NKK SWITCHES

NKK Switches for Medical Electrical Equipment

Technical Reference

Vol. 2.0

IEC 60601-1, Edition 3.1 (JIS T 0601-1:2017) compliant

NKK SWITCHES CO., LTD.

NKK SWITCHES

For Medical Electrical Equipment

NKK switches for the medical market

High quality requirements proven under harsh operating conditions.

Improvements in medical technology and progress in the development of medical equipment have lead to advanced medicines and treatments based on early detection to preventative healthcare.
NKK's medical product offering complies with stringent electrical and biocompatibility safety standards to ensure reliable, consistent on-off control.

High quality means high reliability. It constitutes the margin of performance exceeding proven durability and specifications. Each NKK product is the result of advanced, precise technology and expertise cultivated over sixty years as a leading manufacturer of electromechanical devices designed specifically for industrial equipment.

NKK products have continued to evolve alongside developments in medical equipment, supplying reliable products and proven solutions to the medical market.

Mandatory standards for medical electrical equipment IEC 60601-1 (JIS T 0601-1)

Approval and certification for the sale of medical electrical equipment requires compliance with IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), an international standard. This standard stipulates a wide range of requirements to ensure the safety of patients, operators, and others in the vicinity in using medical equipment. These standards also include a large number of stipulations related to switches.

This means that switches play an important role in providing safe medical electrical equipment to the market.

IEC 60601-1 applies to key components including switches.

Key components, including switches, whose failure can generate hazardous situations must comply with applicable safety standards. “4.8 Components of ME Equipment” stipulates the following:

4.8 * Components of ME EQUIPMENT

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings (…).

(…) They shall comply with one of the following:

a) the applicable safety requirements of a relevant IEC or ISO standard;

b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.

Switches incorporated into ME equipment must comply with the corresponding safety standards that apply to switches.

Many of NKK products are certified as complying with applicable international standards by testing and certification organizations (such as UL, CSA, and VDE) to ensure the safe use of switches and indicators.

Power supply switches

A large number of stipulations regarding power supply switches (AC isolation, primary power supply) are found in “8.11 Mains Parts, components and, layout” of “8 Protection against electrical hazards from ME equipment” in Issue 3.1 of IEC 60601-1 (JIS T 0601-1:2017).

8.11.1 Isolation from the SUPPLY MAINS

a) * ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously.

PERMANENTLY INSTALLED ME EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 c).

b) Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.9.3.1).

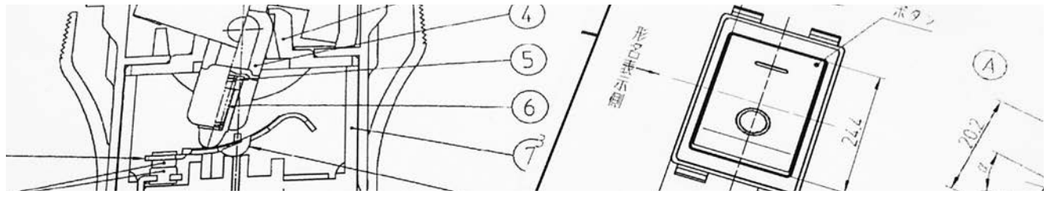
Power supply switches designed to achieve isolation from a power supply circuit must be configured with a dual-isolating circuit using DPST (Double Pole Single Throw) switches that enable both poles to be opened simultaneously. In the case of polyphase power supply mains for permanently installed ME equipment, the neutral conductor must be also isolated simultaneously if the voltage on it exceeds the limits specified in 8.4.2 c.

The requirements for power supply switches are described in Annex A, as shown below:

Annex A 8.11.1 a)

Skilled persons, such as SERVICE PERSONNEL, who need to gain access to internal, possibly hazardous, ME EQUIPMENT parts, need a means by which the ME EQUIPMENT can be isolated from the SUPPLY MAINS.

A mains isolating switch, where provided, could also serve as a functional off switch for routine use or for disabling hazardous output in an emergency.



ME equipment receiving power from a SUPPLY MAINS must have means to isolate its circuits electrically from the SUPPLY MAINS by a switch.

8.11.1 Isolation from the SUPPLY MAINS

c) * A SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV.
NOTE: Table 22 in IEC 61058-1:2000 specifies different values for contact separation depending on the MAINS TRANSIENT VOLTAGE, which is referred to in that table as the “rated impulse withstand voltage.”

IEC 61058-1:2000

Table 22 - Minimum clearances for basic insulation

Rate impulse withstand voltage [2] kV	Minimum clearances in air in millimetres up to 2 000 m above sea-level [1) 7) 3)]		
	Pollution degree 1	Pollution degree 2	Pollution degree 3
0.33	0.01	0.2 [4) 5)]	0.8 [5)]
0.50	0.04	0.2 [4) 5)]	0.8 [5)]
0.80	0.10	0.2 [4) 5)]	0.8 [5)]
1.5	0.5	0.5	0.8 [5)]
2.5	1.5	1.5	1.5
4.0	3	3	3
6 [6)]	5.5	5.5	5.5

NOTE: The values given in table 22 are equal to IEC 60664-1 and are not increased because only minimal reduction of clearances, for example, due to mechanical abrasion during the lifetime of the switch, is expected and because of the generally smaller overall dimensions of switches for appliances.
NOTE [a)]: Clearances for altitudes above 2,000 m sea-level shall be multiplied by altitude correction factor specified in annex N.

IEC 60601-1 stipulates minimum clearances for A SUPPLY MAINS switch contacts. A SUPPLY MAINS switch mounted in ME equipment must satisfy minimum clearances requirements related to rated impulse withstand voltages (power supply transient voltages) stipulated in this standard, citing standard IEC 61058-1:2000. As shown in Table 22 above, the minimum clearance in air specified is 3 mm for an impulse withstand voltage of 4 kV (to an altitude of up to 2,000 m with pollution degree of 1 to 3). For example, at an altitude of 3,000 m, multiplied by the altitude correction factor of 1.14 in annex N, indicating that an air clearance of 3.4 mm is required.

This requirement constitutes a key point examined in testing as part of the approval and certification of ME equipment. It is checked via the acquisition of international standards such as VDE (certificate submission) or the submission of a private document indicating contact minimum clearance. (Components may be disassembled for measurements in the absence of a certificate of conformance.)

8.11.1 Isolation from the SUPPLY MAINS

e) The actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.

In “5 Actions and effects" of IEC 60447 (JIS C 0447) “Basic and safety principles for man-machine interface, marking and identification - Actuating principles” specifies the operating directions and corresponding effects.

Power supply switches must be oriented when mounted so that the directions of operation shall be “left = off / right = on” and “down = off / up = on” in the normal installation configuration, as “Power off = reduced effect / Power on = increased effect.”

And while IEC60601-1 (JIS T0601-1) does not stipulate the directions of operation of switches other than power supply switches, medical practice requires maintaining consistency with the operational directions used for power supply switches to standardize the human-machine interface and improve usability.

Markings

The requirements related to markings on switches and indicators in ME equipment are set forth in “7 ME equipment identification, marking and documents.”

7.4 Marking of controls and instruments (see also Table C.3)

7.4.1 * Power switches

Switches used to control power to ME EQUIPMENT or its parts, including mains switches, shall have their “on” and “off” positions:

- marked with symbols IEC 60417-5007 (DB:2002-10) and IEC 60417-5008 (DB:2002-10) (see Table D.1, symbols 12 and 13); or
- indicated by an adjacent indicator light; or
- indicated by other unambiguous means.

Table D.1, symbol 12
(IEC 60417-5007)

Table D.1, symbol 13
(IEC 60417-5008)

Power supply switches must use the graphic symbols “|” and “O” or indicators to clearly indicate the power on/off status.

IEC 60417-5007/5008 (example JW Series)

If a push button with bistable positions is used:

- it shall be marked with symbol IEC 60417-5010 (DB:2002-10) (see Table D.1, symbol 14); and
- the status shall be indicated by an adjacent indicator light; or
- the status shall be indicated by other unambiguous means.

Table D.1, symbol 14
(IEC 60417-5010)

For concerns pushbutton switches (illuminated and non-illuminated type). Bistable position refers to a locking mechanism in which the switch has stable on and off positions.

If a push button with momentary on position is used:

- it shall be marked with symbol IEC 60417-5011 (DB:2002-10) (see Table D.1, symbol 15); or
- the status shall be indicated by an adjacent indicator light; or
- the status shall be indicated by other unambiguous means.

Table D.1, symbol 15
(IEC 60417-5011)

These requirements are applied when the operator holds down the button of a momentary pushbutton switch to keep on status of the ME equipment only at that button position.

7.4.2 * Control devices

(…) A control device or switch that brings the ME EQUIPMENT into the “stand-by” condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).

Table D.1, symbol 29
(IEC 60417-5009)

Switches that set ME equipment to a standby state correspond to those that turn power on or off by activating a relay or semiconductor when a momentary pushbutton switch is pressed. In this case, the switch opens and closes a secondary circuit, not the primary circuit, but the switch marking must clearly distinguish it from a primary power switch; the switch may use symbol 29 in Table D.1 (IEC 60417-5009), commonly referred to as the standby symbol.

IEC 60417-5009 example
(LB series, YB2 series)

The colors for power supply switches and other switches and indicators are stipulated in “7.8 Indicator lights and controls.”

7.8.1 Colours of indicator lights

The colours of indicator lights and their meanings shall comply with Table 2.

(…)

Table 2 - Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning - immediate response by the OPERATOR is required
Yellow	Caution - prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

7.8.2 Colours of controls

The colour red shall be used only for a control by which a function is interrupted in case of emergency.

Illuminated power supply switches are generally illuminated in green when “on,” indicating “ready.” It is also necessary to select switches and indicators with color lights corresponding to the particular purpose, function, and status, such as alarm, warning, standby, and individual operations.

“15 Construction of ME equipment” also includes stipulations related to indicators.

15.4.4 * Indicators

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose.

If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light unless it is otherwise apparent to the OPERATOR from the normal operating position.

Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARDOUS SITUATION could exist unless it is otherwise apparent to the OPERATOR from the normal operating position.

NOTE: This does not apply to heated stylus-pens for recording purposes.

Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a HAZARDOUS SITUATION.

Colours of indicator lights are described in 7.8.1.

In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR.

If a power supply switch is located in a position where it is not visible from the normal operating position for ME equipment and turning on the switch enables operation of the ME equipment, an indicator must be provided at a position visible from the normal operating position to clearly signal that the equipment is “Ready.” Indicators must also be provided to indicate the ME equipment status in situations where individual operations of the ME equipment are not apparent to the operator.

In addition to switches, NKK offers a range of indicators designed to complement many of switch series.

Switch and indicator mounting methods

Stipulations related to the construction of ME equipment are found in “15 Construction of ME equipment.” Layout and mounting methods must be carefully considered regarding switches and indicators mounted on ME equipment.

15 Construction of ME EQUIPMENT

15.1 * Arrangements of controls and indicators of ME EQUIPMENT

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT in the USABILITY ENGINEERING PROCESS. See 12.2.

Compliance is checked by inspection of the RISK MANAGEMENT FILE as specified in IEC 60601-1-6.

It is essential that control equipment, switches and indicators are configured in easy-to-understand layouts to ensure the safe use of ME equipment. Layouts must fully take into account the operation method, ease of use, and the switch function (momentary, latchdown, alternate action) for switches such as pushbuttons, rockers, and membranes. They must also take into account the function of the switches (e.g., power, setting, operation) in relation to the ME equipment.

Mechanical strength

Stipulations on the mechanical strength of ME equipment are found in “15.3 Mechanical strength.” Risk management is required depending on the type of ME equipment and type of mechanical stress expected. It is also necessary to consider the durability of switches mounted externally on ME equipment or in locations where the switches are subject to the mechanical pressure transmitted from the equipment exterior.

15.3 Mechanical strength

15.3.1 General

ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in an unacceptable RISK loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

Compliance is checked by application of the tests in Table 28. The tests are not applied to handles, levers, knobs, the face of cathode ray tubes (see 9.5.2), or to transparent or translucent covers of indicating or measuring devices unless with the handle, lever, knob, or cover removed there is an unacceptable RISK of electric shock. (…)

Switches must be designed to incorporate the durability required to withstand the mechanical stress specified for each type of ME equipment. Switches must be designed and positioned to ensure that in the case of ME equipment failure, its failure mode is free of deviations from the air clearances and creepage distances stipulated in section 8.9 and free of deviations from the permissible electric current and voltage values acting on the operator and patient, as stipulated in section 8.4.

15.3.2 * Push test

ENCLOSURES of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptable RISK.

Compliance is checked by the following test.

External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE of ME EQUIPMENT having a mass of more than 18 kg.

After the test, any damage sustained that results in an unacceptable RISK, as determined by constitutes a failure. (…)

15.3.3 * Impact test

ENCLOSURES of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable RISK.

Compliance is checked by the following test.

Except for HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are HAND-HELD, ENCLOSURES and other external insulating parts, the deterioration of which could result in unacceptable RISK, are tested as indicated below.

A sample consisting of the complete ENCLOSURE, or a portion thereof representing the largest unreinforced area, is supported in its normal position. A solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, is permitted to fall freely from a 1.3 m height once onto each relevant part of the test sample.

To test vertical surfaces, the steel ball is suspended by a cord and allowed to swing like a pendulum in order to apply a horizontal impact, dropping though a vertical distance of 1.3 m once against each relevant part of the test sample.

The test is not applied to flat panel displays, to the platen glass of ME EQUIPMENT (for example film scanners), or to cathode ray tubes (see 9.5.2).

After the test, any damage sustained that results in an unacceptable RISK, as determined by inspection of the RISK MANAGEMENT FILE, constitutes a failure. (…)

15.3.4 * Drop test

15.3.4.1 HAND-HELD ME EQUIPMENT

HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts shall not result in an unacceptable RISK as a result of a free fall.

Compliance is checked by the following test.

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part is used (as specified in the ACCOMPANYING DOCUMENTS), or from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT ME EQUIPMENT part shall not result in an unacceptable RISK. (…)

15.3.5 * Rough handling test

MOBILE ME EQUIPMENT and ME EQUIPMENT parts that are MOBILE shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable RISK.

Compliance is checked by the following tests.

The sample is tested in transport position with any SAFE WORKING LOAD in place and in the most adverse condition permitted in NORMAL USE. During the test, suitable precautions shall be taken to prevent over-balance caused by the rough handling stress/shock.

a) Ascending step shock (…)

b) Descending step shock (…)

c) Door frame shock

The sample is moved three times in its normal direction of travel at a speed of 0.8 m/s ±0.1 m/s, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be higher than the ME EQUIPMENT contact point(s). The direction of movement is perpendicular to the face of the obstacle.

After each test, any damage sustained that results in an unacceptable RISK. (…)

For other than electrical contact parts, switches and indicators generally use molded resin components and feature complex construction designs due to the need to ensure insulating properties and ease of use. For this reason, many switches and indicators themselves do not possess sufficient durability against mechanical stresses.

If a switch or indicator fails due to mechanical stress, live contacts or terminals may be exposed in failure mode and the creepage distances and air clearances may fall below the figures stipulated in 8.9, or result even in contacting. Such consequences pose risk of injury to patients or operators due to proximity to or contact with live electrical parts as specified in section 8.4.

For switches and indicators mounted externally on ME equipment, the recommendation is to provide a concave segment of a surface and to mount the switch or indicator at the bottom of this concave-portion so that mechanical stresses are borne by the exterior casing of the ME equipment; alternatively, the design and construction should be capable of absorbing or averting mechanical stresses to eliminate the risk of failure due to mechanical stresses acting directly on the switch or indicator. (Mounting switches within such concave-portions also offers the secondary benefit of preventing malfunctions due to accidental contact with the switch.)

15.3.6 * Mould stress relief test

ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.

Compliance is checked by inspection of the construction and available data were appropriate or by the following test.

One sample consisting of the complete ME EQUIPMENT, or of the ENCLOSURE together with any supporting framework, is placed in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the ENCLOSURE during the test of 11.1.3, but not less than 70 °C, for a period of 7 h, then permitted to cool to room temperature.

NOTE: Relative humidity need not be maintained at a specific value during this conditioning.

For large ME EQUIPMENT where it is not practical to condition a complete ENCLOSURE, it is permitted to use a portion of the ENCLOSURE representative of the complete assembly with regard to thickness and shape, including any mechanical support members.

Any damage that results in an unacceptable RISK constitutes a failure.

As mentioned earlier, switches and indicators generally use molded resin components. The switches and indicators themselves must be designed to withstand molding stresses. While standard NKK's switches comply with thermal resistance testing at the condition of 24 hours at 70°C (operating) and 24 hours at 85°C (storage), some switches have lower thermal resistance. In such cases, thorough evaluation is suggested to avoid failure leading to unacceptable risks.

Careful evaluation is also suggested when mounting switches and indicators on molded resin casings. The consequences of molding stresses exerted by the case on the switches and indicators should be considered as well.

Protection against water or dust

Stipulations related to water resistance and dust resistance of ME equipment are found in “6 Classification of ME equipment and ME systems,” “7 ME equipment identification, marking and documents,” and “11 Protection against excessive temperatures and other hazards.”

6.3 * Protection against harmful ingress of water or particulate matter

ENCLOSURES shall be classified according to the degree of protection against harmful ingress of water and particulate matter as detailed in IEC 60529 (see 7.2.9 and 11.6.5).

11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

11.6.1 General

The construction of ME EQUIPMENT and ME SYSTEMS shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.

11.6.2 * Overflow in ME EQUIPMENT

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. (…)

11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE, including ME EQUIPMENT or ME SYSTEMS used in an environment where the PROCESS has determined that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed that spillage does not wet parts that are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. (…)

11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.9. (…)

If the ME equipment may be exposed to particles or liquids under normal circumstances, the equipment must incorporate protective features in accordance with the IP ratings stipulated in IEC 60529 (Degrees of protection provided by enclosures) against liquids in locations posing the risk of spilled liquids. Measures must be taken in particular to keep out liquids in settings that pose the risk of harmful electrical effects. Although switches are frequently mounted on the exterior (panels) of equipment, since they are generally designed with some clearances between component parts to prevent mutual interference when operating, they are also vulnerable to the ingress of particles and liquids. Thus, care is required so that they are not mounted in locations exposed to particles or liquids or that the switches selected incorporate the appropriate dust and water resistance.

NKK's dustproof and waterproof switches are designed to ensure smooth mechanical operation and to prevent the ingress of liquids and particles into the switch (to the electrical contacts). They are also designed to prevent the ingress of liquids and particles within the equipment through the mounted locations. Both dustproof and waterproof types are available in a wide range of “panel seal types” designed with a dust and water resistant mounting (panel face). Some switches are fully waterproof, with a completely water and dust resistant switch construction.

Products carry an IP rating to indicate compliance with the requirements stipulated in IEC 60529. This provides selection of the ideal product for a given IP rating for the ME equipment on which it is to be installed and for given operating conditions.

Chemical resistance and biocompatibility

Stipulations related to the biocompatibility and the effects of cleaning, disinfection, sterilization, and chemicals on ME equipment are found in “7 ME equipment identification, marking and documents” and “11 Protection against excessive temperatures and other hazards.”

7.9.2.12 Cleaning, disinfection and sterilization

For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during NORMAL USE, the instructions for use shall contain:

– details about cleaning and disinfection or sterilization methods that may be used; and
– list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.

See also 11.6.6 and 11.6.7.

This requirement does not apply to any material, component, ACCESSORY or ME EQUIPMENT that is marked as intended for a single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or ME EQUIPMENT is to be cleaned, disinfected or sterilized before use (see 7.2.1).

11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection PROCESSES specified in the instructions for use. See also 7.9.2.12.

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. (…)

11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12. (…)

11.6.8 * Compatibility with substances used with the ME EQUIPMENT

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. (…)

Switches are made of metal, resin (plastic), rubber components, or others. If switches are mounted on ME equipment (reusable ME equipment or ME equipment specified for cleaning and disinfection) likely to be cleaned or disinfected or if the switches are likely to be affected by such actions, resistance to the chemicals used (including regular ethyl alcohol, methyl alcohol, and isopropyl alcohol) must be verified for each switch component material.

The effects of medical agents used for treatment must also be verified.

The chemical resistance of materials to sterilization must also be verified, alongside the resistance of the switch construction to sterilization processes.

11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993 series of standards. (…)

If switches are designed to be operated or touched by patients, either directly or indirectly, the biocompatibility of the materials likely to be touched (switch outer casing and operating parts) must also be verified.

NKK provides information on component materials related to this verification where required. NKK also accepts inquiries regarding the customization of switches to comply with particular standards. (Please contact your nearest NKK sales representative to ascertain whether customization is possible for particular products.)

Customization of switches for medical equipment

NKK offers customization of switches to suit medical equipment applications. This includes matching to suit mounting methods, operating requirements, and ambient operating conditions, as well as compatibility with IEC and ISO standard requirements and European or North American standards.

Notes:
* Minimum purchase order quantities apply to products with customized specifications.
* Depending on specific customization requirements, the customer may be required to bear certain initial costs.
* For inquiries and orders concerning customized products, please contact your nearest NKK sales representative.
* When we consider customization specifications, we may need to request information related to the product on which the switch is to be mounted; uses and operating conditions; and applicable standards. In some cases, NKK will enter into confidentiality agreements.

● MB2521 waterproof specifications

Target equipment	Image diagnosis system
Switch use	Interlock
Customization	Waterproof specification based on MB2521

Customization of the MB series light-touch type pushbutton switch to waterproof specifications. This involves modifying the plunger shape and inserting waterproof O-rings inside the mechanism and panel mounting to prevent the ingress of water inside the switch and panel interior. Waterproofing performance is equivalent to IP67 (in the initial state).

This switch is to be mounted on a part to which the image diagnostic system probe is inserted and functions as an interlock. Since it is likely to be disinfected using alcohol and rinsing water, some of the liquid may remain on the probe. Therefore, the switch was made waterproof to prevent the ingress of water into the switch or the equipment. Since the rinsing water remaining on the probe might be strongly acidic or alkaline, options are also considered to improve chemical resistance by replacing the plunger and bushing materials with stainless steel.

● JPL26BA indicating compliance to some standards

Target equipment	Image diagnosis system
Switch use	Power supply (AC isolation device)
Customization	Addition of standard certification labeling and specified lot control labeling on product packaging

The JP series pushbutton switch is certified to comply with VDE (EN 61058-1), UL, and CSA; standard certification labeling is an optional item for the standard product.

This customization involved the addition of VDE certification labeling to indicate compliance with requirements (e.g., contact separation distance in accordance with IEC 61058-1) for power switches (AC isolation devices) stipulated in IEC 60601-1. It also involved adding c-UL-us certification labeling for UL and CSA standard certification to comply with export regulations to North America.

It also features customized specifications with the lot control labeling specified by the purchasing manufacturer on the product packaging for lot control of installed part procurement in accordance with ISO 13485.

Actual product specifications remain the same; this is an example of the flexible support provided to meet various standards for medical equipment.

* ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

Customers wishing to mount NKK products on ME equipment should contact their nearest NKK sales representative to obtain specifications and to confirm applicable details before ordering products for the sufficient rating and performance margins. Products should be mounted in accordance with the methods outlined in NKK specifications and meeting the requirements of IEC 60601-1 edition 3.1, as well as other standards applying to the specific medical equipment.
Safety measures to cope with possible deficiencies should be implemented in accordance with the requirements of IEC 60601-1 edition 3.1 and other individual standards.

Customization of NKK products is available to provide support for QMS (e.g., ISO 13485) in the manufacture of medical equipment and support for chemical resistance and biocompatibility, in addition to the requirements of international standards (e.g., IEC 60601-1 and other individual standards). Please contact your nearest NKK sales representative for more information.

The information provided in this document concerning laws, regulations, and standards, is correct as of April 1, 2017. While the greatest care has been taken to confirm the accuracy of the details presented here, the information contained within does not constitute a guarantee, and NKK rejects all liability. The customer is responsible for confirming the documentation of applicable laws, regulations, and standards and for ensuring compliance.
The details provided in this document are subject to change without notice to allow product improvements and for other reasons.

References:
International standard: IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and Amendment 1:2012

Supervised by:
Toshihiko Hagiwara, SiMeD

Edited by
NKK Switches Co., Ltd.

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NKK SWITCHES CO., LTD.

NKK Corporate Headquarters
Japan
NKK SWITCHES CO., LTD.
Tel: 81 44 813 8001 Fax: 81 44 813 8031
www.nkkswitches.co.jp E-mail: nkkswitches@nkkswitches.co.jp

Global Offices:
Europe
NKK SWITCHES CO., LTD.
European Liaison Office
Tel: 49 61 96 400 187 Fax: 49 69 2073 4927
www.nkkswitches.eu / www.nkkswitches.de
E-mail: contact@nkkswitches.eu

Americas
NKK SWITCHES OF AMERICA, INC.
Tel: 1 480 991 0942 Fax: 1 480 998 1435
www.nkkswitches.com E-mail: customerservice@nkkswitches.com

Asia
NKK SWITCHES HONG KONG CO., LTD.
Tel: 852 2366 6634 Fax: 852 2366 6803
www.nkkswitches.com.hk E-mail: info@nkkswitches.com.hk

China
NKK SWITCHES CHINA CO., LTD.
Tel: 86 21 6249 6574 Fax: 86 21 6248 3375
www.nkkswitches.com.cn E-mail: info@nkkswitches.com.cn

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