Title of Research Study: RAPID: a comparison study of a novel ultrasound device for automated congenital heart imaging

Investigator Team Contact Information: *Dr. Gwenyth Fischer*

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Gwenyth Fischer, MD Investigator Departmental Affiliation: Pediatric Critical Care Medicine Phone Number: 612-626-6678 Email Address: fisch662@umn.edu	Study Staff (if applicable): Ethan Beltrand Phone Number: 612-626-6982 Email Address: beltr113@umn.edu

If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: The University of Minnesota

Key Information You Should Know Before Agreeing to Participate

The information below will help you learn about this research study and decide if you want to join. Make sure to read the whole consent form or have someone read it with you. If you have any questions or don't understand something, ask the researcher or study team before you sign the consent form.

What is this study about?

Currently, infants and children seen at small or rural hospitals may not have immediate access to an Echocardiogram or "ECHO" (images of the heart taken with ultrasound) performed by an expert tech who has trained in congenital heart disorders. This can cause a delay in diagnosis of critical congenital heart disorders in children which may affect their outcome.

The purpose of this study is to test the RAPID device as a screening tool of the pediatric heart compared to the gold standard echocardiogram performed by an expert. This device is not approved by the FDA. This study may benefit future infants and children who are initially seen in hospitals without access to a congenital heart ECHO expert. The goal is to help these patients get diagnosed quickly, so that they can get treated faster.

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

Why am I being asked to take part in this research study?

We are asking you and your child to take part in this research study because you are the parent of a child who is scheduled for an echocardiogram (ECHO) or have already received an ECHO in the last 3 months. We are looking to compare the image taken of your child's heart (echocardiogram) as standard of care to another portable device created by a company called Bloom Standard (RAPID Device). We are comparing the two to see if the portable RAPID device is as reliable at initial diagnosis as a standard of care echocardiogram (ECHO) which is currently the gold standard for cardiac imaging. The images of the heart will be put into a database for the University of Minnesota study staff to access. The comparison of the image database will allow researchers to understand the feasibility of the RAPID device as a future screening method.

What are the risks I should know about?

The RAPID device is safe to use on children. Your child may be uncomfortable while having the image collected due to having to sit still while the device is collecting the image. To help prevent this, we will have the images taken in the same room as the echo is performed or in their room while they are in the hospital.

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will this study benefit me or others?

- There are no benefits to you or others by participating in this study.

How is research different from clinical care?

- The goal of research is to learn new things to help people in the future.
- Researchers follow the same plan with many participants and usually don't change that plan for one research participant.
- By volunteering for a research study, you might or might not be helped personally.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Voluntary Participation and Right to Stop at Any Time

- You get to decide whether you participate or not.
- You can decide not to participate.
- You can say yes at first and then change your mind at any time.
- If you decide not to participate or to leave the study, it won't change your relationship with your doctors or the medical care you receive.
- If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

How long will the research last?

We expect that your child will be in this research study for a one-time visit taking no longer than 5 minutes of imaging being collected.

What will I need to do to participate?

To participate in this study, we ask that we scan your child's chest using he Bloom Standard Rapid device either at your ECHO appointment or while they are in the hospital and have already had an echo within the last 3 months.

What happens if I do not want to be in this research?

- There are no known alternatives, other than deciding not to participate in this research study.

Will it cost me anything to participate in this study?

- It will not cost you any money to participate in this study.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

More Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect up to 50 children will be in this research study at the University of Minnesota Masonic Children Hospital and Cardiac Clinic.

What happens if I say "*Yes, I want to be in this research*"?

After you consent, we will use the RAPID device either before or after your child's scheduled echocardiogram to capture an additional image of your child's heart. Your child's RAPID image will be captured either by the echo tech performing your child's ECHO or trained study staff in your child's room at the hospital. The RAPID should take less than 5 minutes to complete.

You child's echocardiogram and RAPID images will be de-identified and compared and reviewed to learn the feasibility of this devices image by a cardiologist.

What happens if I say "Yes", but I change my mind later?

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)). This information will also be shared with our sponsor, Bloom Standard. The Food and Drug Administration may also inspect the study records.

We may publish the results of this research or share the resulting data. However, we will keep your name and other identifying information confidential.

If you agree to participate in this research study, a signed copy of this consent document and the HIPAA authorization form *may* be filed in your electronic medical record (EMR) and your study participation *may* be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

What will be done with my data and specimens when this study is over?

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Whom do I contact if I have questions, concerns or feedback about my experience?

If you have questions later regarding the study or your participation, you are encouraged to contact the research team. Please see the "Investigator Contact Information" section at the beginning of this form.

A description of this clinical trial will be available at https://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include your name or any other direct identifiers such as your contact information. The website may include a summary of the results of this research. You can search this website at any time.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB which is part of the Human Research Protections Program (HRPP). If there is an issue you would like to discuss with someone who is *not* on the research team you are encouraged to call the HRPP Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. For example:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to provide feedback about this research to someone who is not on the study team.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Optional Research Activities:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. The investigator will share these recordings broadly for these purposes and my identity may be shared as part of this activity.

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

Signature Block for Parental Permission:

Your signature documents your permission to allow your child to take part in this research. You will be provided a copy of this signed document.

_____

Printed Name of Child

_____ _____

Signature of Parent Date

_____

Printed Name of Parent

_____ _____

Signature of Person Obtaining Parental Permission Date

_____

Printed Name of Person Obtaining Parental Permission

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information
☐ The participant is visually impaired
☐ The participant is non-English speaking
☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970

For the Consent of Non-English Speaking Participants when a Professional Interpreter is Used:
A**s** someone who understands both English and the language spoken by the participant, I represent that the English version of the consent form was presented orally to the participant in the participant's own language, and that the participant was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Professional Interpreter:
As someone who understands both English and the language spoken by the participant, I represent that the English version of the consent form was presented orally to the participant in the participant's own language, and that the participant was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual

Approved for use by UMN IRB
Effective on 3/27/2025
IRB Study Number: STUDY00020970