

Wpro Descaler Safety Datasheet

-Exposure to magnetic fields-

W-Pro MWC013 - 4801 817 00939

To establish whether an Electromagnetic Field can interfere with an implantable device as a pacemaker or an ICD you have to examine the **device**, the **intensity of the electromagnetic field** (in Volt/metre) and the **intensity of the magnetic field** (in Tesla). International Organisation (International Commission On Non-Ionizing Radiation Protection - ICNIRP, American National Standard Institutes - ANSI, and in Italy the CENELEC Committee) established exposure levels limits (for prolonged exposure) 5 KV/m for intensity of electric field and 100 microTesla for the magnetic one – for brief exposures: 10 KV/m and 1000 microTesla) which ensure **people health protection** but which cannot guarantee implantable devices can be immune to interferences at exposure levels lower than limit levels set by regulations.

According to regulations CEI-ENV 50166 – 1 IRPA/ICNIRP 1994 (“Guidelines on limits of exposure to static magnetic fields” Health Physics 66/1, 1994) reference levels for pacemaker carriers are the following:

	CEI and ICNIRP Limit
Maximum daily exposure / body / limbs	200 mT / 2T / 5T
	IRPA/ICNIRP recommendations: maximum level
Pacemaker and defibrillator carriers	0,5 mT
Carriers of electronic hearing aid, insulin pumps, electronic controlled active aids and muscle stimulating systems	A few mT

As you can note, exposure levels are extremely different. You have to know not all pacemakers are the same, even if the same functional features are stated. The responses of these devices to electromagnetic interferences depend on a large number of variables, including the nature and signal power, the distance from the source and some device intrinsic features.

Even of the current communitarian regulations impose to exclusively comply with CEI regulations ensuring the health protection of people only and not of implanted devices, we have always believed necessary to plan and realize our products considering the requirements and safety of all users, non excluded. Therefore, also Descaler Wpro comply with IRPA/ICNIRP regulations for pacemaker and defibrillators carriers. Even though complying with the limit value of 0,5 mT recommendations and general precaution apply:

- keep a distance of at least 15 cm between the product and the implanted device;
- avoid prolonged exposures.

We enclose a documented test report No. 0616/1194/11.