1. What is EN 60601-1-2?

The EN series of standards known as EN 60601 **defines safety requirements and ergonomic standards for medical equipment and medical systems**. These norms are divided into different partial or collateral standards:

- EN 60601-1 General Requirements
- EN 60601-1-1 System Standard (can only be used with EN 60601-1:1990, its content has now been included in Section 16 of EN 60601-1:2006)
- EN 60601-1-2 EMC Standard
- EN 60601-1-3 General Radiation Protection in Diagnostic X-Ray Equipment
- EN 60601-1-4 Software Standard (can only be used with EN 60601-1:1990, its content has now been included in Section 14 of EN 60601-1:2006)
- EN 60601-1-6 Usability
- EN 60601-1-8 Alarm Systems
- EN 60601-1-9 Reducing Effects on the Environment
- EN 60601-1-10 Physiologic Closed-Loop Controllers
- EN 60601-1-11 Medical Equipment in a Home Health Care Environment
- EN 60601-1-12 Medical Equipment for Use in an Emergency Medical Services Environment

EN 60601-1-2 (also known as IEC[2] 60601-1-2) is a collateral standard, as indicated above, and **applies to medical electrical/ electronic equipment.**

Its full title is:

"Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests."

2. Which products need to be certified according to this standard?

Any products, which are defined as a "medical product" or "medical system" according to Section 3 of the German Medical Products Act, need to be tested and certified according to EN 60601 or one of its partial standards. Manufacturers can also certify their products according to this standard or one of its partial standards on a voluntary basis, even if their items are not defined as a medical product.

3. What does EN 60601-1-2 involve?

Medical electrical products have to be absolutely safe. They are not allowed to break down or malfunction if any radiation interference comes from other electrical units like mobile phones or tablets. Conversely, medical products are not allowed to negatively affect the environment through electromagnetic emissions either (other medical products, the phone and radio networks, computers or the electricity supply).

In essence, EN 60601-1-2 defines the requirements for electromagnetic compatibility (EMC), which is why people often refer

to it as the EMC standard. The standard defines the term electromagnetic compatibility as the **"capacity of a medical device or a medical system to function satisfactorily in its electromagnetic environment without introducing any electromagnetic disturbance into this environment, which includes other equipment too."**

It specifically stipulates the following:
- The types of electromagnetic interference that medical products have to cope with without any problems
- How much electromagnetic radiation medical products may emit
- How the requirements in this respect may depend on the specific environment where the unit is used and the risk emanating from the product
- How it is necessary to measure, test and document these measurements; and how the manufacturer must mark the product and which information must be found in the operating instructions

4. Which version of EN 60601-1-2 is the latest one?

EN 60601-1-2 Edition 4 has been in force since 1 January 2019. It therefore replaces Edition 3, which had been mandatory since 2017. All medical electrical equipment has had to meet the new requirements for electromagnetic compatibility (EMC) since the beginning of this year.

5. Why is there a new Edition (4) of EN 60601-1-2?

The environments, where medical equipment is being used, are more complex now than ever before. Technologies are continuing to develop at a rapid pace and this makes it necessary to permanently adapt the requirements that are stipulated in standards.

One of the most important new features in EN 60601-1-2 Edition 4 is the stronger focus on "intended usage environments", for which risk management is necessary in each case, according to EN 4971 [3]. This describes the increases in requirements for professional health care, for health care at home and for "special" environments. The tougher EMC test specifications in Edition 4 are also designed to ensure resistance to interference in the relevant conditions.

6. What are the major differences between the previous Edition 3 and the current valid Edition 4 in relation to EMC tests?

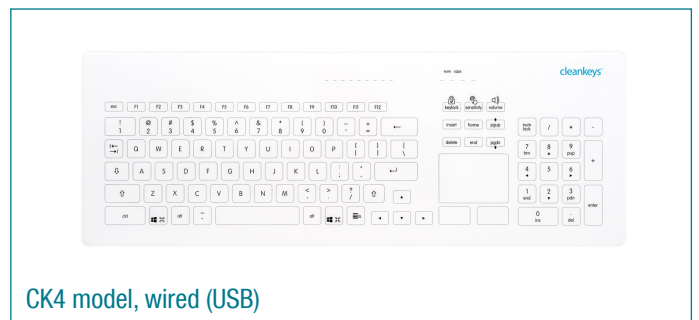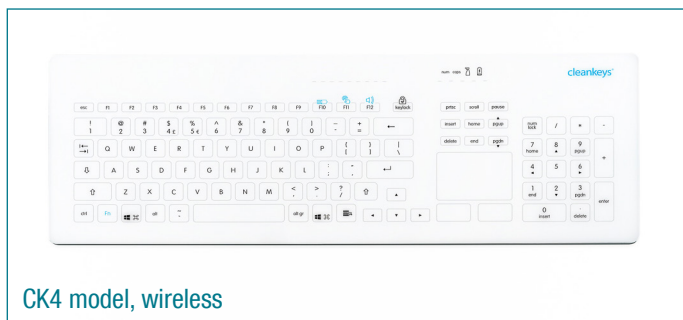|	Test	Edition 3	Edition 4
ESD according to EN 61000-4-2	Contact discharge Air discharge	± 2, 4, 6 kV ± 2, 4, 8 kV	± 2, 4, 8 kV ± 2, 4, 8, 15 kV
Interference resistance against radiated fields according to EN 61000-4-3	Enclosures	3 V/m, life-sustaining unit 10 V/m 80% AM at 1 kHz or 2 Hz, 80 MHz to 2500 MHz	3 V/m, home health care 10 V/m 80% AM at 1 kHz or critical frequency, 80 MHz up to 2700 MHz
Fast transients and burst immunity according to EN 61000-4-4	AC mains or DC input I/O Ports	± 2kV, 5kHz pulse repetition frequency	± 2kV, 100kHz pulse repetition frequency
		± 1kV, 5kHz pulse repetition frequency	± 1kV, 100kHz pulse repetition frequency

7. Which GETT products are subject to EN 60601-1-2?

As far as the company's catalog products are concerned, no product is subject to mandatory certification in line with EN 60601 or EN 60601-1-2. Keyboards or computer peripheral items are not defined as medical equipment in the sense of the Medical Products Act. However, **in order to provide evidence of their special suitability for use in the relevant fields (clinics, medical practices), some keyboards and one PC mouse have been subjected to an EMC test in line with the strict criteria of EN 60601-1-2 Edition 4 (see Section 8).**

As far as customized products are concerned, certification would only become necessary if this involved a medical product/system in line with the Medical Products Act. However, as this would be managed as an individual project and only if certification was necessary, no general measures can be derived to cover this situation.

8. Which GETT products comply with the conditions for the EMC criteria in EN 60601-1-2?

As outlined in Section 7, some of our models **comply with the EMC requirements in line with EN 60601-1-2 Edition 4.** The complete EMC reports can be requested from your GETT contact partner at any time.

CK4 model, wireless

CK4 model, wired (USB)

InduProof Smart Classic

InduProof Smart Pro

InduMouse® Pro

9.   Which statements can be made about the certification of keyboards?

The keyboards are specifically not certified in line with EN 60601-1-2 (Edition 4). The reason for this is primarily based on risk management, which needs to consider all the relevant areas of medical usage. As a keyboard is part of the so-called general or basic equipment, it can be used in almost any specific environment. It is therefore almost impossible to assess or manage the risks in question (which must take place according to EN 14971) – and it is not a beneficial process either. In this respect, the tests performed on the keyboards according to EN 60601-1-2 Edition 4 solely relate to their EMC. The models completely passed this EMC test. The products are therefore formally suitable for use in medical and medically-related environments.

This is the best possible way of stating this in English:
(The keyboard) complies with the EMC guidelines in EN 60601-1-2 Edition 4 (or alternatively IEC 60601-1-2 Edition 4)

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¹ European standard. The European standards (EN) are rules that have been ratified by one of the three European committees for standardization (European Committee for Standardization or CEN, European Committee for Electrotechnical Standardization or CENELEC and the European Telecommunications Standards Institute or ETSI).

² The International Electrotechnical Commission is an international organization that establishes standards in the fields of electrotechnology and electronics. Some of its norms are jointly defined with EN standards.

³ EN 14971 is the standard for "Applying Risk Management to Medical Products." It describes a risk management process, which is designed to guarantee that the risks caused by medical products are known and managed and are acceptable in comparison to their benefits.

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