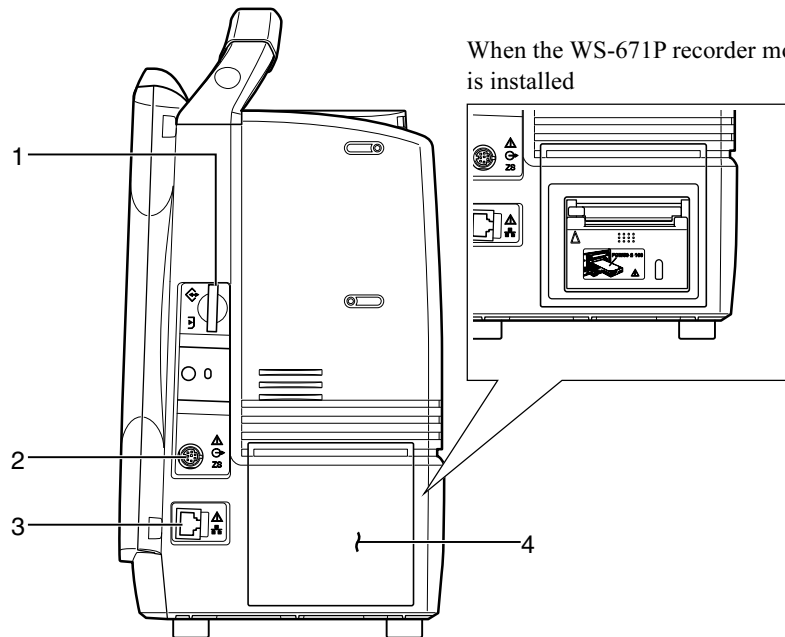
For alarms and sync sound.

Left Side Panel



- 1 Input unit socket**
Connects the AY-631P/AY-633P/AY-651P/AY-653P/AY-661P/AY-663P/AY-671P/AY-673P input unit.
- 2 Battery pack holder**
For an SB-671P battery pack.

Right Side Panel

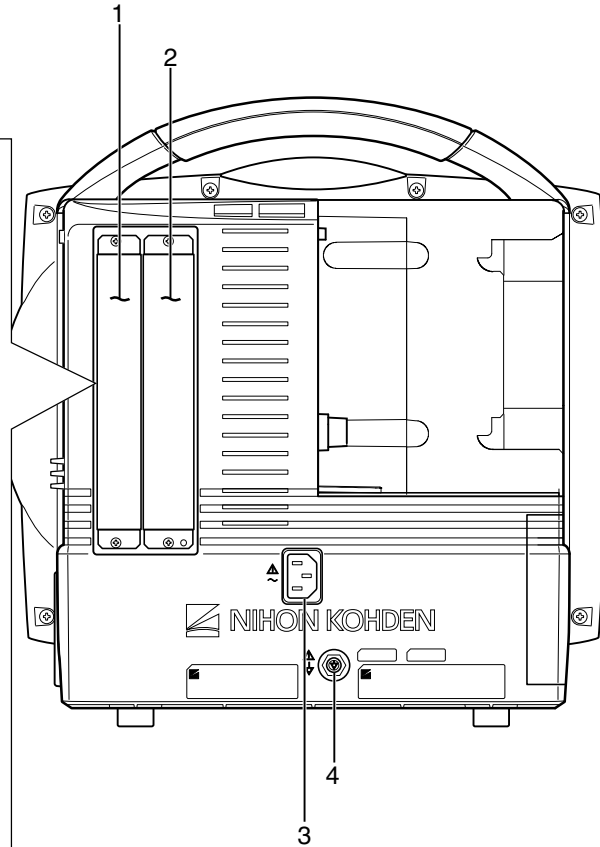
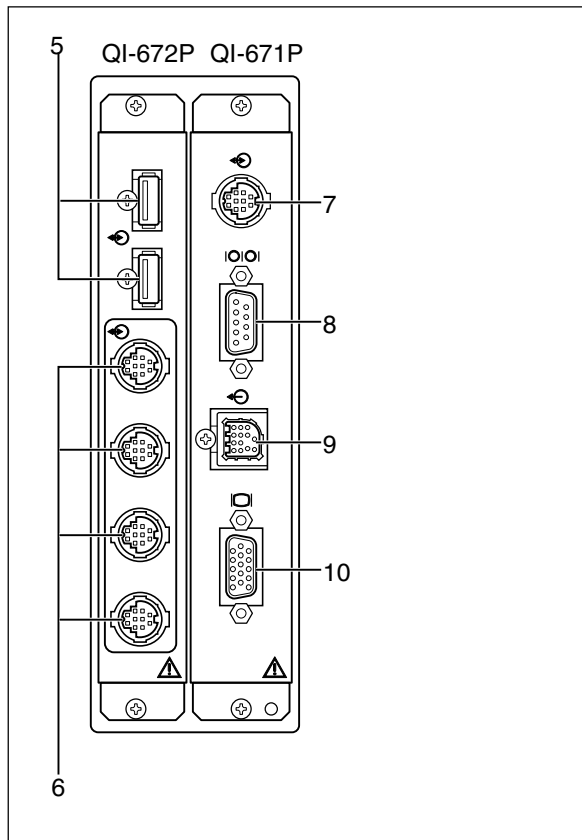


- 1 SD card slot**
For an SD card or program card.
- 2 ZS socket**
For the ZS-900P* transmitter.
* ZS-900P transmitter is not available in USA
- 3 Network socket**
Connects to monitor network system via the network separation unit.
- 4 Recorder module holder**
For the WS-671P recorder module.

1. GENERAL

Rear Panel

When the optional interface is connected



1 QI-672P interface socket

Connects the QI-672P interface.

2 QI-671P interface socket

Connects the QI-671P interface.

3 AC SOURCE power cord socket

For the AC power cord.

4 Equipotential grounding terminal

For an equipotential grounding lead.

5 USB sockets

Connects the mouse.

6 Multi-link sockets

Connects a QF series interface or IF series communication cable.

7 Multi-link sockets

Connects a QF series interface or IF series communication cable.

8 RS-232C socket

Not available.

9 Alarm socket

Not available.

10 RGB socket

Outputs the RGB video signal. Connects to the dual display or slave display.

AY Series Input Unit

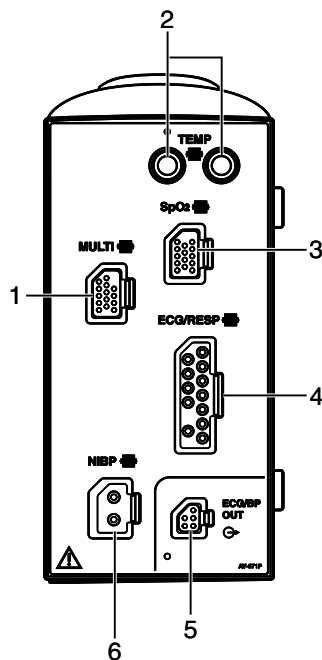
AY-631P/AY-650P/AY-651P/AY-660P/AY-661P/AY-671P: One MULTI socket

AY-633P/AY-653P/AY-663P/AY-673P: Three MULTI sockets

Front Panel

One MULTI socket

Example is AY-671P input unit.



1 MULTI socket

Connects to the connection cord of the parameter to be monitored. The type of parameter is automatically recognized.

NOTE

Only IBP and CO₂ monitoring are available when an AY-660P input unit is used.

2 TEMP socket

Connects to the temperature probe cord.

NOTE

The number of TEMP sockets on the input unit depends on the types of input unit.

AY-660P: one TEMP socket

AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P and AY-673P: two TEMP sockets

3 SpO₂ socket

Connects to the SpO₂ connection cord.

4 ECG/RESP socket

Connects to the ECG connection cord.

5 ECG/BP OUT socket

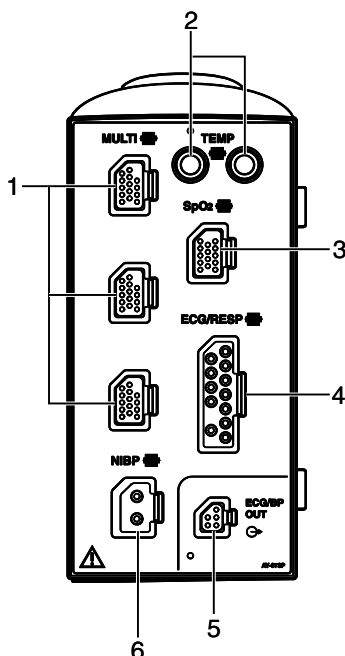
Outputs 100 mmHg/V IBP waveform of the IBP connected to the MULTI socket, 1 mV/V ECG waveform and heart rate trigger by using the YJ-910P or YJ-920P ECG/BP output cable. These analog signals can be used as the synchronization signal for other equipment, such as IABP.

6 NIBP socket

Connects to the air hose.

Three MULTI sockets

Example is AY-673P input unit.



WARNING

Connect only the specified instrument to the monitor and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause fire or instrument malfunction.

Using MULTI Sockets for CO Monitoring

WARNING

When performing defibrillation during cardiac output monitoring, never touch the CO connection cord. The discharged energy may cause electrical shock or injury.

NOTE

CO monitoring using the MULTI socket does not comply with the defibrillator proof type CF.

Using the Output Signal from the ECG/BP OUT Socket

CAUTION

When using the output signal from the monitor as the synchronization signal for other equipment such as an IABP (intra-aortic balloon pump) or defibrillator:

- Set the timing of the IABP by checking the waveform on the IABP screen.
- Check the condition of the bedside monitor at all times. The output signal may become unstable.
- Check that the delay time of the output signal is within the range of the connected equipment.

CAUTION

Only a Nihon Kohden defibrillator can use the output signal from the monitor as a synchronization signal. Check that the delay time of the output signal (heart rate trigger 20 ms maximum) is within the range of the connected defibrillator.

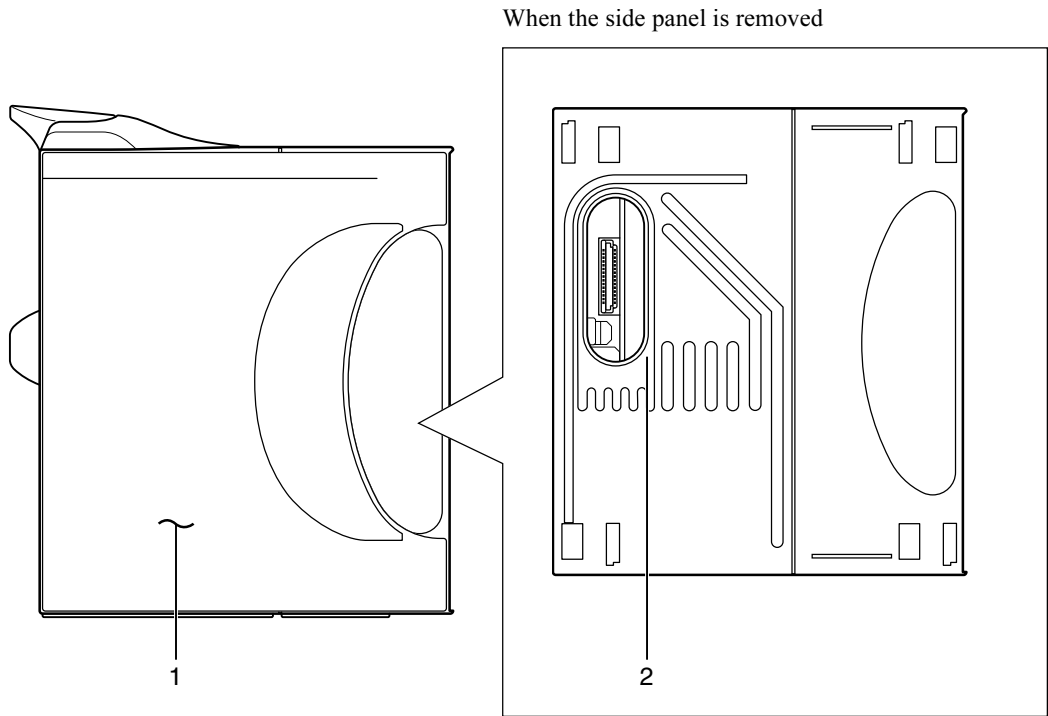
NOTE

- Analog ECG, analog BP and HT output are not available when an AY-660P input unit is used.
- The output signal from the ECG/BP OUT socket may become unstable in the following conditions.
 - Electrode is dry or detached.
 - Electrode lead is damaged or disconnected from the electrode.
 - Electrode lead is pulled.
 - AC interference or EMG noise superimposed.
 - Air bubbles or blood clog in the circuit for monitoring IBP.
 - Cord or cable is disconnected or damaged.
- All instruments which are to be connected to the ECG/BP OUTPUT socket must use a YJ-910P or YJ-920P ECG/BP output cable and comply with the IEC 60601-1 safety standard for medical equipment.
- When more than one IBP waveforms are acquired, the IBP waveform is output in following priority: ART > ART-2 > RAD > DORS > AO > FEM > UA > LVP > P1 > P2 > P3 > P4 > P5 > P6 > P7.
- When using an IABP, set <CALCULATION METHOD> on the OTHER page of the PRESS window to “PEAK” to improve measurement accuracy.

Output Signal Delay Time

Output Signal	Delay Time
ECG	maximum 20 ms
IBP	maximum 40 ms
Heart rate trigger	maximum 20 ms

Left Side Panel



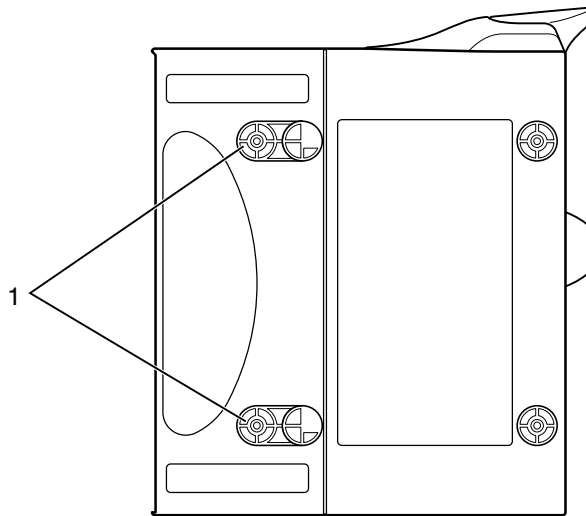
1 Side panel

Remove to attach an AA-672P/AA-674P smart expansion unit.

2 Smart expansion unit socket

Connects an AA-672P or AA-674P smart expansion unit (AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P or AY-673P only).

Right Side Panel

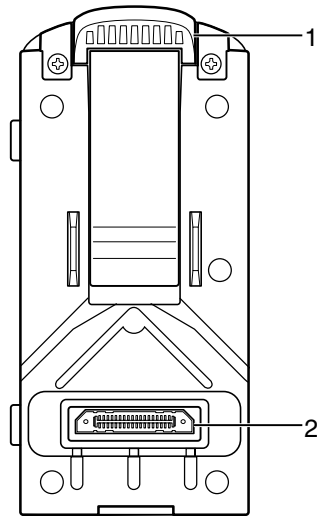


1 Tabs

Match the tabs on the input unit to the slots on the bedside monitor.

1. GENERAL

Rear Panel



1 Lock release lever

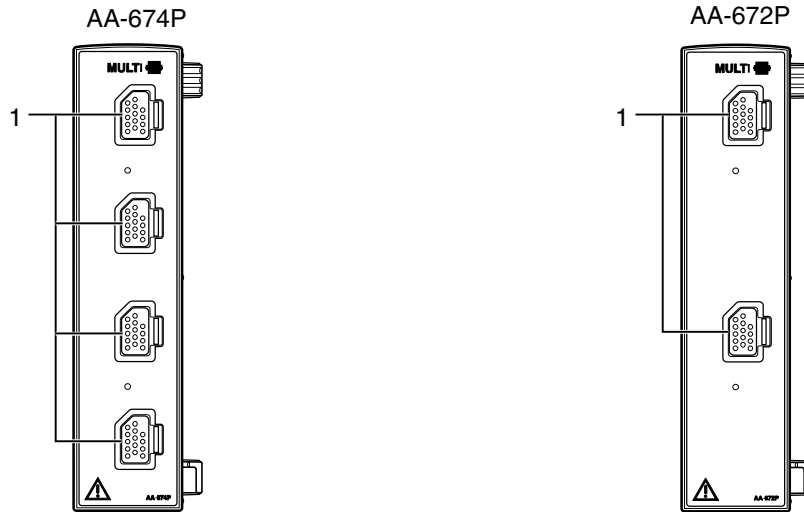
Lift up the lever to remove the input unit from the bedside monitor.

2 Input unit socket

For connecting a bedside monitor.

AA-672P/AA-674P Smart Expansion Unit

Front Panel



1 MULTI socket

Connect to the connection cord of the parameter to be monitored (IBP, temperature, CO, CO₂, O₂, respiration by thermistor method or BIS). The type of parameter is automatically recognized.

Using MULTI Sockets for CO Monitoring

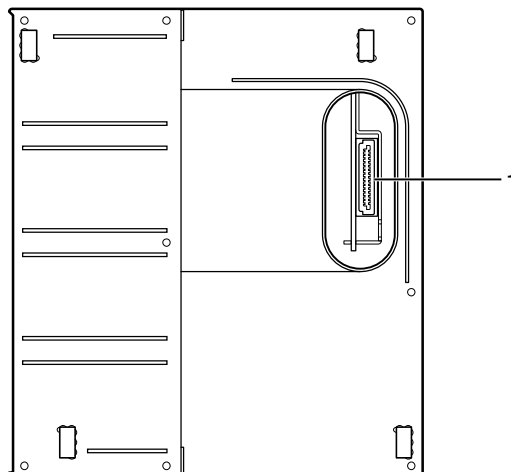
WARNING

When performing defibrillation during cardiac output monitoring, never touch the CO connection cord. The discharged energy may cause electrical shock or injury.

NOTE

CO monitoring using the MULTI socket does not comply with the defibrillator proof type CF.

Right Side Panel

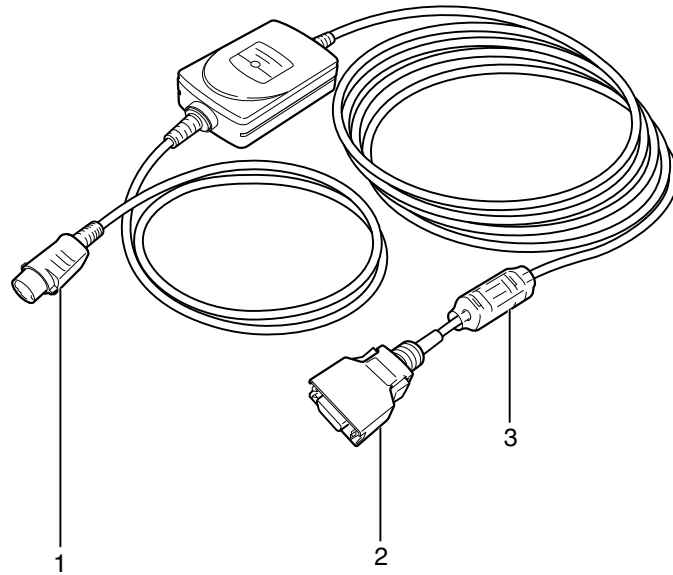


1 Connector

Connects an AY-631P, AY-633P, AY-651P, AY-653P, AY-661P, AY-663P, AY-671P or AY-673P input unit.

1. GENERAL

QF series Interface and IF series Communication Cable



1 Multi-link connector

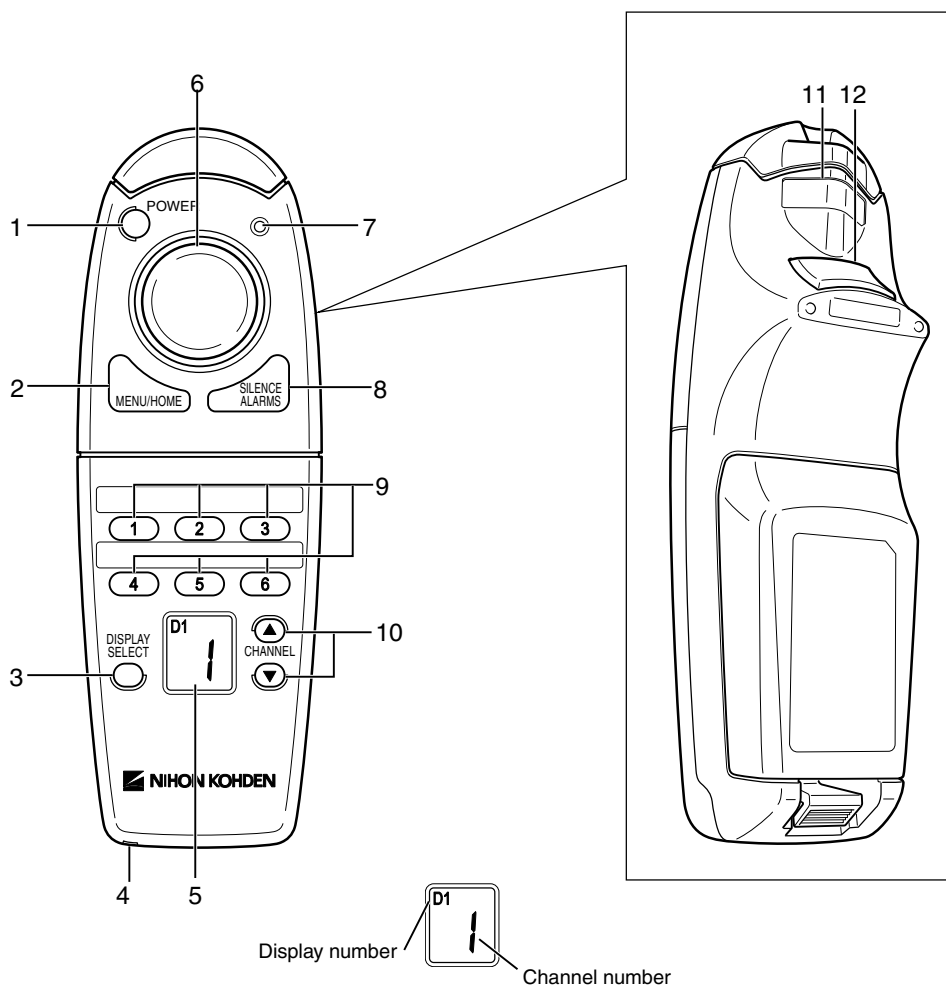
Connect to the multi-link socket on the bedside monitor.

2 External device connector

Connect to an external device.

3 Ferrite core

RY-910PA Remote Control

**1 Power button**

When the power cord is connected between the bedside monitor and AC outlet, turns the monitor power on or off.

2 MENU/HOME key

Opens the MENU window. Closes the window and displays the home screen when a window is opened.

3 DISPLAY SELECT key

Not available.

4 Strap hole

Use a strap to prevent dropping the remote control.

5 Display

Displays the channel number and the display number.

6 Selection knob

Move this knob up/down/left/right to move the cursor or mouse pointer on the screen.

7 LED

Lights when the pointer on the screen is moved by the selection knob. Blinks when a key on the remote control is pressed.

8 SILENCE ALARMS key

Silences the alarm sound.

9 Customized keys

Windows and functions can be assigned to each key for shortcut key operations.

10 CHANNEL keys

Select the monitor when a channel is assigned to the monitor.

11 Transmitter

Signal is transmitted from here. Point the transmitter to the remote control sensor on the bedside monitor when operating the monitor with the remote control.

12 ENTER key

Registers the setting selected on the screen.

Storage and Transport

Follow these procedures when storing or transporting the instrument.

Storage

Before storing the instrument for a long time, perform the following steps:

1. Disconnect the power cord from the instrument.
2. Cover the instrument with a dust cover.
3. If possible, store the instrument in its original shipping container.
4. Make sure the storage place meets the following storage conditions for the duration of the storage.

Storage temperature: -20 to $+65^{\circ}\text{C}$ (-4 to $+149^{\circ}\text{F}$)

Storage humidity: 10 to 95% RH

Transport

To transport the instrument, perform the following steps:

1. Disconnect the power cord from the instrument.
2. Cover the instrument with a dust cover.
3. If possible, transport the instrument in its original shipping container.

Following transport conditions are required.

Transport temperature: -20 to $+65^{\circ}\text{C}$ (-4 to $+149^{\circ}\text{F}$)

Transport humidity: 10 to 95% RH

Hard Keys and Soft Keys

Hard Keys

The instrument has six hard keys: Silence Alarms, NIBP Interval, NIBP Start/Stop, Menu, Home and Record.

These keys always have the same functions, regardless of the screen display.

Soft Keys

When the Menu key is pressed or the screen is touched, the screen displays several keys which have different functions depending on the screen display. For example, when the HR numeric display is touched, the ECG setting screen appears and several tabs such as ST ALARM, ARRHYTH, OTHER, etc are displayed.

Upgrading the System Software and Changing Language on the Screen

CAUTION

Upgrading the system software and changing the language on screen erases all system and monitoring settings. Write down these settings so they can be re-entered after the software upgrade.

The instrument uses a program card for upgrading its system software and changing the screen language. When the instrument detects that a program card is inserted into its SD card slot during the booting stage after it is turned on, it checks the program card for a system program or language. If the program card contains a newer version of the system program or language, the instrument automatically replaces its current system program or language information with the new one. If the program card contains a system program whose version number is the same or older than the one in the instrument, you have the option to replace or keep the current system program. If the program card does not contain a system program, the instrument continues the boot-up process.

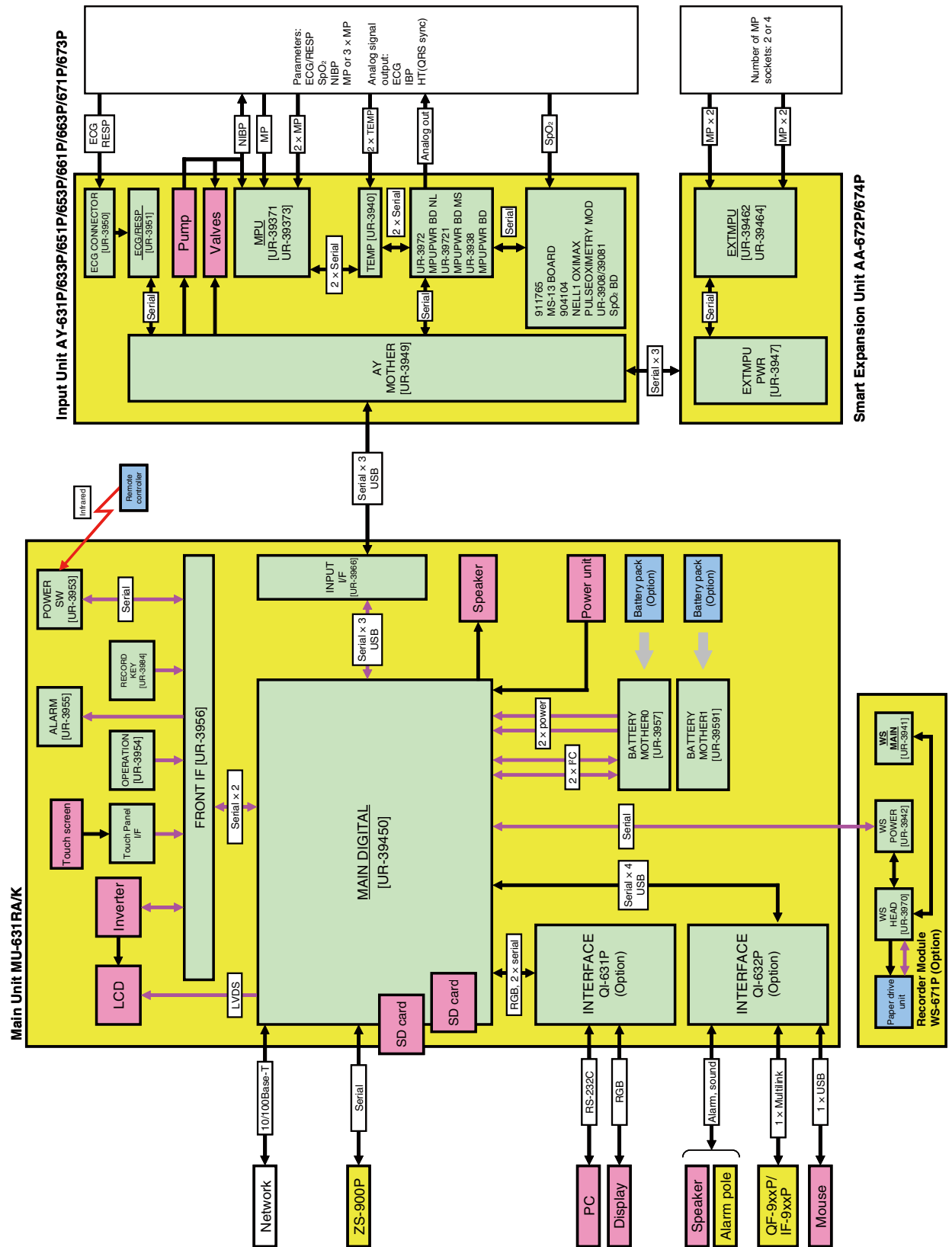
In the system software upgrading or language changing process, the instrument first deletes the old system software or language stored in its system ROM. Then it checks whether the data in the system ROM is completely deleted. When the data is completely deleted, it copies the new version of the system program or language information from the program card to the system ROM and then checks the copy process. After the data is successfully copied, it performs the self-check programs to check the equipment.

Procedure

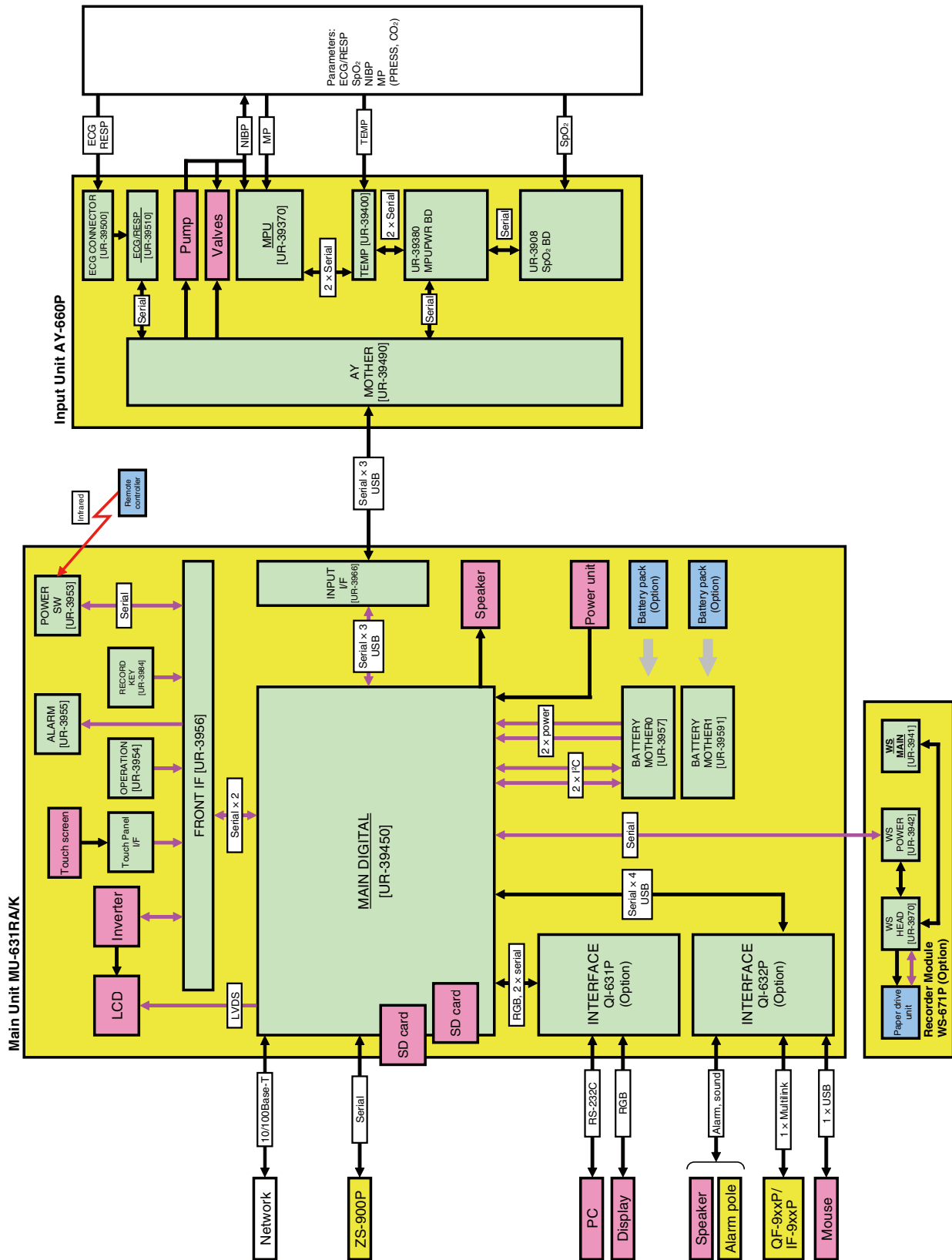
1. Write down the System Setup settings and monitoring settings of the instrument.
2. Insert the program card into the SD card slot on the right side panel of the instrument.
3. Turn on the instrument. The instrument performs the upgrading process and self-check programs. The DIAGNOSTIC CHECK screen appears.
4. Confirm that the new system software version number appears.

Board/Unit Connection Diagram

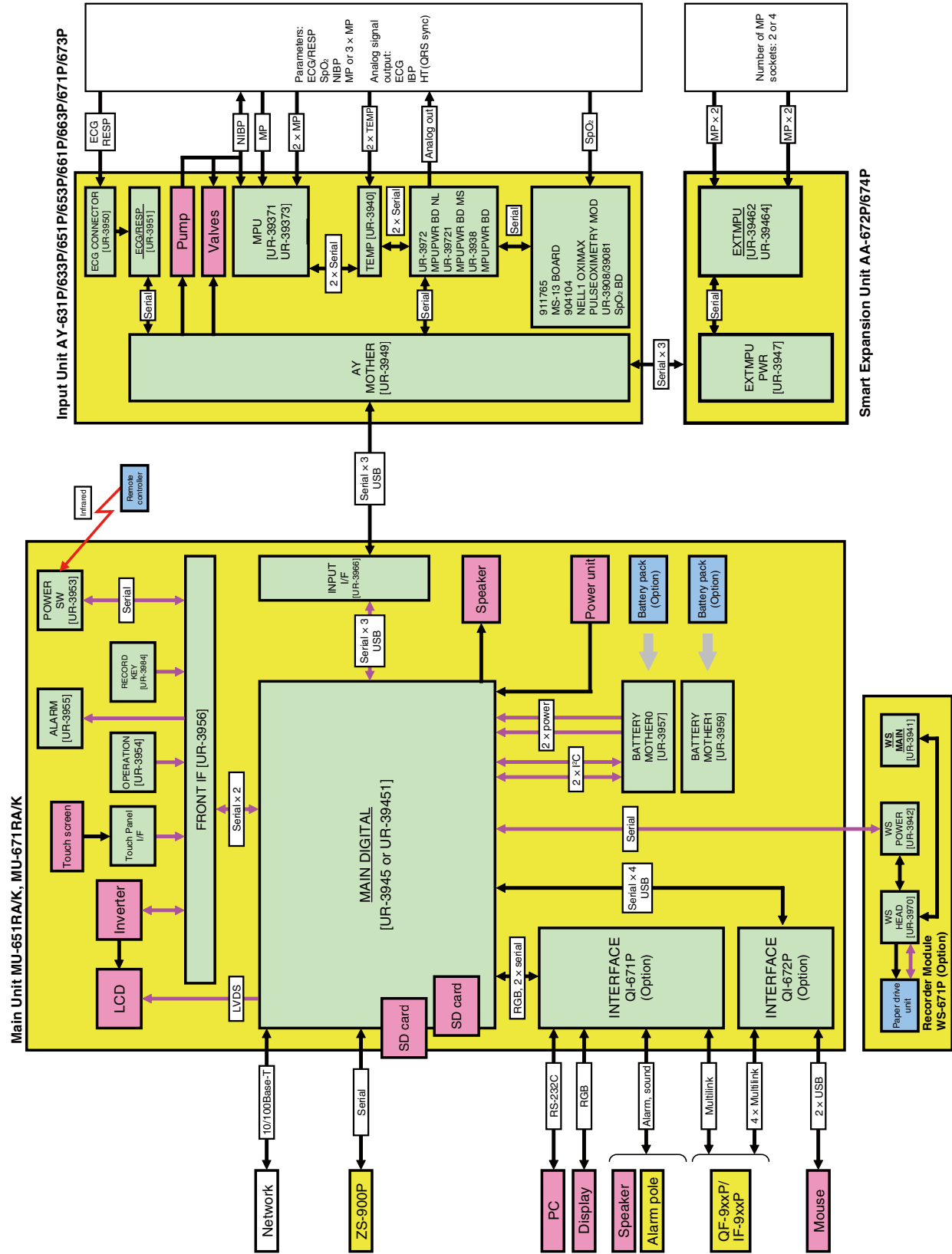
BSM-6301A/K



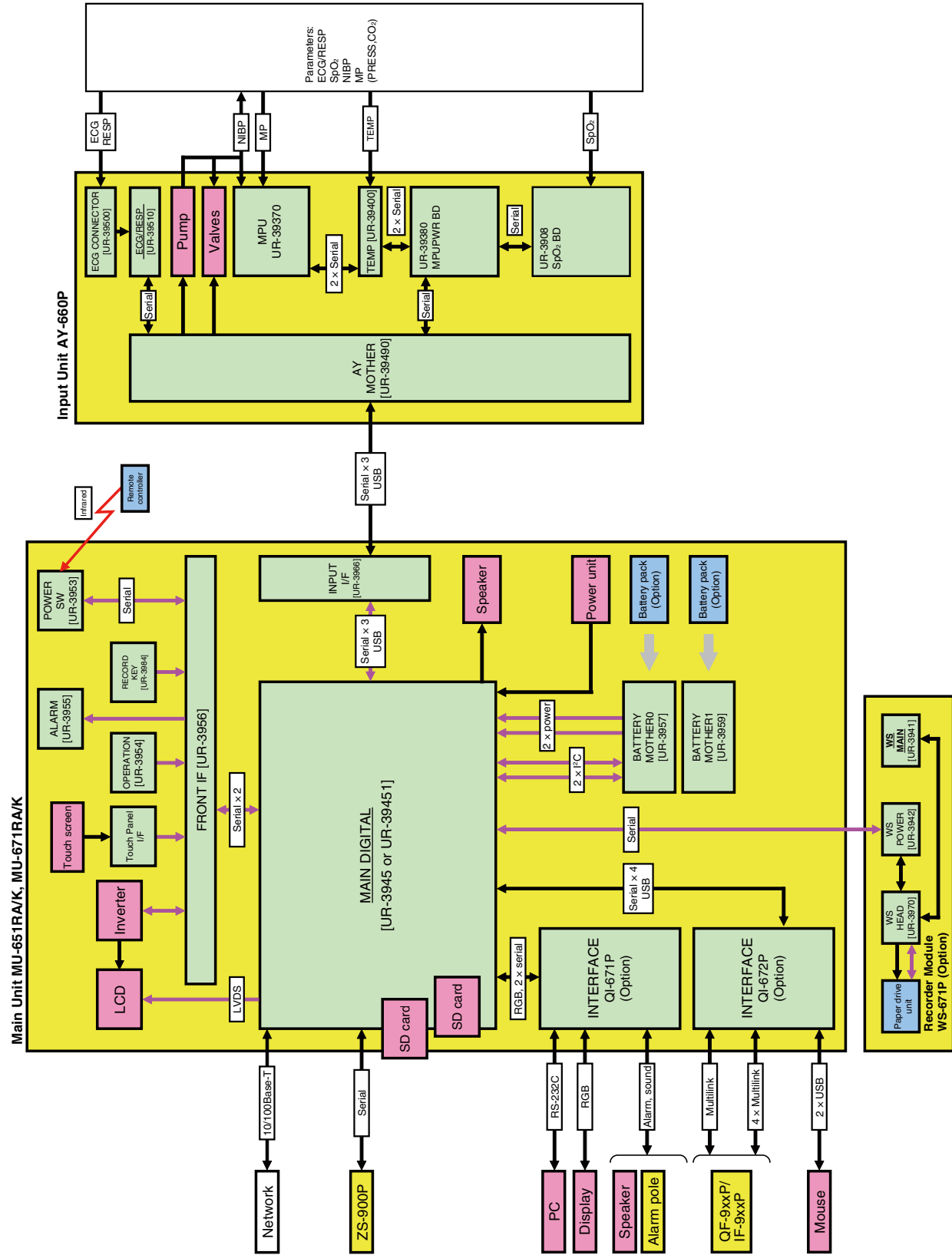
1. GENERAL



BSM-6501A/K and BSM-6701A/K



1. GENERAL



Section 2 Troubleshooting

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General

Use the troubleshooting tables to locate, identify, and solve a problem in the instrument. The problems are divided into general problem areas. Each category has its own troubleshooting table for fast and easy troubleshooting.

If these sections do not solve the problem, contact your Nihon Kohden representative.

NOTE

Before contacting your Nihon Kohden representative for technical support, please provide additional detailed information on the problem. This will allow your Nihon Kohden representative to provide you with the best support.

How to use the troubleshooting table

1. Determine which troubleshooting table to use.
2. In the “Trouble” column, find the trouble item that matches the problem.
3. Do the action recommended in the “Action” column.
4. If the problem is not solved, do the action for the next possible cause or criteria.
5. If none of the actions solve the problem, contact your Nihon Kohden representative.

Troubleshooting

NOTE: Available monitoring parameters depend on the types of input units.

AY-631P, AY-633P, AY-651P and AY-653P input unit

ECG, Respiration (Impedance and Thermistor method), IBP, Temperature, SpO₂, CO₂, O₂, BIS, NIBP

AY-660P input unit

ECG, Respiration (Impedance method), IBP, Temperature, SpO₂, CO₂, NIBP

AY-661P, AY-663P, AY-671P and AY-673P input unit

ECG, Respiration (Impedance and Thermistor method), IBP, Temperature, SpO₂, Second SpO₂, CO₂, O₂, BIS, NIBP

Monitoring

Trouble	Possible Cause/Criteria	Action
The screen is dark.	The brightness of the screen is not appropriate.	Adjust the setting on the BRIGHT window.
	The backlight is old.	Contact your Nihon Kohden representative.
	The monitor is operating on battery.	If necessary, set <POWER SAVE MODE> to OFF on the GENERAL window.
No sync sound.	The sync sound setting is turned OFF.	Select the ON button of <SYNC SOUND VOLUME>.
	The sync sound volume is turned down.	Adjust the volume setting on the VOLUME window.
	The sleep mode is turned on.	The sleep mode is turned off when: <ul style="list-style-type: none"> • An alarm occurs • The touch screen is touched • Key on the bedside monitor is pressed
The time displayed on the upper right corner of the screen is not correct.	The date and time setting is not correct.	Set the correct date and time on the DATE window.
	The backup battery is old.	Check the date and time setting on the DATE window and turn the power of the monitor off and on. If the time is incorrect, replace the battery with a new one. Contact your Nihon Kohden representative.
The monitor is too hot.	The vent hole is obstructed.	Remove the cause.
The touch screen keys do not function.	The pressed position and activated position do not match.	Calibrate the touch screen.
The monitor only operates for less than 90 minutes (BSM-6301/BSM-6501) or 60 minutes (BSM-6701) with a fully charged battery.	The battery pack is old.	Replace the battery pack with a fully charged new one.
Some part of the review data is deleted or the time is incorrect.	The monitor was turned off during the system check screen display.	The remaining data may not be reliable. Delete all data.

2. TROUBLESHOOTING


Network

Trouble	Possible Cause/Criteria	Action
The monitor cannot be connected to the network.	The network settings are not correct.	Set the correct network settings on the NETWORK page of the SYSTEM CONFIGURATION screen.
	The monitor is not selected as a monitored bed on the central monitor or receiving instrument.	Select the monitor as a monitored bed on the central monitor or receiving instrument.
	Discontinuity in the network cable or faulty hub.	Replace the network cable or the hub with a new one.

Remote Control

Trouble	Possible Cause/Criteria	Action
The remote control does not function.	The batteries in the remote control are old.	Replace the batteries with new ones.
	Wrong bed is selected.	Select the correct remote control channel of the bed.
Nothing appears on the display window of the remote control.	The batteries in the remote control are weak.	Replace the batteries with new ones.
LED on the remote control does not blink or light.	The batteries in the remote control are weak.	Replace the batteries with new ones.

Recording

Trouble	Possible Cause/Criteria	Action
There is no printing (only paper feeding).	The recording paper is upside down.	Reload the recording paper into the recorder correctly.
Waveforms can be recorded but the trend and list recording cannot.	Dust in the sensor inside the recorder.	Clean the surface of the sensor inside the recorder with a dry cotton swab.
Printing is faint.	The NK-specified paper is not used.	Use the FQW50-2-100 recording paper.
	The thermal head is dirty.	Clean the thermal head with the thermal head cleaning pen.
Dots are missing.	The thermal head is dirty.	Clean the thermal head with the provided thermal head cleaning pen.
Recording suddenly starts without key operation.	Alarm recording or periodic recording mode is set to ON.	Select OFF button of the alarm recording or periodic recording mode on the RECORDING window if not needed. Press the  [Record] key on the bedside monitor to stop recording.
No paper is feeding.	The recorder door is open.	Push the recorder door closed until it clicks.
	Dust may have collected in the gears.	Contact your Nihon Kohden representative.
Recorder operates only some of the time.	Dust in the sensor inside the recorder.	Clean the surface of the sensor inside the recorder with a dry cotton swab.

ECG

2

Trouble	Possible Cause/Criteria	Action
The heart rate is inaccurate.	The QRS amplitude is small.	Change the sensitivity so that the QRS amplitude is larger than 1 cm.
	The QRS is not detected correctly.	Change to a lead which provides good QRS. Change the lead or electrode position so that the QRS is large and T wave is small.
	The pacing detection setting on the ECG window is not appropriate.	When the patient does not have an implanted cardiac pacemaker or neonate's ECG is monitored, set the pacing detection to OFF on the ECG window.
The arrhythmia alarm occurs frequently when heart rate is normal.	The dominant QRS is not appropriate for arrhythmia monitoring.	Re-learn the patient ECG or change the dominant QRS.
	Patient moved or EMG noise is superimposed.	Change the electrode position to where there is less muscle.
ECG waveform does not appear on the screen when electrodes are attached properly.	<NUMBER OF ELECTRODES> setting on the ECG window is not correct.	Set the correct number for <NUMBER OF ELECTRODES> setting.
AC interference on the ECG waveform.	An electrical blanket is used.	Use another warming method or place a shield cover around the electrical blanket.
	The electrode is dry.	Replace the electrode with a new one.
	<FILTERS> on the ECG window is set to DIAG.	Set <FILTERS> to MONITOR.
Baseline wandering.	The baseline is not stable due to respiration or body movement.	Change the electrode position to where there is less muscle.
	The electrode is dry.	Replace the electrode with a new one.
	The contact resistance between the skin and electrode is high.	Rub the skin with "skinPure" skin preparation gel.
	<FILTERS> on the ECG window is set to MONITOR or DIAG.	Set <FILTERS> to MAXIMUM.

2. TROUBLESHOOTING

Respiration

Impedance Method

Trouble	Possible Cause/Criteria	Action
The respiration waveform is not displayed on the screen.	<IMPEDANCE MEASUREMENT> on the RESP/CO ₂ window is set to OFF.	Set <IMPEDANCE MEASUREMENT> to ON.
	Electrodes, electrode leads, ECG connection cord are not connected correctly.	Connect them properly.
	The electrode is dry.	Replace the electrode with a new one.
	The skin-electrode contact impedance is high.	Reduce the impedance by using “skinPure” skin preparation gel.
The respiration waveform and respiration rate are not stable.	The electrode positions are not appropriate for measuring respiration.	Check the attached position of the electrodes.
	The electrode is dry.	Replace the electrode with a new one.
	<NOISE REDUCTION ON IMPEDANCE RESP> is set to OFF and the respiration waveform amplitude is too small.	Change the sensitivity so that the amplitude is larger than 10 mm.
	<NOISE REDUCTION ON IMPEDANCE RESP> is set to ON and the timing of the respiration and heart rate coincide.	Set <NOISE REDUCTION ON IMPEDANCE RESP> on the SYSTEM SETUP window to ON.
There is sine wave noise on the respiration waveform.	Equipotential grounding is not acquired.	Connect the equipotential ground terminal on the monitor to the equipotential ground terminal on the wall with the grounding lead.

Thermistor Method

Trouble	Possible Cause/Criteria	Action
The respiration waveform is not displayed on the screen.	Malfunction of the respiration pickup.	Replace the respiration pickup with a new one.
The amplitude of the respiration waveform is small or becomes a baseline.	When measuring at the nostrils, the position of the respiration pickup is not appropriate.	Attach the respiration pickup to a position where sufficient temperature changes can be seen.
	The respiration pickup for nose is used for measuring a patient with trachea tube inserted.	Measure with a respiration pickup for airway.
	The temperature difference between inspiration and expiration is small due to increase in temperature of the inspired air.	Use the impedance method.
The expiration and inspiration phases are reversed.	The inspiration temperature is higher than the expiration temperature.	Use the impedance method.
The respiration rate is not accurate.	The respiration waveform amplitude is too small.	Change the sensitivity so that the amplitude is larger than 10 mm.

CO₂

Mainstream Method

2

Problem	Possible Cause/Criteria	Action
The measured value is low.	CO ₂ is mixed in the inspiration. (TG-900P/TG-920P only)	Refer to the CO ₂ section.
	The airway adapter/nasal adapter is dirty.	Replace the adapter with a new one.
	The measurement is performed where atmospheric pressure is low, such as at high altitude. (TG-900P/TG-920P only)	Consider the atmospheric pressure when making evaluations.
	Zero calibration is not performed. (TG-950P only)	Calibrate the CO ₂ sensor.
The measured value is high (Error is approx. 8 mmHg (1.07 kPa)).	Anesthetic gas is used. O ₂ : 4 L/min, N ₂ O: 2 L/min, sevoflurane: 1%	Set the correct inspired gas composition.
The measured value is inaccurate.	Oscillation.	Check the respirator and remove the cause.
	Currently doing suctioning. (TG-900P/TG-920P only)	After completing suction, wait for at least 20 seconds for the correct value to appear.
	A Jackson Rees respiration circuit or Mapleson D respiration circuit is connected to the patient. (TG-900P/TG-920P only)	Cannot measure correctly.
	The respiration rate of the patient is very high or respiration is irregular.	Cannot measure correctly.
The respiration waveform does not appear.	Oscillation.	Check the respirator and remove the cause.
	The airway adapter/nasal adapter is disconnected from the CO ₂ sensor kit.	Connect the adapter to the CO ₂ sensor kit.
The red LED on the CO ₂ adapter blinks.	CO ₂ sensor or CO ₂ adapter is faulty. (TG-900P/TG-920P only)	Replace the CO ₂ sensor or CO ₂ adapter with a new one.
	Apnea for longer than 20 seconds. (TG-900P/TG-920P only)	The red LED blinks when apnea is longer than 20 seconds regardless of the alarm setting on the monitor.

Sidestream Method

Trouble	Possible Cause/Criteria	Action
Cannot measure CO ₂	The FilterLine is clogged.	Replace the FilterLine with a new one.
	The exhaust gas adapter is clogged.	Remove the clog or replace the exhaust gas adapter with a new one.
	The CO ₂ unit is faulty.	Contact your Nihon Kohden representative.
Low CO ₂ value	The sample gas is leaking from the FilterLine connector.	Connect the FilterLine properly.
	The sample gas is leaking from the airway adapter.	Replace the airway adapter with a new one.
	The measuring sensitivity is not stable.	Perform CO ₂ calibration.
High CO ₂ value	The measuring sensitivity is not stable.	Perform CO ₂ calibration.
The standby lamp on the CO ₂ unit does not light.	The power cord is not connected to the CO ₂ unit or AC outlet properly.	Connect the power cord properly. Refer to the AG-400RK CO ₂ Unit manual.

2. TROUBLESHOOTING

Trouble	Possible Cause/Criteria	Action
The MEASURE lamp on the CO ₂ unit does not light when the MEASURE switch is pressed to on.	The power cord is not connected to the CO ₂ unit or AC outlet properly.	Connect the power cord properly. Refer to the AG-400RK CO ₂ Unit manual.
	The interface cable is not connected properly.	Connect the connection cable to the CO ₂ unit and bedside monitor properly. Refer to the AG-400RK CO ₂ Unit manual.
	The bedside monitor to which the CO ₂ unit is connected is not turned on.	Turn on the bedside monitor power.

When Using Microcap® Monitor

Trouble	Possible Cause/Criteria	Action
The measured value for the Microcap® monitor is not displayed.	The Microcap® monitor is not connected to the bedside monitor.	Connect the Microcap® monitor to the bedside monitor with the QF-921P interface. Refer to the QF-921P interface manual.
	The interface is connected to a wrong socket on the Microcap® monitor.	Connect the interface to the correct socket. Refer to the QF-921P interface manual.
	The communication settings do not match.	Set the correct communication setting. Refer to the QF-921P interface manual.

SpO₂

Trouble	Possible Cause/Criteria	Action
Unstable SpO ₂ value.	The probe size is inappropriate.	Use the correct size probe.
	The probe is attached to the same limb that is used for NIBP or IBP measurement.	Attach the probe to the other limb.
	An ESU is used.	Locate the ESU as far as possible from the probe and wait until the pulse wave stabilizes.
	Measuring on the venous pulse.	Cannot measure correctly.
SpO ₂ value on the monitor and CO oximeter do not match.	The probe is not attached properly.	Attach the probe correctly. (The emitter and detector of the probe must face each other.)
	The attachment site is inappropriate.	Attach the probe to a site 6 to 14 mm thick.
	The measuring site is not clean.	If necessary, remove nail polish and clean the measuring site.
	Too much abnormal hemoglobin (HbCO, MetHB, etc.).	Cannot measure correctly.
	Dye (methylene blue or indocyanine green) is injected in the blood.	Cannot measure correctly.
	Measuring during CPR.	Cannot measure correctly.
Probe is damaged.	Probe is disinfected by an unspecified procedure.	Disinfect the probe using the specified method.
	The probe is repeatedly used.	Replace the probe with a new one when the expiration date passes.
Sine wave noise on the pulse wave	Light interference.	Cover the attachment site with a blanket.
	The line frequency setting on the monitor is not correct.	Set the correct line frequency on the monitor.
No SpO ₂ data on the screen (with Nellcor probe only).	The SpO ₂ connection cord other than JL-650P is used.	Only the JL-650P SpO ₂ connection cord can be used.
No SpO ₂ data on the screen (with Masimo probe only).	The SpO ₂ probe and/or connection cord other than specified is used.	Only use the specified SpO ₂ probe and connection cord.
	The probe is not connected to the connection cord correctly.	Connect the probe to the connection cord with the logo labels facing the same direction.

NIBP

2

Trouble	Possible Cause/Criteria	Action
Cuff inflation pressure is less than 10 mmHg or NIBP data display disappears for a few seconds.	The cuff hose is not connected to the cuff socket properly.	Connect the cuff hose to the socket properly.
	The cuff is not wrapped around the arm or is wrapped too loosely.	Wrap the cuff around the upper arm.
The cuff does not inflate when the [NIBP Start/Stop key] is pressed.	The cuff hose is not connected to the cuff socket.	Connect the cuff hose to the socket firmly.
	The cuff hose or air hose may be folded or squeezed when the cuff pressure display on the screen increases quickly but the actual cuff does not inflate.	Check the cuff hose and air hose.
Abnormal measurement results are displayed.	The cuff size is not correct.	Select the cuff which fits the patient's limb circumference.
	The cuff is not wrapped around the arm correctly.	Wrap the cuff around the upper arm, not too tightly or too loosely.
	NIBP data is not correct because of body movement.	Prevent the patient from moving during measurement.
	Measurement on the wrong site.	Measure NIBP at the correct site.
The cuff is suddenly deflated during inflation.	The [NIBP Start/Stop] key is pressed during inflation.	—
Auto measurement does not start even when the time interval has passed.	The time interval for the NIBP auto measurement is set incorrectly.	Set the correct time interval.
The cuff suddenly inflates.	The measurement mode is set to auto mode.	Check the time interval.
	NIBP measurement is triggered by PWTT.*	Set PWTT on the NIBP window to OFF when measuring NIBP with PWTT is not necessary.
Cannot connect cuff to the air hose.	Unspecified cuff is used.	Use a cuff specified by Nihon Kohden.
Cannot measure NIBP.	Noise which disables calculation of the blood pressure has interfered.	Remove the cause.
	The pulse wave is unstable due to arrhythmia.	Ask the patient not to move too much and perform invasive blood pressure measurement as required.
	The air hose is bent or squeezed.	Remove the cause.
	The cuff has worn out.	Use a new cuff.
Blood congestion occurs.	Measuring over a long period of time at intervals less than 2.5 minutes.	Increase the measuring interval.
		Do not measure NIBP over a long time.
Thrombus occurs.	Measuring a sickle anemia patient.	Do not perform NIBP measurement on a sickle anemia patient.
NIBP data on the screen is dark or “---” appears.	The preset time elapsed from the last measurement.	When NIBP is measured again, the data is displayed in normal brightness.

* AY-660P/AY-661P/AY-663P/AY-670P/AY-671P/AY-673P only

2. TROUBLESHOOTING

IBP

Trouble	Possible Cause/Criteria	Action
The acquired blood pressure value is different from the estimated value.	Air bubbles remain in the circuit.	Remove the air bubbles.
	An extra tube is connected in the circuit.	Remove the extra tube.
	The position of the blood pressure transducer is inappropriate.	Check the position of the blood pressure transducer.
	A blood pressure transducer with different sensitivities is used.	Check the blood pressure transducer.
	Other causes.	Perform zero balance adjustment again.
No invasive blood pressure value appears on the screen.	The measurement is out of range.	Check the measuring condition.
	The blood pressure transducer is damaged.	Replace the blood pressure transducer with a new one.
No waveform is output from the ECG/BP OUTPUT socket.	The IBP connection cord is not connected to the MULTI socket.	Connect the IBP connection cord to the MULTI socket.
	More than one IBP waveforms are acquired.	Only the IBP waveforms of the highest priority can be output from the ECG/BP output socket.

Temperature

Trouble	Possible Cause/Criteria	Action
The temperature value is not displayed on the screen.	The temperature probe or temperature connection cord is faulty.	Replace the temperature probe or temperature connection cord with a new one.
	Monitor malfunction.	Contact your Nihon Kohden representative.

BIS

Trouble	Possible Cause/Criteria	Action
Nothing appears on the BIS window.	BIS processor failure.	Replace the BIS processor with a spare if available and contact your Nihon Kohden representative.

Cardiac Output

Trouble	Possible Cause/Criteria	Action
Infarction occurs.	The balloon burst.	Remove the catheter from the patient, treat the infarction and insert the new catheter into the patient. Check that the balloon is not damaged before use.

GAS

Trouble	Possible Cause/Criteria	Action
Gas calibration cannot be performed.	1 hour has not elapsed after monitor power on.	Perform gas calibration 1 hour after turning the monitor power on.
	The gas concentrations of the gas cylinder used for calibration and the monitor screen do not match.	Set the gas concentration correctly on the GAS window.
	The reading on the GAS window is not stable 30 seconds after starting gas flow.	Wait for the reading to become stable.
The “Warming up” message does not disappear.	The sampling tube or exhaust gas adapter has bent.	Correct the bent portion and turn on a power supply again.
	The dryline or sampling line is kinked or blocked.	Replace with a new one.
	The multigas unit is not connected properly.	Connect the sampling gas exhaust outlet of the multigas unit to the scavenging system of the anesthetic machine properly.
The measured value is too low.	The sampling gas is leaking from a sampling tube, airway adapter or dryline.	Check that the dryline or sampling line is connected properly. Replace with a new one if necessary.
	The measurement sensitivity has shifted.	Perform gas calibration.
The measured value is too high.	The measurement sensitivity has shifted.	Perform gas calibration.

O₂

Trouble	Possible Cause/Criteria	Action
The measured value is abnormal.	The direction of the oxygen sensor changed considerably after calibration.	Face the oxygen sensor downwards and calibrate again.
	Peripheral equipment problem.	Check the state of the equipment connected to the patient.

Ventilation

Trouble	Possible Cause/Criteria	Action
The measured value for the ventilator is not displayed.	The ventilator is not connected to the bedside monitor.	Connect the ventilator to the bedside monitor with the interface or communication cable. Refer to the QF series interface or IF series communication cable manual.
	The interface or communication cable is connected to a wrong socket on the ventilator.	Connect the interface or communication cable to the correct socket. Refer to the QF series interface or IF series communication cable manual.
	The communication settings do not match.	Set the correct communication setting. Refer to the QF series interface or IF series communication cable manual.
	The value is out of display range.	Check the measured data on the ventilator screen.
	The software version of the ventilator, bedside monitor and communication cable do not match. (IF-923P only)	Contact your Nihon Kohden representative.

2. TROUBLESHOOTING

TOF

Trouble	Possible Cause/Criteria	Action
The TOF measured value is not displayed.	The TOF-watch® SX is not connected to the bedside monitor.	Connect the TOF-watch® SX to the bedside monitor with the QF-909P Interface. Refer to the QF-909P Interface manual.

CCO

When Using Vigilance Monitor

Trouble	Possible Cause/Criteria	Action
The measured value for the CCO monitor is not displayed.	The CCO monitor is not connected to the bedside monitor.	Connect the CCO monitor to the bedside monitor with the QF-903P Interface. Refer to the QF-903P Interface manual.
	The interface is connected to a wrong socket on the CCO monitor.	Connect the interface to the correct socket. Refer to the QF-903P Interface manual.
	The communication settings do not match.	Set the correct communication setting. Refer to the QF-903P Interface manual.

When Using PiCCO Monitor

Trouble	Possible Cause/Criteria	Action
The measured value for the PiCCO monitor is not displayed.	The PiCCO monitor is not connected to the bedside monitor.	Connect the PiCCO monitor to the bedside monitor with the QF-911P Interface. Refer to the QF-911P Interface manual.
	The interface is connected to a wrong socket on the PiCCO monitor.	Connect the interface to the correct socket. Refer to the QF-911P Interface manual.
	The communication settings do not match.	Set the correct communication setting. Refer to the QF-911P Interface manual.

CCO/SvO₂

Trouble	Possible Cause/Criteria	Action
The measured value for the SO ₂ /CCO monitor is not displayed.	The SO ₂ /CCO monitor is not connected to the bedside monitor.	Connect the SO ₂ /CCO monitor to the bedside monitor with the IF-922P communication cable. Refer to the IF-922P communication cable manual.
	The communication cable is connected to a wrong socket on the SO ₂ /CCO monitor.	Connect the interface to the correct socket. Refer to the IF-922P communication cable manual.
	The communication settings do not match.	Set the correct communication setting. Refer to the IF-922P communication cable manual.

Transmitter

Trouble	Possible Cause/Criteria	Action
“SIGNAL LOSS” message appears on the receiving monitor.	The sending monitor power is off.	Turn on the power of the sending monitor. When operating on battery, change to the fully charged battery.
	Telemetry reception failure.	Contact your Nihon Kohden representative.

12 Lead ECG

Trouble	Possible Cause/Criteria	Action
12 lead analysis result is not correct.	There was body movement when the waveforms for analysis were taken in.	Have the patient relax and perform analysis again.
	Electrodes were detached.	Attach the electrodes properly and perform analysis again.
	Patient's gender is not entered for the patient information.	Enter the patient's gender. When the patient's gender is not specified, the analysis is performed with the patient as male.
	Patient's date of birth is not entered for the patient information.	Enter the patient's date of birth. When the patient's date of birth is not entered, the analysis is performed with the patient as 35 years old.

Section 3 Diagnostic Check and Safety Check

Displaying the DIAGNOSTIC CHECK Screen.....	3.2
Displaying the MANUAL CHECK Screen	3.2
ALARM INDICATOR Check.....	3.4
Safety Check	3.5
Checking the Temperature	3.7

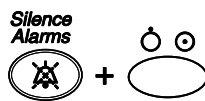
Displaying the DIAGNOSTIC CHECK Screen

Use this screen to view the error history or perform manual check or system setup and initialization.

CAUTION

This procedure interrupts all monitoring. Only change these settings before or after monitoring.

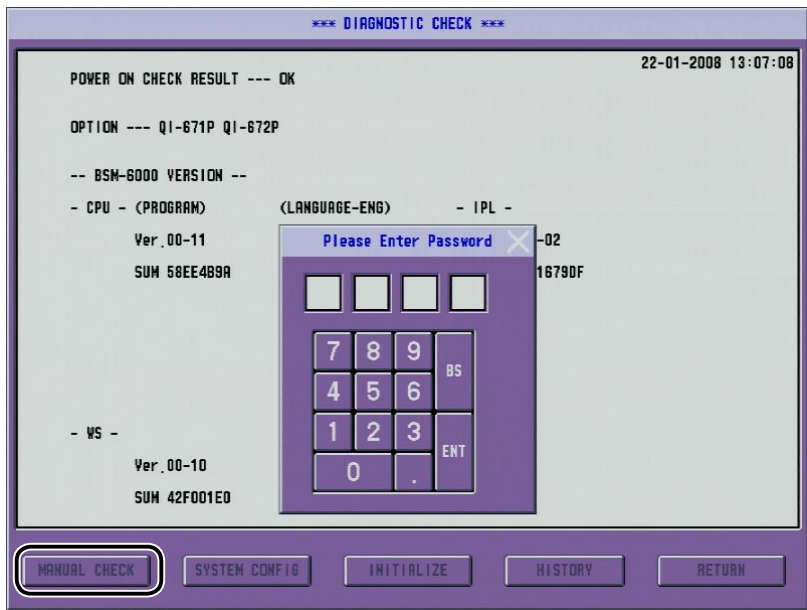
1. Turn the monitor power off.
2. Press the [Power] switch while pressing the [Silence Alarms] key on the front panel until the DIAGNOSTIC CHECK screen is displayed.



3. To exit the DIAGNOSTIC CHECK screen and return to the home screen, touch the RETURN key.

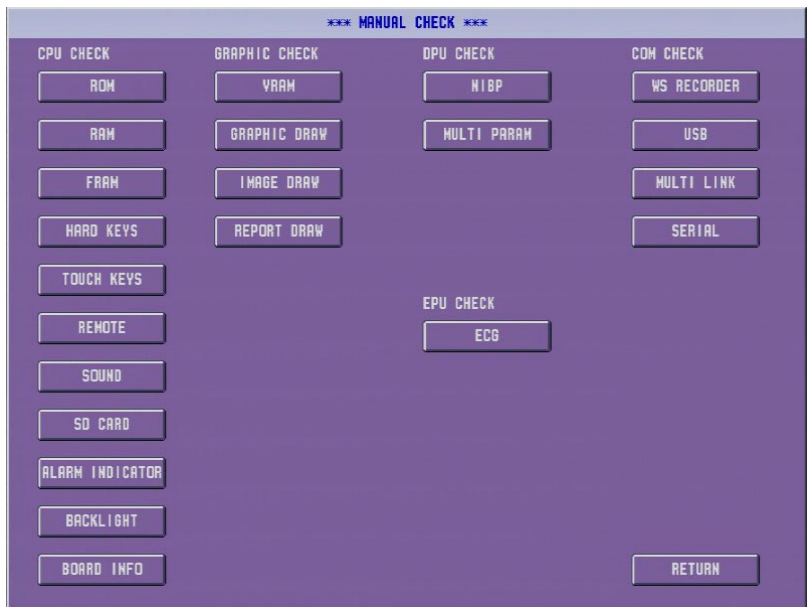
Displaying the MANUAL CHECK Screen

1. Touch the MANUAL CHECK key. The dialog box to enter the password appears.



2. Enter the password with the number keys and touch the ENT key. The MANUAL CHECK screen appears.

The default password is “1234”.



3. To exit the MANUAL CHECK screen and return to the DIAGNOSTIC CHECK screen, touch the RETURN key.

ALARM INDICATOR Check

This item checks the function of the alarm indicator located on the top of the monitor. Check the light of indicator lamp according to the screen indication.

If the color does not light, the connection cable is loose or disconnected or the MAIN board or indicator board is faulty. If the indicator lights partially, the indicator board is faulty.

1. Display the INDICATOR CHECK screen.

MANUAL CHECK key → Enter password → ALARM INDICATOR key

When the AUTO key is pressed, the lighting color is highlighted on the screen sequentially. When the key of each color is pressed, the lighting color is highlighted on the screen.



2. Touch the RETURN key to return to the MANUAL CHECK screen.

Safety Check

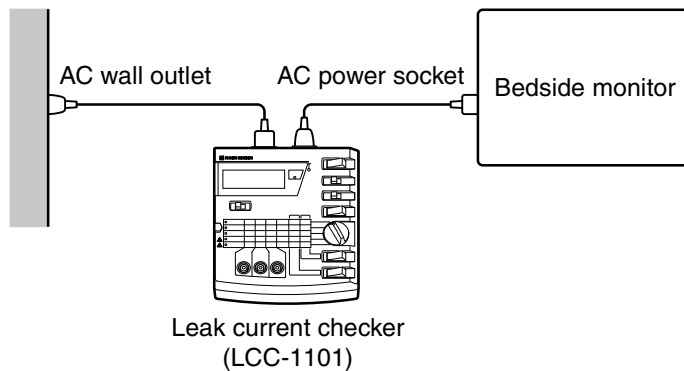
3

Safety check is performed while the components are connected. You need to measure four different currents (grounding leak current, exterior leak current, patient leak current and patient measurement current) in both the normal state and a single-failure state to make sure that the allowable value is not exceeded. You also need to record the measured values.

NOTE

Performing safety inspection requires a special instrument of measuring leak currents.

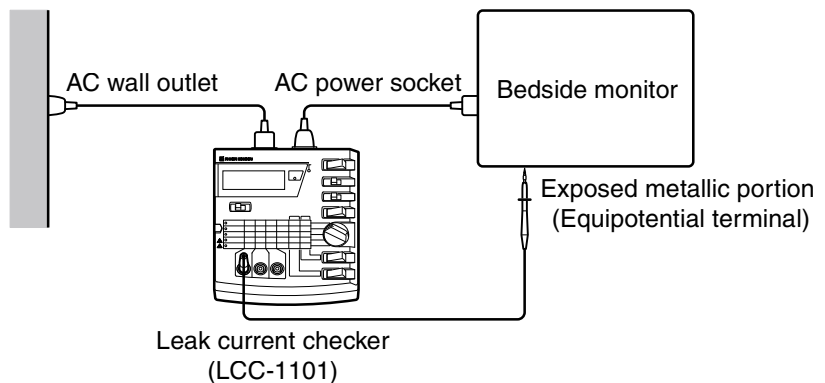
<Example of measuring grounding leak current>



- Make sure that the measured value is within the range below.

Normal state	500 μ A or less
Single-fault state	1 mA or less

<Example of measuring exterior leak current>

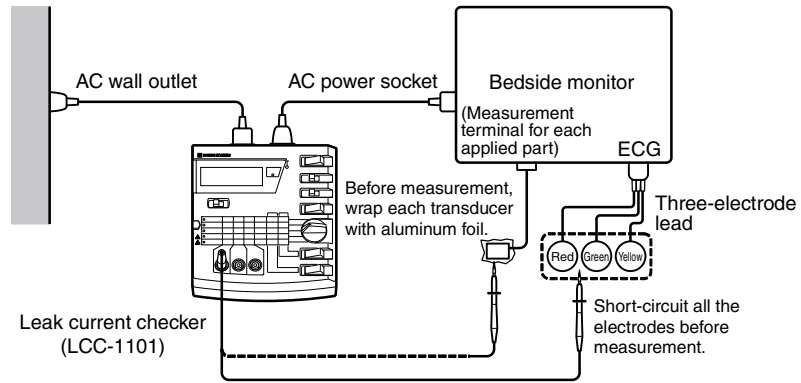


- Make sure that the measured value is within the range below.

Normal state	100 μ A or less
Single-fault state	500 μ A or less

3. DIAGNOSTIC CHECK AND SAFETY CHECK

<Example of measuring patient leak current I>



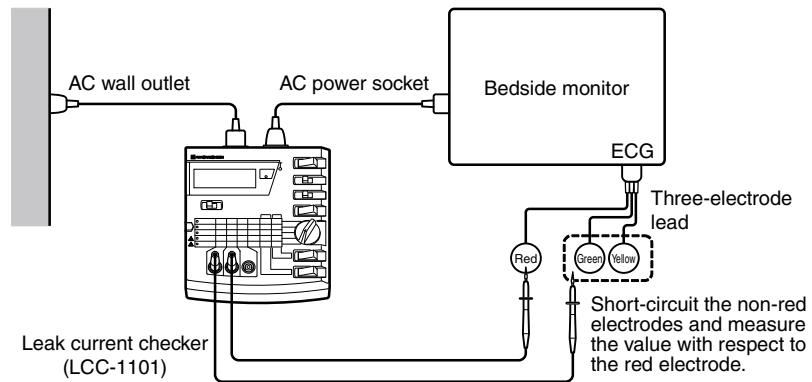
Measure the patient leak current flowing in the measurement system for each parameter. For the ECG, short-circuit all the electrode leads before measurement. For the other parameters, wrap the transducer with aluminum foil before measurement.

- Make sure that the measured value is within the range below.

Normal state	10 μA or less
Single-fault state	50 μA or less

* If you are using the LCC-1101 leak current checker as a leak current measuring instrument, first measure the current in the DC+AC mode to make sure that the above “DC” range is satisfied. If the allowable value is exceeded, you need to measure the current in the DC mode again; the result is considered successful if the above “DC” range is satisfied.

<Example of measuring patient measurement current>



For the ECG, measure the patient measurement current (AC). Short-circuit the non-red electrode leads for the ECG and measure the value with respect to the red one.

- Make sure that the measured value is within the range below

Normal state	10 μA or less
Single-fault state	50 μA or less

Checking the Temperature

Connect the AX-400G vital sign simulator to the bedside monitor and check the accuracy of the temperature. This check should cover both the MULTI and TEMP sockets. After the check, return the setting to your setting used at your facility.

<Required cable>

For the TEMP socket:

Compatible with the HR10 connector AX-800P Connection Cable

For the MP socket:

BSS cable for the AX-400G

Check the accuracy of temperature

Set the temperature output from the AX-400G vital sign simulator and make sure that the temperature shown on the instrument is within the accuracy range shown in the table below.

AX-400G settings	Indication on the instrument
25°C	24.8 to 25.2°C
37°C	36.8 to 37.2°C
44°C	43.8 to 44.2°C

Checking the Connector-Off Detection

Make sure that the connector-off is detected. During the input of the temperature signal on the AX-400G vital sign simulator, disconnect the temperature connection cord from the MULTI socket and make sure that you see a “CONNECTOR OFF” message on the monitor screen.

Checking the Sensor-Off Detection

Make sure that the sensor-off is detected. During the input of the temperature signal on the AX-400G vital sign simulator, remove the temperature cable plug from the TEMP socket and make sure that you see a “CHECK SENSOR” message on the monitor screen.