

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM  
(Second Group)**

**TITLE:** SONOCINE SONOMAMMOGRAPHY

**PROTOCOL NO.:** 2  
WIRB® Protocol #20040464

**SPONSOR:** SonoCine, Inc.  
Venice, California  
United States

**INVESTIGATOR:** Gary L. Wood, M.D., M.S.  
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Albuquerque, New Mexico 87109  
United States

**SITE(S):** Radiology Associates of Albuquerque, PA  
Suite 150  
4411 The 25 Way NE  
Albuquerque, New Mexico 87109  
United States

**STUDY-RELATED**

**PHONE NUMBER(S):** Gary L. Wood, M.D., M.S.  
505-332-5800

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**Nature and Purpose of the Study:**

You are being asked to participate in a clinical research study to determine if automated whole breast ultrasound is useful in combination with mammography in finding breast cancer in women who have no breast lumps or other clinical signs or symptoms of breast cancer.

You had a mammogram about 6 months ago, the information obtained from this research study will be in addition to the information from the mammogram. You are also being asked to have another screening mammogram in about 6 months from now (at the expected time of your annual

mammogram). At that time you will answer some questions concerning your breast health during the six months following the automated ultrasound.

**SonoCiné Study Procedure:**

Today you will have an automated breast ultrasound as follows:

You will be asked to put on a camisole and lie face-up on an examining table. You will be turned a little bit up on your side and a lumbar sponge placed under your back so that you can rest comfortably during the test. You will also be asked to place your hand above or behind your head. A four-inch soft solid gel pad will be placed on each nipple and covered with liquid gel under the camisole. Then the breast that is turned up will be covered with warm gel through the camisole.

A motor driven carrier containing an ultrasound probe will pass over your breast from top to bottom. The motor driven carrier for the ultrasound probe is an experimental (investigational) device that is not approved for general use. An investigational device is one which is not cleared for marketing by the U.S. Food and Drug Administration (FDA).

The probe will press lightly on the camisole and your breast. The pressure is much less than with a mammogram. The probe will begin along your side and will make about 4 to 6 passes from the top of your breast to the bottom as it moves toward your breastbone. Once your breast has been imaged completely, the same procedure will be repeated with the other breast.

The entire procedure should take about ½ hour. Although breast ultrasound is used for evaluation of breast lumps, this procedure is considered experimental because it is being performed to evaluate ultrasound as a screening tool.

Your whole breast ultrasound will be reviewed within 1 week by one of the study doctors and a report will be given to your personal doctor. A letter will be sent to you if the test is normal. If any abnormality is found that requires further evaluation, you will be contacted directly.

**Risks:**

As a result of this study your breasts will be exposed to ultrasonic vibrations. There are no known risks from these vibrations. They are presently used in many medical imaging studies including diagnostic studies of the breasts. Ultrasonic vibrations are used in imaging the fetuses of pregnant women. An approved ultrasound gel is used on your skin to transmit the ultrasound waves to and from your breasts. A skin allergy could occur from this gel, but the risk is less than 1%.

There is a chance that the screening breast ultrasound will be falsely positive. This means that the test could suggest that you have breast cancer when in reality you do not.

If you are called back for an ultrasound finding that is subsequently shown not to be a cancer, you may have further expense for evaluation of this finding. You may even need to have a needle biopsy to determine that the lesion is benign.

There may be risks or side effects which are unknown at this time.

The risks to an embryo, fetus or infant from exposure to the study device are unknown. Pregnant women or nursing mothers cannot participate. If you suspect that you have become pregnant while participating in the study, you are to contact the study doctor immediately.

**New Findings:**

You will be told about any new information that might change your decision to be in this study.

**Benefits:**

This study is being performed to determine if whole breast ultrasound can identify a significant number of breast cancers before they can be seen by mammography. If this hypothesis is true, and you presently have a cancer not visible on your most recent mammogram, you may benefit from early detection by ultrasound. However, this is an unproven procedure and it may not benefit you.

Results from this research study may help develop a way to identify breast cancer by routine use of screening breast ultrasound in the future.

**Cost to Subject:**

Because this is a self-funded study, it will cost you up to \$300.00 for the automated breast ultrasound and is not covered by health insurance. Both mammograms, which will be due about 6 months after this SonoCiné examination, will be charged to you at the usual rate for the Radiology Associates of Albuquerque, PA. You or your insurance company will be responsible for the cost of this screening mammogram, as usual. Screening mammograms are covered by most health insurances. Your health insurance company may or may not pay for these charges.

If the whole breast ultrasound or the screening mammogram about 6 months from now, finds an abnormality, you and/or your insurance company will have the responsibility for the expense of further imaging and/or needle biopsy.

**Payment for Participation:**

You will not be paid to be in this study.

**Alternatives to this Study:**

This is not a treatment study. Your alternative is not to participate in this study.

The standard of care for breast cancer screening is to have routine mammography screening. Other alternatives such as contrast MRI (use of a magnetic field to produce an image) can be discussed with your study doctor.

**Compensation for Injury:**

No injuries are anticipated from this study. No provision has been made for compensating you in case of injury.

**Source of Funding:**

Funding for this research study will be provided by SonoCiné, Inc. and money collected from subjects.

**Authorization To Use And Disclose Information For Research Purposes:**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

**What information may be used and given to others?**

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Records about the study device

**Who may use and give out information about you?**

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

**Who might get this information?**

Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The Western Institutional Review Board® (WIRB®)

**Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In

addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

**What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

**Questions:**

For answers to any questions about this study, about your results, or if at any time you feel you have experienced a research-related injury, contact the study doctor:

Dr. Gary L. Wood  
Radiology Associates of Albuquerque, PA  
Suite 150  
4411 The 25 Way NE  
Albuquerque, New Mexico 87109  
505-332-5800

or

If you have any questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, Washington 98502  
Telephone: 1-800-562-4789

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**Voluntary Participation/Withdrawal:**

In order to participate in the study you agree that we may keep the original mammograms used in this study. If needed, duplicates of the original mammograms will be made available to you at no charge.

Participation in this study is voluntary, and refusal to participate will not result in any penalty or loss of benefits to which you are entitled. You may withdraw from the study at any time without penalty or loss of benefits to which you are entitled. Unless you withdraw from the study, you grant us permission to find out the results of the further evaluations of any abnormality found by the mammograms and/or the ultrasound.

You may be withdrawn from the study without your consent, if you refuse to get a screening mammogram about 6 months after your SonoCiné.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

Up to 32,000 women, similar to you, will participate in this study.



**Commercial Issues:**

You shall have no right, title or interest in any product, patent or outcome arising from or in connection with this research and shall make no claim regarding any results from this research.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form.

**Consent:**

I have read the above information concerning the SonoCiné Breast Ultrasound Study (or it has been read to me). I have had the opportunity to ask questions about the study's procedures as well as any inconveniences, hazards and adverse (bad or harmful) effects. All of my questions have been answered.

I voluntarily consent to participate in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

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Signature of Subject	Date	Time
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I, the undersigned, have fully explained the relevant details of the study to the subject named above.

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Signature of Person Conducting Informed Consent Discussion	Date
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Signature of Investigator or Facility Employee (if different from above)	Date
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----- Use the following only if applicable -----

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

\_\_\_\_\_  
Signature of Impartial Witness

\_\_\_\_\_  
Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.