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Automatic Identification and Data Capture Techniques

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Title: Information and Comment for PDTR 20017

Dear SC31 members,

In Japan, during the expansion period of 2nd-generation active cellular phones that date back well over five years, it became known that the radio waves emitted from cellular phones would potentially affect implantable cardiac pacemakers and cardioverter defibrillators (ICDs) under certain conditions. In the case of very sensitive and susceptible ICDs, which extend to approx. 30 different types internationally, there is a possibility that a cellular phone may possibly hamper the operation of active implantable medical devices (AIMDs) due to electromagnetic interference (EMI) emitted from the cellular phone operating within a 15 cm distance. Having said that, however, about 75% of the ICDs tested passed the experimental investigation and were confirmed to function properly without any problems. It has also been verified that the 3rd-generation cellular phones do not do any particular harm to ICDs.

The same kind of effects or impact on AIMD caused by an anti-theft device have also been reported, in which the cardiac pacemaker was actually stopped although only temporarily. Reflecting on this incident, the range of investigation was scaled up to include anti-theft devices to evaluate their potential effects on AIMD. The investigation into anti-theft devices indicates that highly sensitive ICDs are potentially affected and their operation disturbed if the separation distance from the radio frequency identification (RFID) integrator's antenna becomes less than 25 cm.

In parallel with that, some experimental evaluations were also conducted on contactless IC card integrators running at 13.56 MHz and RFID integrators used in the 13.56 MHz, 860 to 960 MHz, and 2.45 GHz frequency range respectively, following the case of anti-theft devices in Japan. These experimental evaluations have confirmed that electromagnetic waves interfered with the operation of some highly sensitive ICDs when they were brought near the integrator's antenna (within the 75 cm zone).

The result of these experimental investigations were publicly announced and all patients wearing ICDs were informed of this fact in Japan, and the use of special labels or signs on RFID integrators, indicating the existence of electromagnetic sources, is strongly recommended by the AICD industry to warn AIMD patients not to approach RFID integrators too closely.

The document PDTR 20017 describes the methods for experimental EMI evaluation and a method of mitigating the EMI on AIMDs generated by RFID interrogators. How the electromagnetic waves from integrators will act on other types of devices, such as infusion pumps and electrocardiograms, is not considered in this PDTR 20017, however. This issue is assumed to be in the category outside of this PDTR 20017 and, if required, should be developed as another technical report (TR), which is referred to explicitly in PDTR 20017 at its introduction part. The following is an excerpt of an article from the introduction of PDTR 20017.

"Several current reports indicate that various electric or electronic devices occasionally may cause malfunctions in active implantable medical devices (AIMD) such as implantable cardiac pacemakers and cardioverter defibrillators (ICDs) through electromagnetic coupling (interference). One well-known example is the microwave electromagnetic interference (EMI) created by active cellular phones. Some reports have experimentally confirmed that some radio frequency identification (RFID) interrogators might trigger an AIMD malfunction. Among them, a FDA report concluded that the clinical risk is low. On the other hand, this technical report shows inconsistent results from the various tests. It is probable that the inconsistencies are mainly due to the differences in the devices tested in both experiments. No standard methodology for evaluating the EMI from RFID interrogators on AIMDs is available at present.. However, this technical paper provides fundamental information which can be used when investigating or decreasing EMI risk which is currently needed in present situations.

The observed characteristics of the EMI were shown to depend upon the transmission radio wave specifications, the antenna performance of the interrogator, AIMD type, and AIMD operation mode setting. The typical cases indicate that the EMI is most likely to occur directly in front of the interrogator

antenna.

This technical report describes the technologies needed to implement experimental EMI evaluation methods and a method of mitigating the EMI from RFID interrogators on AIMDs. Some experimental evaluation results for typical devices are also presented. In this report, since an EMI event is estimated based upon an engineering stand point, for example whether or not any change in the pacing behaviour occurred, the EMI experimental results shown by this report do not necessarily reflect direct risk to patients. The clinical significance estimations remain to be discussed in future studies."

The main purpose of PDTR 20017 is to inform that "No standard methodology for evaluating the EMI from RFID interrogators on AIMDs is available at present. However, this technical paper provides fundamental information which can be used when investigating or decreasing EMI risk which is currently needed in present situations," as stated above.

Table 1 shows the estimated number of ICDs that were implanted in patients around the world in 2009. It should be noted that since an accurate statistical figure is not available and unknown, the figures in this list are only approximate values. The total number of these medical devices currently being used in European nations, including UK, Germany, France, Netherlands, Greece, Sweden, Austria, Portugal, Switzerland, Denmark, Norway, Ireland, Italy, Spain, Belgium, Czech Republic, and Finland, is calculated to be 496,000 units (see Table 1).

Table 1: The number of cardiac pacemakers and cardioverter defibrillators implanted in 2009

USA	570,000	GERMANY	137,000	DENMARK	6,000
JAPAN	60,000	FRANCE	76,000	NORWAY	4,000
Singapore	10,000	NETHERLANDS	17,000	IRELAND	3,000
CHINA	35,000	GREECE	11,000	ITALY	85,000
AUSTRALIA	25,000	SWEDEN	10,000	SPAIN	39,000
RUSSIA	18,000	AUSTRIA	10,000	BELGIUM	15,000
Argentina	13,000	PORTUGAL	10,000	CZECH REPUBLIC	11,000
UK	50,000	SWITZERLAND	7,000	FINLAND	5,000
				TOTAL	**1,227,000**

In general, a life cycle of battery used for each ICD is regarded as approx. seven years on average. It can be said from the figures in Table 1 that the total number of patients with a cardiac pacemaker or cardioverter defibrillator is estimated as many as 8,589,000 as of 2009 (see Table 2). However, the number of patients who died during this seven-year period is not deducted from this calculation, when the average life of battery is limited to seven years.

Table 2: The total number of cardiac pacemakers and cardioverter defibrillators in use as of 2009

USA	3,990,000	AUSTRALIA	175,000
JAPAN	420,000	RUSSIA	126,000
Singapore	70,000	Argentina	91,000
CHINA	245,000	Europe	3,472,000
		TOTAL	**8,589,000**

With all these factors taken into consideration, it is predictable that more than 8.5 million patients are actually using AIMDs such as ICDs worldwide as of 2009, and this figure is expected to increase on a year-to-year basis in the future.

The National Body of Japan regards this PDTR 20017 as an essential instrument for the progress of RFID technologies. All the national bodies involved are kindly requested to fully understand the aim and purpose of PDTR 20017.

Thank you in advance for your cooperation.

Yours faithfully,

SC31 Japan Chairman

Akira Shibata