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Glossary of terms used in medical electrical equipment (general terms)

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

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Glossary of terms used in medical electrical equipment (general terms)

1 Scope This Japanese Industrial Standard specifies general terms relating to medical electrical equipment (hereafter referred to as “terms”) and their meaning.

2 Classification Terms are classified into the following areas:

- (1) Safety
- (2) Biomedical information
- (3) Performance
- (4) Configuration, construction and component
- (5) Information processing and combined technique
- (6) Marking, record, unit and document
- (7) Test
- (8) Use, inspection, maintenance, storage and facility

3 Number, term, and definition As for the number, term and definition, the following remarks shall be referred to.

English equivalent is shown for information.

Remarks 1 The number is expressed by a first letter in English and six numerals with a hyphen “-” being placed between them.

The first letter A denotes a general term and the following three numerals denote the classification numbers (100 to 800).

The last three numerals are serial numbers in the same classification.

- 2 In such a case that a part of a term is enclosed by parentheses “()”, it means that the said part may be omitted. In this procedure, there is no precedence given between the case where the inside of parentheses is omitted and the other case where it is not omitted.
- 3 In the case where two or more terms with different description but with the same meaning are often used, such fact is expressed by using brackets “[]”.
- 4 Omitted, because this item relates to the Japanese expression only.
- 5 Simplified expression, grammatical use, etc. are shown in parentheses “()” following to the term.
Example 1 “PAE (head characters)” (see A 300-009)
Example 2 “C (simplified)” (see A 300-010)
- 6 When a term is used in multiple classifications, the term is shown in the classification considered most appropriate.

- 7 When a term has several different meanings, each of the meanings is specified and prefixed by (1), (2), ... In this case there is no precedence among them.
- 8 If the description of a meaning is conceptional and not easily understood, a practical example shall be shown as Example:
- 9 As for the reading of terms, only the readings of terms which are not easily read are shown in braces “[]”.

Information : The parentheses “()” and brackets “[]” used in English equivalent express the same notes as those in Remarks 2, 3 and 5.

Normative reference and related standards: see page 34.

(1) Safety

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-001	安全	ANZEN	Protection against a hazard and/or a safety hazard.	safety
A 100-002	危険	KIKEN	The influence which may detrimentally affect the patient, operator, third person, or the environment thereof, resulting from electricity, machine, radiation, heat, etc.	hazard
A 100-003	危害	KIGAI	The influence which may detrimentally affect the patient, operator, third person, or the environment thereof, directly caused by the equipment due to failure of components, ingress of dust or liquid into the equipment, ignition of flammable atmosphere, erroneous operation, etc.	safety hazard
A 100-004	侵襲(的)	SINSYŪ (TEKI)	To cause a safety hazard such as some pain or external injury to a living body.	invasive
A 100-005	無侵襲(的)	MUSINSYŪ (TEKI)	Not to cause a safety hazard such as pain or external injury to a living body.	non-invasive
A 100-006	観血(的)	KANKETU (TEKI)	Such a phenomenon that bleeding appears when medical electrical equipment or apparatus are used.	direct
A 100-007	非観血(的)	HIKANKETU (TEKI)	Such a phenomenon that bleeding does not appear when medical electrical equipment or apparatus are used.	indirect
A 100-008	電気(的)安全	DENKI (TEKI) ANZEN	Protection against hazard and safety hazard directly resulting from voltage or current.	protection against electrical hazard
A 100-009	機械(的)安全	KIKAI (TEKI) ANZEN	Protection against hazard and safety hazard resulting from mechanical movement, falling substances, scattering, etc.	protection against mechanical hazard
A 100-010	放射線防護	HÔSYASEN BÔGO	Protection against obstruction and damage of material resulting from ionizing radiation.	radiological protection

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-011	AP類機器	AP-RUI KIKI	Medical electrical equipment which is so protected that it will not become an ignition source with the ambient atmosphere and any combustible anaesthetic mixture. Remarks: AP means "anaesthetic-proof".	category AP equipment
A 100-012	APG類機器	APG-RUI KIKI	Medical electrical equipment which is so protected that it will not become an ignition source with atmosphere consisting of oxygen or nitrous oxide (laughing gas) and combustible anaesthetic mixture. Remarks: G means that the function of category AP equipment is "greatly" reinforced.	category APG equipment
A 100-013	保護インピーダンス	HOGO INPĪDANSU	An impedance which is allowed to be connected between the live part or the part which may become live at single fault condition and the accessible metal part or applied part. Remarks: It is necessary that this impedance provides such high impedance, construction and reliability that they will not cause electric shock.	protective impedance
A 100-014	保護カバー	HOGO KABĀ	The enclosure or guard of the part which will cause hazard by contact, that is provided for the purpose of preventing accidental contact with live part, high temperature part, etc. or scattering and the like.	protective cover
A 100-015	電撃	DENGEKI	Such a shock that a current gives to a human body.	electric shock
A 100-016	(最小)感知電流	(SAISYŌ) KANTI DENRYŪ	The minimum current at which electric shock is sensed when a current is passed through a human body from its surface.	(minimum) sensation current
A 100-017	離脱電流	RIDATU DENRYŪ	The maximum current at which separation action is possible against stiff muscle when a current is passed through a human body from its surface.	let-go current

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-018	ミクロショック	MIKURO-SYOKKU	The electric shock caused by a current which directly passes through the heart.	micro-shock
A 100-019	マクロショック	MAKURO-SYOKKU	The electric shock given to a human body by a current which enters from a part of the human body, i.e. mainly its surface and leaves from another part.	macro-shock
A 100-020	過熱保護	KANETU HOGO	Protection against hazard due to overheating.	overheating protection
A 100-021	装着部	SÔTYAKUBU	The part of mechanical or electrical equipment which is intentionally contacted with or inserted into a patient for medical examination and treatment. Remarks: The patient cord and all the conductive parts connected thereto are included.	applied part
A 100-022	F形絶縁装着部	F-GATA ZETUEN SÔTYAKUBU	The part which is isolated from all the parts of a medical electrical equipment so that the current which flows between the applied part and the earth, when a voltage equals to 1.1 times the maximum rated supply voltage is applied, will not exceed the limit value of permissible patient leakage current under single fault conditions. Remarks: F means floating.	F-type isolated applied part (floating applied part)
A 100-023	生き	IKI	Such a state that a current which may cause electric shock can flow when a man comes in contact with the part.	live
A 100-024	導電接続	DÔDEN SETUZOKU	A connection through which a current exceeding permissible leakage current flows.	conductive connection
A 100-025	クラスI機器	KURASU-I KIKI	Medical electrical equipment which provides a means for connection with medical earth terminals of the installation to avoid the accessible metal parts becoming live when a failure occurs on the basic insulation, where the protection against electric shock does not only rely upon the basic insulation.	class I equipment

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-026	クラスII機器	KURASU-II KIKI	Medical electrical equipment which provides double insulation or reinforced insulation in which the protection against electric shock which is not protectively earthed does not only rely upon the basic insulation.	class II equipment
A 100-027	B形機器	B-GATA KIKI	Medical electrical equipment which provides the protection against electric shock by means of the limit of permissible leakage current and protective earth connection.	type B equipment
A 100-028	BF形機器	BF-GATA KIKI	Type B equipment having F-type isolated applied part.	type BF equipment
A 100-029	CF形機器	CF-GATA KIKI	Medical electrical equipment which has F-type isolated applied part and which especially provides the protection relating to leakage current of a higher degree than that of type B equipment.	type CF equipment
A 100-030	漏れ電流	MOREDENRYŪ	A current which flows along the surface or through the inside of the insulating material and has no relation with the function of the equipment.	leakage current
A 100-031	接地漏れ電流	SETTI-MORE DENRYŪ	A current which flows from the power supply along the surface or through the inside of the insulating material to the protective earth conductor.	earth leakage current
A 100-032	外装漏れ電流	GAISŌ-MORE DENRYŪ	The leakage current which flows from the body of the equipment or the part accessible by the patient or operator during normal service, excluding the applied part, to the earth or the other part of the body of equipment, through a conductor other than the protective earth conductor.	enclosure leakage current

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-033	患者漏れ電流	KANZYA-MORE DENRYŪ	The leakage current, excluding patient functional current, which flows from the applied part to the earth through the patient, or from the patient to the earth through F-type isolated applied part resulting from occurrence of unintentional voltage on the patient caused by external power supply.	patient leakage current
A 100-034	安全特別低電圧	ANZEN TOKUBETU TEIDEN'ATU	A voltage not exceeding 25 V a.c. or 60 V d.c. which is isolated from commercial power supply and not earthed, and available from a transformer or converter operating at the rated supply voltage.	safety extra-low voltage
A 100-035	高電圧	KÔDEN'ATU	A voltage exceeding 1 000 V a.c., 1 500 V d.c. or a voltage with a peak value exceeding 1 500 V.	high voltage
A 100-036	過電流開放器	KADENRYŪ KAIHÔKI	A protective device which operates to open the circuit instantaneously or with a time lag when the load current exceeds the set value.	over-current release
A 100-037	正常状態	SEIZYÔ ZYÔTAI	Such a condition that all the means providing protection against hazards are perfect and satisfy the specified performances.	normal condition
A 100-038	単一故障状態	TAN'ITU KOSYÔ ZYÔTAI	Such a condition that one of the means provided by the medical electrical equipment is faulty or one abnormality exists outside of the equipment.	single fault condition
A 100-039	機械の安全率	KIKATEKI ANZENRITU	The ratio of safe working load to minimum breaking load.	mechanical safety factor
A 100-040	最小破断荷重	SAISYÔ HADAN KAZYŪ	The maximum load in the range when Hooke's rule is applicable.	minimum breaking load
A 100-041	安全動作荷重	ANZEN DÔSA KAZYŪ	The maximum load permitted for equipment under such condition that the equipment is used in accordance with its instruction manual.	safe working load

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 100-042	消毒	SYÔDOKU	Eliminating or annihilating pathogenic microbes which have adhered to substance or organisms, or which are contained inside of them, so the microbes lose their pathogenicity.	disinfection
A 100-043	殺菌(作用)	SAKKIN (SAYÔ)	Annihilating a microbe with pathogenicity.	germicial (action)
A 100-044	滅菌	MEKKIN	Eliminating or annihilating completely all the pathogenic microbes and non-pathogenicity microbes which have adhered to substance, or which are contained inside of them, and making them asepsis.	sterilization
A 100-045	保護接地	HOGO SETTI	The earthing for leading the leakage current to the earth for the purpose of protection against electric shock.	protective earth
A 100-046	追加保護接地	TUIKA HOGO SETTI	A protective earth which is provided in addition to normal protective earth, for protection against hazard due to electric shock at the failure of normal protective earth.	additional protective earth
A 100-047	患者測定電流	KANZYA SOKUTEI DENRYÛ	A current passed between the applied parts through the patient such as the bias current of amplifier, the current for measurement of skin resistance, etc. not intended to give physiological effect.	patient auxiliary current
A 100-048	機械的安全装置	KIKAITTEKI ANZEN SÔTI	A device which protects the patient or operator from dangerous force due to movement exceeding a limit or a falling substance at the failure of hanging mechanism, etc.	mechanical safety device

(2) Biomedical information

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 200-001	心(拍)周期	SIN (HAKU) SYŪKI	The total process or the necessary time of a heart-beat.	cardiac cycle
A 200-002	心拍出量	SINHAKU SYUTURYŌ	Defined as the quantity of blood which the heart ejects.	cardiac output
A 200-003	心駆出率	SINKU SYUTURITU	The ratio between SV (stroke volume) and EDV (end-diastolic volume).	cardiac ejection fraction
A 200-004	心内圧	SINNAIATU	The pressure inside the atrial and heart ventricle.	intracardiac pressure
A 200-005	血圧	KETUATU	The pressure of the blood in the vessels.	blood pressure
A 200-006	不整脈	HUSEIMYAKU	The variation in the rhythm of the heartbeat.	arrhythmia
A 200-007	期外収縮	KIGAI SYŪSYUKU	The unexpected myocardial contraction in an ordinal cardiac cycle.	extrasystole
A 200-008	房室ブロック	BŌSITU BUROKKU	The blockade of passing impulses from the atria to the ventricles.	atrioventricular block [A-V block]
A 200-009	脚ブロック	KYAKU BUROKKU	The blockade of passing impulses in the left and/or right atrioventricular bundle, which is a part of the system of atrioventricular conduction.	bundle branch block [B-B block]
A 200-010	受攻期	ZYUKŌKI	This period means the position of T-wave and its neighborhoods in ERG. In this period VF is usually precipitated by a single early ventricular complex beat which is beyond the threshold.	vulnerable period
A 200-011	心房細動	SINBŌ SAIDŌ	The irregular and uncoordinated fluttering of the multicentric atria of the heart. In this case the heart rate must be beyond 300 beats per minute.	atrial fibrillation
A 200-012	心室細動	SINSITU SAIDŌ	The irregular and uncoordinated fluttering of the multicentric ventricular of the heart. In this case the heart rate must be beyond 300 beats per minute.	ventricular fibrillation

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 200-013	生体電気(現象)	SEITAI DENKI (GENSYÔ)	The electricity (or electric phenomenon) caused by the excitation of cell membranes and so on.	bioelectricity (bioelectric phenomenon)
A 200-014	心電図	SINDENZU	The chart which records the action potential impulses in the heart muscle, sometimes these impulses are led from some points of the body surface.	electrocardiogram (ECG)
A 200-015	P波	P-HA	A sort of wave form in the ERG, which is produced by atrial depolarization.	P wave
A 200-016	R波	R-HA	A sort of the wave forms in the ERG, which follows after Q wave. This is ordinarily the biggest wave in the QRS complex.	R wave
A 200-017	QRS波	QRS-HA	A sort of the wave forms in the ERG, which is produced by ventricular depolarization. Ordinarily it consists of the Q, R, and S waves.	QRS wave (QRS complex)
A 200-018	T波	T-HA	A sort of the wave forms in the ERG, which is produced by ventricular repolarization.	T wave
A 200-019	心雑音	SINZATUON	The sound of the heart (heard through a stethoscope) like noise. Usually this is heard at patients with heart valve problems.	heart murmur
A 200-020	心音	SIN'ON	The sound of the heart (heard through a stethoscope), which is made by the process of heart muscles' contraction.	cardiac sound (heart sound)
A 200-021	心音図	SIN'ONZU	The recording chart of the sounds made by the heart.	phonocardiogram (PCG)
A 200-022	心音図(第I音)	SIN'ONZU (DAI) I-ON	This heart sound is heard at the early systolic phase, and produced by the vibrations with the closure of the atrioventricular valves and the vibrations of the pulsatile blood flow nearby the aortic valve.	(PCG) first sound

Number	Term (Japanese character)	Reading	Definition	English equivalent (informative)
A 200-023	心音図(第)II音	SIN'ONZU (DAI) II-ON	This heart sound is heard at the end-systolic phase, and produced by the vibrations with the blood flow which is made by the closure of the semilunar valve and the vibrations of the cusps.	(PCG) second sound
A 200-024	循環時間	ZYUNKAN ZIKAN	The time necessary for the blood to flow from one point to another in a circulation system.	circulation time
A 200-025	脈波	MYAKUHA	Transmitted peripherally with the heart beat through the vessels and the blood.	pulse wave
A 200-026	抵抗血管	TEIKÔ KEKKAN	This word means the vessels like the arteriola, where the blood flow meets resistance.	resistance vessel
A 200-027	末しょう(梢)抵抗	MASSYÔ TEIKÔ	The resistance made by the peripheral vessels.	peripheral resistance
A 200-028	膜電位	MAKU DEN'I	The electric potential difference between the extra-cellular fluid and intracellular fluid.	membrane potential
A 200-029	活動電位	KATUDÔ DEN'I	The electrical potential change caused by the transient depolarization in the cell membrane.	action potential
A 200-030	局所反応	KYOKUSYO HANNÔ	The biological reactions to some stimulation. The reactions are restricted within just around the stimulated point.	local response
A 200-031	脳波	NÔHA	The chart on which is recorded the action potentials in the brain, or is the potentials themselves.	electroencephalogram (EEG)
A 200-032	α 波	α -HA	A sort of band of the electroencephalogram. The frequency of it is 8 Hz to 13 Hz.	α wave
A 200-033	β 波	β -HA	A sort of band of the electroencephalogram. The frequency of it is beyond 13 Hz.	β wave
A 200-034	δ 波	δ -HA	A sort of band of the electroencephalogram. The frequency of it is below 4 Hz.	δ wave