ABIOMED, Inc.

0034-3340 AbioCor Implantable Controller RF Telemetry – RF Exposure

The AbioCor® Implantable Controller contains the electronic circuitry required to run the AbioCor® Implantable Replacement Heart. The Implantable Controller is surgically implanted in the abdomen of an AbioCor® Implantable Replacement Heart patient. The RF telemetry transceiver is part of the Implantable Controller. An antenna, which is part of the implantable cable, is attached to the Implantable Controller and located in the patient's abdomen.

The AbioCor® Implantable Controller's RF telemetry system was tested to 47 CFR 15.249. Based on correspondence with the FCC, the Implantable Controller and antenna were submersed in a phantom material that simulates human tissue during the testing. The antenna and Implantable Controller were positioned 2 cm inside the phantom material as recommended by the FCC.

Correspondence with the FCC can be found in Attachment 1. The formula for the phantom material and paper referenced in OTE Bulletin 65 Supplement C can be found in Attachment B.

ABIOMED, Inc.

Attachment 1

Correspondence with the FCC

D'Ambrosio, Ralph

From: Phyllis Parrish [Phyllis.Parrish@fcc.gov]
Sent: Tuesday, March 30, 2004 7:06 AM
To: LabHelp
Cc: rdambrosio@abiomed.com
Subject: RE: Question

Question: The AbioCor implantable telemetry system uses an OOK modulated transceiver operating at 916.5 MHz and is designed to comply with 47 CFR 15.249.

Below is some of the information that Richard has requested:

The radiated output power of the device is approximately -8.0 dBm (158uW) at the implantable antenna. The transmitted data uses a bit-balancing scheme, similar to Manchester encoding, since the base band signal is AC coupled. The implantable transmitter is active about 90% of the time. During the remaining 10%, the implantable receiver is enabled to accept inbound commands.

Below are some facts to ease your concern regarding "Part 15 devices, which have no protection against harmful interference, to be used for life-saving/preserving devices" for this application.

1) The RF telemetry is not required to maintain operation of the device. (example: If the RF link is down for a day there will be no adverse
effect)
2) All of the inbound and outbound data use a CRC to maintain data integrity.
3) Commands required to disable the device require multiple messages.
4) The entire AbioCor system will undergo full immunity testing per EN60601-1-2 which include full testing of the EN61000-3 and EN61000-4 families of standards.
5) The AbioCor system has been undergoing clinical trials for the past
2-1/2 years using this telemetry system. Never has interference been interpreted as, or caused desired message to be interpreted as, something other than the intended message.

Please let me know if you require any additional information. Your prompt response is appreciated as we would like to commence testing next week.

You can reach me in the office at 978-646-1709. If you receive my voice mail, please dial "0" and have the operator page me, or you can try my cell phone at 978-314-6517.

Best Regards,

Ralph D'Ambrosio

rdambrosio@abiomed.com

Answer: We will allow testing in the open air or in a fluid that simulates body tissue on an open area test site. The choice is up to

you. ANSI C63.4 requires testing in the open air, however, we have allowed other Part 15 transmitters to be tested in-situ or as-installed. A transmitter tested in air will be placed stand-alone on the tabletop. A transmitter tested in fluid must not be more than 2 cm inside the fluid on the tabletop. Be aware that a device tested in fluid will appear to have more power when compared side-by side to one tested in the open air. This could be advantageous to your future marketing plans. Supplement C to OET Bulletin 65 contains recipes for "phantom materials".

D'Ambrosio, Ralph

From: LabHelp [LabHelp@fcc.gov]
Sent: Tuesday, March 16, 2004 8:29 AM
To: D'Ambrosio, Ralph
Subject: RE: Question

We are in receipt of your e-mail dated March 10, 2004. After some research, it appears that we will need additional time to provide an appropriate response to your inquiry. We will therefore be responding to your e-mail within one to two weeks. If you have any questions, please send me an e-mail with your concerns.

Hello,

I am contacting you at Richard Fabina's direction. Please see the emails below for some background.

The AbioCor implantable telemetry system uses an OOK modulated transceiver operating at 916.5 MHz and is designed to comply with 47 CFR 15.249.

Below is some of the information that Richard has requested:

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mail, please dial "0" and have the operator page me, or you can try my cell phone at 978-314-6517.

Best Regards,

Ralph D'Ambrosio

rdambrosio@abiomed.com

-----Original Message-----
From: Rich Fabina [mailto:Rich.Fabina@fcc.gov]
Sent: Tuesday, March 09, 2004 2:16 PM
To: D'Ambrosio, Ralph
Subject: RE: Question

Ralph,

Yes, the contact should be done before any testing for FCC requirements. You may submit your questions via email to labhelp@fcc.gov.

We'll need information on the output power of the device (EIRP at the antenna) where it touches human tissue and the length of transmission so we can answer any questions you have.

The questions will be forwarded to the appropriate individual for response. You should be aware that allowing Part 15 devices, which have no protection against harmful interference, to be used for life-saving/preserving devices is new and we are struggling with the idea of allowing such use.

Rich Fabina
Chief, Equipment Authorization Branch
Laboratory Division
FCC

-----Original Message-----
From: D'Ambrosio, Ralph [mailto:rdambrosio@abiomed.com]
Sent: Monday, March 08, 2004 5:36 PM
To: Rich Fabina
Cc: Kolifrath, Charles
Subject: Question
Importance: High

Hi Richard,

My name is Ralph D'Ambrosio and I am writing with regards to ABIOMED's AbioCor implantable artificial heart. We have been undergoing FDA clinical trials on the AbioCor system for the past few years.

The AbioCor has a RF telemetry system that operates at 916.5 MHz. The telemetry system allows an external console to monitor the status and collect data from the implantable system as well as allowing the console to send commands to the implantable system. Our telemetry system is designed to meet the requirements of 47 CFR, part 15.249.

We will be testing the AbioCor for compliance at an FCC certified test lab, Intertek Testing Services, next week. During a search of non-MICS implantable systems, Roland Gubisch of Intertek, came across the

following prior determination:

INQUIRY2:

Can a device, even though implanted in the human body, seek certification under other than Part 95 if it is extremely low power (e.g. in compliance with the Section 15.209 power limits at 3 meters)?

Response -

Possibly, but any manufacturer seeking certification of an implant device for unlicensed use pursuant to Part 15 of the Commission's Rules should first contact the Commission's Office of Engineering and Technology. Such an application must be reviewed and processed by the Commission, not a Telecommunication Certification Body. In addition, as noted above, the manufacturer should contact the FDA to determine whether the FDA must also evaluate/approve the implant device. Finally, the designer/manufacturer of an implant device intended for unlicensed use should be aware that the American National Standards Institute measuring standard, ANSI C63.4-2000, does not permit any adjustment for attenuation due to body tissue. Testing other than on an open area test site turntable will have to be addressed with the Commission before the application is filed.

My reason for contacting you is the first sentence of the "Response" above. What is the procedure for contacting the FCC with regards to certifying a non-MICS implantable telemetry system? Should this be done prior to the testing?

I look forward to discussing this with you. Your prompt response is appreciated as we would like to commence testing next week.

Best Regards,

Ralph D'Ambrosio

978-646-1709
rdambrosio@abiomed.com

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Ralph D'Ambrosio

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rdambrosio@abiomed.com

ABIOMED, Inc.

Attachment 2

Phantom Material

Tissue Substitute Material

Instructions outlined in *Simulated Biological Materials for Electromagnetic Radiation Absorption Studies*.

	Ingredient	% by weight	Amount
1	Water (Gallon)	52.5%	**3**
	Water weight **(lbs)**		**25.008**
2	Salt (NaCl) **(oz)**	1.4%	**10.670**
3	Cane sugar (sucrose) **(lbs)**	45.0%	**21.435**
4	HEC (Natrosol 250 HHR) **(oz)**	1.0%	**7.621**
5	Bactericide (Dowicil 75) **(oz)**	0.1%	**0.762**
		100.0%	
	Total Weight (ref) **(lbs)**		**47.634**
			5 gal total

Note: 1 gal of water at 20 deg C. 8.336 lbs

1 Distilled water (3 gallons = 25.01 lbs, 3.6 gallons = 30.01 lbs)
2 Kosher salt
3 Pure granulated sugar

4 Hydroethylcellulose (HEC)
Natrosol 250 HHR (cosmetic grade)
Hercules Inc, Aqualon Division, Wilmington, DE
(800) 345-0447

5 Bactericide
Dowicil 75
Dow Chemical, Midland, MI
(800) 447-4360

Bioelectromagnetics 8:29–36 (1987)

Simulated Biological Materials for Electromagnetic Radiation Absorption Studies

G. Hartsgrove, A. Kraszewski, and A. Surowiec

University of Ottawa, Department of Electrical Engineering, Ottawa, Ontario, Canada

For the study of electromagnetic dosimetry and hyperthermia, it is necessary to simulate human biological materials. This can be done by chemical mixtures that are described in this paper. Formulas are presented for simulating bone, lung, brain, and muscle tissue in the frequency range of 100 MHz to 1 GHz. By using these preparations a realistic equivalent to the human body can be constructed.

Key words: simulated biological materials, electromagnetic dosimetry, tissue equivalent materials

INTRODUCTION

Recently, electromagnetic dosimetry and hyperthermia have required more and more complex models of biological materials to investigate the electric field (SAR, temperature) distributions induced inside a real body. Experimental verification of calculations based on these more complex structures needs a more realistic model of the biological object constructed from materials that simulate the permittivity and conductivity of various tissues in the frequency range of interest. Most of the tissue equivalent materials developed to date simulate skeletal muscle. The majority of these materials lose their properties after a short time, because of sedimentation, chemical reactions, and bacterial action. The purpose of this paper is to present recipes for materials at room temperature that simulate the permittivity and conductivity of muscle, brain, lung, and bone tissues at body temperature (37°C) in the frequency range of 100–1000 MHz. These materials are all easy to prepare, inexpensive, and retain their properties for an extended period of time. Muscle simulating materials that have been prepared have retained these properties for over 1 year.

SIMULATED MATERIALS

Muscle Tissue

Our initial attempt was to simulate the properties of skeletal muscle [Hunt, 1985] because this is one of the major components of man. Previous formulas [Chou et al, 1984; Guy, 1971] have been developed for muscle material but they were found to have problems. The major problems were lumping of the gelling agent during mixing,

Received for review January 28, 1986; revision received June 6, 1986.

Address reprint requests to G. W. Hartsgrove, University of Ottawa, Department of Electrical Engineering, 770 King Edward Avenue, Ottawa, Ontario, Canada K1A 6N5.

Bone Tissue Equivalent Material

The procedure for preparing the bone equivalent material is as follows: (1) Mix the KCl solution in the proportions given in Table 1C. (2) Add one-quarter of the total amount of KCl solution to the epoxy resin and mix until a homogeneous paste is obtained. (3) Add another 25% of the KCl solution and mix until the material is homogeneous, white, and no water appears on the surface. (4) Add the hardener and mix carefully for about 1 min. (5) Add 25% more KCl and mix using an electric mixer until homogeneous (less than 1 min). (6) Add the remainder of the KCl and continue to mix for 1–2 min. (7) Pour the mixture into molds to set. (8) The material will then slowly begin to solidify producing an exothermic reaction. (9) The material will harden in about 4 h.

The material should then be kept in a moist environment to prevent evaporation of water.

MEASURING TECHNIQUES

The dielectric properties of the tissue simulating materials were measured using an open-ended coaxial-line sensor and a computer controlled automatic network analyser [Kraszewski et al, 1983]. The system was calibrated with the sensor open-circuited, short-circuited, and immersed in a saline solution to minimize the errors related to the system imperfections. The sensor was then immersed into the material under test (being a liquid or semi-liquid) or was firmly pressed into the flat smooth surface of the cast bone sample. The uncertainty of the measurement was evaluated as being less than 3% for the dielectric constant and 2% for the conductivity of muscle, brain, and lung materials, and less than 5 and 10%, respectively, for bone simulating material.

A summary of the properties of all the materials that have been described are presented in Table 2. This table gives dielectric constants and conductivities at frequencies of 100, 400, and 900 MHz.

SUMMARY

Formulas have been presented along with mixing instructions for the preparation of simulated bone, lung, brain, and muscle material in the frequency range of 100 MHz to 1GHz. These materials are easy to prepare, inexpensive, reproducible, and retain their properties for a long period of time.

The dielectric properties of each of the described materials can easily be changed to match the particular need of an experiment. In general the amount of sodium chloride (or KCl) is responsible for the material's conductivity, and the amount of water influences mainly the value of its dielectric constant. In a limited range these two parameters can be changed almost independent of each other, thus allowing precise simulation of tissue properties at a particular frequency.

With this information it is possible to construct a more realistic model of man for electromagnetic dosimetry studies.

ACKNOWLEDGMENTS

This work was supported by grants from the U.S. Environmental Protection Agency, Health and Welfare Canada, and from the Natural Science and Engineering

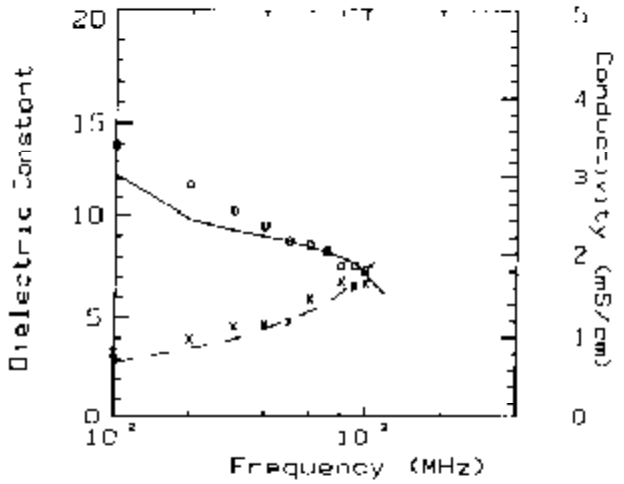

Fig. 4. Electric properties of castable bone-equivalent material.

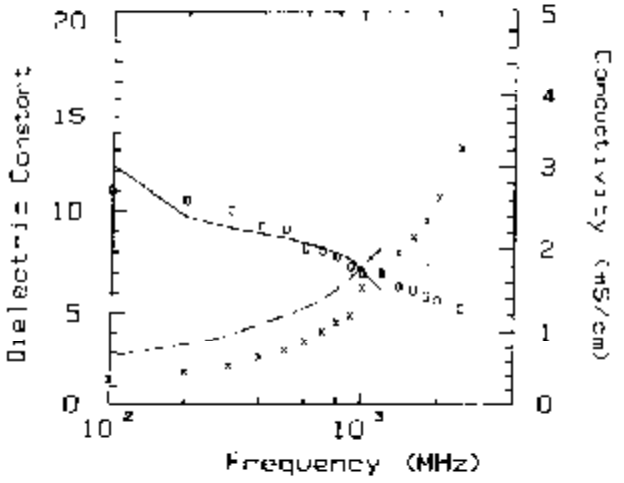

Fig. 5. Electric properties of liquid bone equivalent material.

equivalent material: (1) Weigh all ingredients accurately. (2) Heat water to 40°C. (3) Add salt and bactericide while stirring. (4) Add sugar (and microspheres in case of lung). (5) Continue to stir at low speed to minimize the amount of air bubbles in the solution. (6) Add the hydroxyethylcellulose (HEC). (7) Remove from heat. (8) Continue to stir until mixture thickens. (9) Let cool to room temperature.

When not in use the material should be stored in a covered container to prevent evaporation of water. If, however, the material does lose some water the original properties can usually be restored by the addition of a small amount of water that is simply stirred into the existing material.

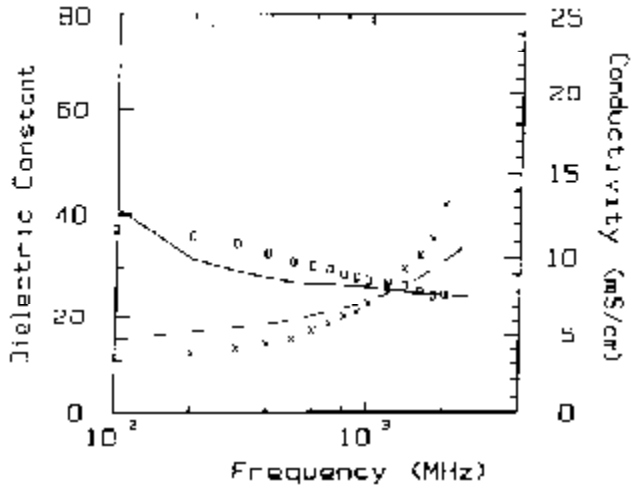

Fig. 3. Simulated lung material dielectric constant and conductivity compared to average properties of inflated and deflated lung.

The castable version is simply made from Devcon two-ton epoxy with a highly conductive potassium chloride (KCl) solution added. The concentration of the salt solution can be adjusted to vary the conductivity of the material and the dielectric constant. The desired conductivity may be achieved when the electrolyte is incorporated into the epoxy, thus forming ionic conductance carriers in the bone equivalent material. The composition of this material is given in Table 1C.

Due to the exothermic reaction some of the water evaporates and the resulting material contains about 0.5% less water than in the original case. The specific density of the resulting material is 0.98 g/cm^{-3}.

This preparation has been found to be easy and fast to produce and it provides reproducible results. The most important aspect of this material is that the dielectric properties of bone material are simulated over a wide frequency range, as shown in Figure 4.

The liquid form of the bone material is made from several chemicals forming a microemulsion. This microemulsion is the same as presented by Foster et al [1982]. Saline solution is added to the microemulsion in order to increase the conductivity.

The amount of NaCl solution and other components of the microemulsion are given in Table 1D. Properties for the liquid bone material are given in Figure 5 and Table 2.

PREPARATION METHODS

The procedure for preparing the tissue equivalent materials are presented here. It is important that the instructions are followed carefully and the material is weighed accurately to obtain reproducible results.

Muscle, Brain, and Lung Tissue Equivalent Material

The following procedure was used to prepare muscle, brain, and lung tissue

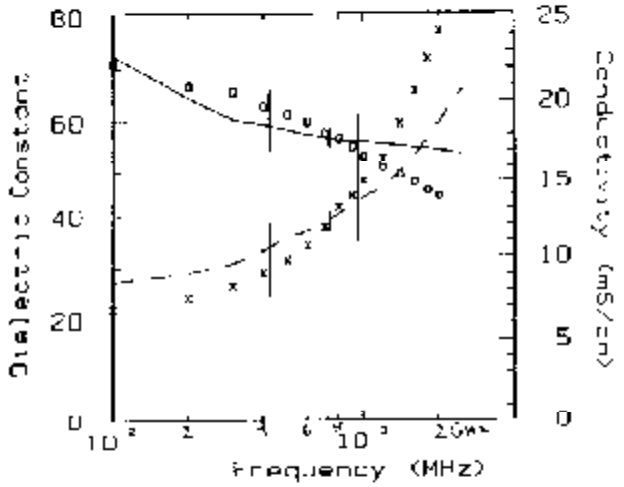

Fig. 1. Dielectric constant (0) and conductivity (X) of muscle equivalent material from 10 MHz to 2.45 GHz. Solid and dashed lines represent expected values of dielectric constant and conductivity, respectively.

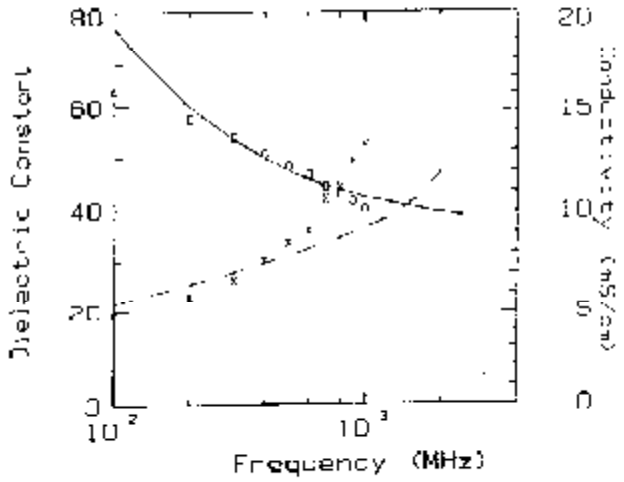

Fig. 2. Properties of simulated brain material compared to expected values (average of white and grey matter). Symbols for Figures 2–5 as in Fig. 1

1984; Stuchly and Stuchly, 1980] differ significantly. The expected values plotted in Figure 4 and 5 are based on an average of the existing data. In order to simulate bone properties a different approach was necessary because of the relatively low dielectric constant and the desire to have a material that can be cast into the shape of a real bone. There are also experimental situations where it would also be desirable to have a liquid form of bone material so that the interior of the bone may be investigated. To this end we have devised two formulas for bone, one liquid, and the other castable.

TABLE 1. (A) Composition by Weight of Muscle and Brain Equivalent Material. (B) Percentage by Volume of Filler Used in Lung Material. (C) Castable Bone Material Components. (D) Liquid Bone Material Components.

A. Muscle and brain material

Material	Percentage by weight	
	Muscle	Brain
Water	52.4	40.4
Salt (NaCl)	1.4	2.5
Sugar	45.0	56.0
HEC	1.0	1.0
Bacteriacide	0.1	0.1

B. Lung material

Material	Percentage by volume
Muscle material (above)	47
Microspheres	53

C. Bone material (castable)

Material	Percentage by weight
Two ton epoxy	
Epoxy	35.0
Hardener	35.0
KCl Solution	28.0

D. Bone material (liquid)

Material	Percentage by weight
TWEEN	57.0
n-Amyl alcohol	28.5
Paraffin oil	9.5
Water	4.5
Salt (NaCl)	0.5

TABLE 2. Dielectric Constant and Conductivity of Tissue Equivalent Materials at Selected Frequencies

	Frequency (MHz)					
	100		400		900	
Material	ϵ'	σ	ϵ'	σ	ϵ'	σ
Muscle	70.5	6.8	62.5	9.0	54.7	13.8
Brain	65.0	4.7	50.3	7.5	41.2	12.2
Lung	37.0	3.4	32.6	4.3	28.0	6.6
Bone cast	13.6	0.08	9.3	1.1	7.4	1.6
Bone liquid	10.8	0.35	9.1	0.66	7.2	1.2

muscle equivalent material to 53% microspheres. The properties of the simulated lung material are shown in Figure 3 and in Table 2.

Bone Tissue

Bone material is a very inhomogeneous structure, containing parts of different dielectric properties. The data found in literature [Foster and Schwan, 1985; Pethig,

Research Council of Canada. The guidance of Dr. S. Stuchly, who proposed this project, is gratefully acknowledged. The authors also wish to thank S. Symons, C. Sibbald, D. M. Bui, J. Dadkhah, and P. Kratchanov for their help in preparing the samples and measuring their dielectric properties.

APPENDIX

List of suppliers for this project includes: Two Ton Epoxy (Devcon Corp., Danvers, MA 01923; NaCl (any grocery store); sucrose (granulated cane sugar, any grocery store); HEC (300,000 A; BP Chemicals) or Natrosol 250 HHR (Hercules Inc., Wilmington, DE 19899); Dowicil 75 (Dow Chemical, Midland, MI 46840); Microspheres (Ecospheres SI, Emerson and Cuming, Canton, MA 02021); KCl, TWEEN, n-amyl alcohol, paraffin oil (Sargent-Welch, Skokie, IL 60077).

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Foster KR, Epstein BR, Jenin PC, Mackay RA (1982). Dielectric studies on aclionic macroemulsions. J Colloid Interface Sci 88:230–246

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Hart WD (1985): Multiterm Debye dispersion relations for permittivity of muscle. IEEE Trans Biomed Eng BME-32:60–64

Kraszewski A, Stuchly SS, Stuchly MA, Symons SA (1983): On the measurement accuracy of the tissue permittivity in vivo. IEEE Trans Instrum Meas IM-32:37–42

Pethig R (1984). Dielectric properties of biological material: Biophysical and medical applications. IEEE Trans Elect Insulation EI-19:453–475.

Stuchly MA, Stuchly SS (1980): Dielectric properties of biological substances—tabulated. J Microwave Power 15:19–26.

Surowiec A, Stuchly SS, Kearney M, Swarup A (in press) Dielectric spectroscopy of inflated and deflated lung. IEEE Trans Biomed Eng

① Natrosol 250 HHR Cosmetic Grade (Hydroxyethylcellulose)
Hercules Inc, Wilmington DE (Aqualon division) Kelly Hendrickson (800) 345-0447

② Dowicil 75
Dow Chemical, Midland, MI (800) 447 4369
Mary Staley

separation of the components of the mixture, and a short lifetime before the onset of bacteria growth. The problems with the previous mixtures appeared to be mostly associated with the gelling agent; therefore, a substitute was sought. A compound used commercially for increasing the viscosity of many water based compounds was found to be a excellent material for our application. This material is a nonionic water-soluble polymerizing agent called hydroxyetheylcellulose (HEC), also known as Natrosol®. This material is available in a wide range of viscosities and is easily mixed with water. Because of the particular requirements of our project (immersion of a fragile probe into the material to measure the electric field), we needed a liquid or semi-liquid form of tissue equivalent materials. All recipes presented here are for semi-liquid materials (except for castable bone) which have viscosities in the range of 15,000–25,000 mPa. However, by increasing the amount of HEC one can obtain a more solid form of the materials with the same electrical properties.

The other components of the muscle material were sodium chloride (NaCl), to increase conductivity, and sucrose to lower the dielectric constant. One other component, a bacteriacide, was also added to prevent breakdown of the polymer by bacterial agents. The bacteriacide used was Dowicil 75®[1 (3-chloroallyl)-3, 5, 7-triaza-1-azoniaadamantane chloride]. Sucrose is available in the form of cane sugar and is much cheaper than polyethelene powder used in previous formulas. See the Appendix for a list of suppliers. Table 1A gives the proportions by weight for each of the materials, and Table 2 lists the dielectric constants and the conductivities in mS/cm at several selected frequencies. Figure 1 shows the dielectric constant and the conductivity for simulated muscle material as well as expected values based on data from several sources [Hart, 1985; Stuchly and Stuchly, 1980; Foster et al, 1985; Pethig, 1984; Durney et al, 1978]. The measured dielectric constants are shown as circles, crosses depict the measured conductivities, solid lines present the expected dielectric constant, and dashed lines the conductivity.

Brain Tissue

The properties of brain tissue [Foster et al, 1979] are similar to those of skeletal muscle and the same components are used to produce brain equivalent material. Most of the brain consists of both grey and white matter with grey material having a higher dielectric constant and conductivity than white matter. The formula that is presented here will give properties averaged between those of white and grey matter. The recipe is presented in Table 1A, and frequency characteristics are shown in Figure 2 and in Table 2.

Lung Tissue

The lungs also have been identified as a part of the human body that has properties significantly different from skeletal muscle. It is, however, a complex structure that has different properties depending upon whether the lungs are inflated or deflated [Surowiec et al. in press]. In order to provide the best simulation an average was taken of these two states.

The basis of the lung simulation is the same as the skeletal muscle, as described above, but with the addition of hollow silica microspheres that range in diameter from 30–180 μm with a wall thickness of about 1.5 μm. This size is of the same order as the aveoli in the human lung, which is in the range of 100–200 μm in diameter. The skeletal muscle material is mixed with the microspheres by volume in a ratio of 47%