

Radio frequency (RF) signals

THIS MODEL PHONE MEETS THE GOVERNMENT'S REQUIREMENTS FOR EXPOSURE TO RADIO WAVES.

Your wireless phone is a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government and by Health Canada. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC and Health Canada is 1.6W/kg.* Tests for SAR are conducted using standard operating positions accepted by the FCC and Industry Canada with the phone transmitting at its highest certified power level in all tested frequency bands. Although the SAR is determined at the highest certified power level, the actual SAR level of the phone while operating can be well below the maximum value. This is because the phone is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

Before a phone model is available for sale to the public in the US and Canada, it must be tested and certified to the FCC and Industry Canada that it does not exceed the limit established by the

government-adopted requirement for safe exposure. The tests are performed in positions and locations (for example, at the ear and worn on the body) as approved by the FCC and Industry Canada for each model. The highest SAR value for this model phone as reported to the FCC and available for review by Industry Canada when tested for use at the ear is 1.296 W/kg, and when worn on the body, as described in this user guide, is 1.034 W/kg. (Body-worn measurements differ among phone models, depending upon available accessories and FCC requirements.) While there may be differences between the SAR levels of various phones and at various positions, they all meet the government requirement.

The FCC and Industry Canada have granted an Equipment Authorization for this model phone with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this model phone is on file with the FCC and can be found under the Display Grant section of <http://www.fcc.gov/oet/fccid> after searching on FCC ID:P6PSND100, Industry Canada ID: IC:4279A-SND100 or MET Listing no:E112302. For body-worn operation, to maintain compliance with FCC RF exposure guidelines, use only Sendo-approved accessories. When carrying the phone while it is on, place the phone in the original Sendo carry case that has been tested for compliance.

Use of non-Sendo-approved accessories may violate FCC RF exposure guidelines and should be avoided.

*In the United States and Canada, the SAR limit for mobile phones used by the public is 1.6 watts/kg (W/kg) averaged over one gram of tissue and allows for testing and other tolerances. The standard incorporates a substantial margin of

safety to give additional protection for the public and to account for any variations in measurements.



The U.S. Food and Drug Administration's Center for Devices and Radiological Health Consumer Update on Mobile Phones

FDA has been receiving inquiries about the safety of mobile phones, including cellular phones and PCS phones. The following summarizes what is known—and what remains unknown—about whether these products can pose a hazard to health, and what can be done to minimize any potential risk. This information may be used to respond to questions.

Why the concern?

Mobile phones emit low levels of radiofrequency energy (i.e. radiofrequency radiation) in the microwave range while being used. They also emit very low levels of radiofrequency energy (RF), considered non-significant, when in the stand-by mode. It is well known that high levels of RF can produce biological damage through heating effects (this is how your microwave oven is able to cook food). However, it is not known whether, to what extent, or through what mechanism, lower levels of RF might cause adverse health effects as well. Although some research has been done to address these questions, no clear picture of the biological effects of this type of radiation has emerged to date. Thus, the available science does not allow us to conclude that mobile phones are absolutely safe, or that they are unsafe. However, the available scientific evidence does not demonstrate any adverse health effects associated with the use of mobile phones.

What kinds of phones are in question?

Questions have been raised about hand-held mobile phones, the kind that have a built-in antenna that is positioned close to the user's head during normal telephone conversation. These types of mobile phones are of concern because of the short distance between the phone's antenna—the primary source of the RF—and the person's head. The exposure to RF from mobile phones in which the antenna is located at greater distances from the user (on the outside of a car, for example) is drastically lower than that from hand-held phones, because a person's RF exposure decreases rapidly with distance from the source. The safety of so-called "cordless phones," which have a base unit connected to the telephone wiring in a house and which operate at far lower power levels and frequencies, has not been questioned.

How much evidence is there that hand-held mobile phones might be harmful?

Briefly, there is not enough evidence to know for sure, either way; however, research efforts are ongoing. The existing scientific evidence is conflicting and many of the studies that have been done to date have suffered from flaws in their research methods. Animal experiments investigating the effects of RF exposures characteristic of mobile phones have yielded conflicting results. A few animal studies, however, have suggested that low levels of RF could accelerate the development of cancer in laboratory animals. In one study, mice genetically altered to be predisposed to developing one type of cancer developed more than twice as many such cancers when they were exposed to RF energy compared to controls. There is much uncertainty among scientists about whether results obtained from animal studies apply to the use of mobile phones. First, it is uncertain how to apply the results obtained in rats and mice

to humans. Second, many of the studies that showed increased tumor development used animals that had already been treated with cancer-causing chemicals, and other studies exposed the animals to the RF virtually continuously—up to 22 hours per day.

For the past five years in the United States, the mobile phone industry has supported research into the safety of mobile phones. This research has resulted in two findings in particular that merit additional study:

- 1 In a hospital-based, case-control study, researchers looked for an association between mobile phone use and either glioma (a type of brain cancer) or acoustic neuroma (a benign tumor of the nerve sheath). No statistically significant association was found between mobile phone use and acoustic neuroma. There was also no association between mobile phone use and gliomas when all types of types of gliomas were considered together. It should be noted that the average length of mobile phone exposure in this study was less than three years.

When 20 types of glioma were considered separately, however, an association was found between mobile phone use and one rare type of glioma, neuroepitheliomatous tumors. It is possible with multiple comparisons of the same sample that this association occurred by chance. Moreover, the risk did not increase with how often the mobile phone was used, or the length of the calls. In fact, the risk actually decreased with cumulative hours of mobile phone use. Most cancer-causing agents increase risk with increased exposure. An ongoing study of brain cancers by the National Cancer Institute is expected to bear on the accuracy and repeatability of these results¹.

- 2 Researchers conducted a large battery of laboratory tests to assess the effects of

exposure to mobile phone RF on genetic material. These included tests for several kinds of abnormalities, including mutations, chromosomal aberrations, DNA strand breaks, and structural changes in the genetic material of blood cells called lymphocytes. None of the tests showed any effect of the RF except for the micronucleus assay, which detects structural effects on the genetic material. The cells in this assay showed changes after exposure to simulated cell phone radiation, but only after 24 hours of exposure. It is possible that exposing the test cells to radiation for this long resulted in heating. Since this assay is known to be sensitive to heating, heat alone could have caused the abnormalities to occur. The data already in the literature on the response of the micronucleus assay to RF are conflicting. Thus, follow-up research is necessary².

FDA is currently working with government, industry, and academic groups to ensure the proper follow-up to these industry-funded research findings. Collaboration with the Cellular Telecommunications Industry Association (CTIA) in particular is expected to lead to FDA providing research recommendations and scientific oversight of new CTIA-funded research based on such recommendations.

Two other studies of interest have been reported recently in the literature:

- 1 Two groups of 18 people were exposed to simulated mobile phone signals under laboratory conditions while they performed cognitive function tests. There were no changes in the subjects' ability to recall words, numbers, or pictures, or in their spatial memory, but they were able to make choices more quickly in one visual test when they were exposed to simulated mobile phone signals. This was the only change

noted among more than 20 variables compared³.

- 2 In a study of 209 brain tumor cases and 425 matched controls, there was no increased risk of brain tumors associated with mobile phone use. When tumors did exist in certain locations, however, they were more likely to be on the side of the head where the mobile phone was used. Because this occurred in only a small number of cases, the increased likelihood was too small to be statistically significant⁴.

In summary, we do not have enough information at this point to assure the public that there are, or are not, any low incident health problems associated with use of mobile phones. FDA continues to work with all parties, including other federal agencies and industry, to assure that research is undertaken to provide the necessary answers to the outstanding questions about the safety of mobile phones.

What is known about cases of human cancer that have been reported in users of hand-held mobile phones?

Some people who have used mobile phones have been diagnosed with brain cancer. But it is important to understand that this type of cancer also occurs among people who have not used mobile phones. In fact, brain cancer occurs in the U.S. population at a rate of about 6 new cases per 100,000 people each year. At that rate, assuming 80 million users of mobile phones (a number increasing at a rate of about 1 million per month), about 4800 cases of brain cancer would be expected each year among those 80 million people, whether or not they used their phones. Thus it is not possible to tell whether any individual's cancer arose because of the phone, or whether it would have happened anyway. A key question is whether the risk of getting a particular

form of cancer is greater among people who use mobile phones than among the rest of the population. One way to answer that question is to compare the usage of mobile phones among people with brain cancer with the use of mobile phones among appropriately matched people without brain cancer. This is called a case-control study. The current case-control study of brain cancers by the National Cancer Institute, as well as the follow-up research to be sponsored by industry, will begin to generate this type of information.

What is FDA's role concerning the safety of mobile phones?

Under the law, FDA does not review the safety of radiation-emitting consumer products such as mobile phones before marketing, as it does with new drugs or medical devices. However, the agency has authority to take action if mobile phones are shown to emit radiation at a level that is hazardous to the user. In such a case, FDA could require the manufacturers of mobile phones to notify users of the health hazard and to repair, replace or recall the phones so that the hazard no longer exists. Although the existing scientific data do not justify FDA regulatory actions at this time, FDA has urged the mobile phone industry to take a number of steps to assure public safety. The agency has recommended that the industry: support needed research into possible biological effects of RF of the type emitted by mobile phones; Design mobile phones in a way that minimizes any RF exposure to the user that is not necessary for device function; and cooperate in providing mobile phone users with the best possible information on what is known about possible effects of mobile phone use on human health.

At the same time, FDA belongs to an interagency working group of the federal agencies that have responsibility for different aspects of mobile phone safety to ensure a coordinated effort at the federal level. These agencies are:

- ◆ National Institute for Occupational Safety and Health
- ◆ Environmental Protection Agency
- ◆ Federal Communications Commission
- ◆ Occupational Health and Safety Administration
- ◆ National Telecommunications and Information Administration

The National Institute of Health also participates in this group.

In the absence of conclusive information about any possible risk, what can concerned individuals do?

If there is a risk from these products—and at this point we do not know that there is—it is probably very small. But if people are concerned about avoiding even potential risks, there are simple steps they can take to do so. For example, time is a key factor in how much exposure a person receives. Those persons who spend long periods of time on their hand-held mobile phones could consider holding lengthy conversations on conventional phones and reserving the hand-held models for shorter conversations or for situations when other types of phones are not available.

People who must conduct extended conversations in their cars every day could switch to a type of mobile phone that places more distance between their bodies and the source of the RF, since the exposure level drops off dramatically with distance. For example, they could switch to a mobile phone in which the antenna is located outside the vehicle,

a hand-held phone with a built in antenna connected to a different antenna mounted on the outside of the car or built into a separate package,

or

a headset with a remote antenna to a mobile phone carried at the waist.

Again, the scientific data do not demonstrate that mobile phones are harmful. But if people are concerned about the radiofrequency energy from these products, taking the simple precautions outlined above can reduce any possible risk.

Where can I find additional information?

For additional information, see the following websites:

Federal Communications Commission (FCC) RF Safety Program (select "Information on Human Exposure to RF Fields from Cellular and PCS Radio Transmitters"):

<http://www.fcc.gov/oet/rfsafety>

World Health Organization (WHO) International Commission on Non-Ionizing Radiation Protection (select Qs & As):

<http://www.who.int/emf>

United Kingdom, National Radiological Protection Board:

<http://www.nrp.gov.uk>

Cellular Telecommunications Industry Association (CTIA):

<http://www.wow-com.com>

U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health:

<http://www.fda.gov/cdrh/consumer/>

1 Muscat et al. Epidemiological Study of Cellular Telephone Use and Malignant Brain Tumors. In:

State of the Science Symposium; 1999 June 20; Long Beach, California.

2 Tice et al. Tests of mobile phone signals for activity in genotoxicity and other laboratory assays. In: Annual Meeting of the Environmental Mutagen Society; March 29, 1999, Washington, D.C.; and personal communication, unpublished results.

3 Preece, AW, Iwi, G, Davies-Smith, A, Wesnes, K, Butler, S, Lim, E, and Varey, A. Effect of a 915-MHz simulated mobile phone signal on cognitive function in man. *Int. J. Radiat. Biol.*, April 8, 1999.

4 Hardell, L, Nasman, A, Pahlson, A, Hallquist, A and Mild, KH. Use of cellular telephones and the risk for brain tumors: a case-control study. *Int. J. Oncol.*, 15: 113-116, 1999.