Informed Consent Form

Participant Information Sheet

Protocol Title	Consistency Study of Multiple Measurement Methods for Left Diaphragmatic Excursion in Critically Ill Patients
Principal Investigator at This Center	Liu Kai
Sponsor	Zhongshan Hospital, Fudan University
Version / Date	V1.1 / January 8, 2026

Dear Participant,

You are being invited to participate in the study entitled "Consistency Study of Multiple Measurement Methods for Left Diaphragmatic Excursion in Critically Ill Patients," supported by Zhongshan Hospital, Fudan University. Please read this informed consent form carefully and consider whether you wish to participate. Participation is entirely voluntary. As a participant, you must provide written informed consent before joining the study. When your study doctor or study staff discuss this form with you, you may ask them to explain anything that is unclear. We encourage you to discuss participation fully with your family and friends before making a decision. You have the right to refuse participation or to withdraw at any time without penalty and without losing any rights or benefits to which you are otherwise entitled. If you are currently participating in another study, please inform your study doctor or study staff. The background, purpose, procedures, and other important information about this study are described below.

1. Background

The diaphragm is the main muscle of respiration and contributes approximately 60%-80% of the work of breathing during active inspiration in healthy individuals. Diaphragmatic disuse atrophy, phrenic nerve conduction impairment, and related factors can greatly affect respiratory function. In patients with unilateral or bilateral muscle weakness (such as stroke, phrenic nerve injury, or severe limb trauma), diaphragmatic function may decline to varying degrees because of immobility and nerve injury.

Traditional methods for evaluating diaphragmatic structure and function, such as computed tomography, chest radiography, and transesophageal transdiaphragmatic pressure monitoring, are limited by invasiveness and complexity. In recent years, ultrasound evaluation of diaphragmatic function has received increasing clinical attention. By dynamically measuring diaphragmatic excursion during breathing, ultrasound provides important information for assessing diaphragm function and guiding rehabilitation. Diaphragm ultrasound is noninvasive, convenient, and repeatable, and is increasingly accepted in intensive care, emergency medicine, rehabilitation, and respiratory medicine.

However, ultrasound examination of left diaphragmatic excursion is difficult because the left side is affected by the stomach, bowel gas, and lung air. At conventional ultrasound scanning sites, obtaining images of the left diaphragm and measuring movement during breathing can be challenging. Some authors have therefore proposed using right diaphragmatic function to represent overall diaphragm function, but this is not suitable in patients with bilateral asymmetry or unilateral surgery.

Based on long-term clinical practice and previous research, this study uses multiple measurement methods to improve bilateral diaphragm ultrasound techniques and clinically evaluates the accuracy of these modified methods for measuring diaphragmatic excursion, with the aim of developing additional practical assessment methods.

2. Study Purpose

This study will use ultrasound to measure bilateral diaphragmatic indices in critically ill patients, focusing on the left diaphragm, to evaluate the agreement and reliability among multiple ultrasound measurement positions for assessing diaphragmatic excursion.

3. Study Procedures

3.1 How many people will participate? Approximately 35 patients will participate in this study at our hospital. Each participant will be assigned a study number and a case report form will be created.

3.2 What will happen if you agree to participate? If you agree to participate, we will collect your vital signs such as heart rate and blood pressure from the bedside monitor and use ultrasound to measure diaphragmatic movement. No extra blood will be drawn and no other additional examinations will be performed specifically for this study.

The study mainly includes two phases: (1) Screening phase: after you sign the consent form, we will collect information such as your age, sex, and current mode of respiratory support. (2) Examination phase: we will collect general health information such as height, weight, and diagnosis, but will not record personal identifiers such as your name or hospital admission number. An experienced ultrasound physician who is not involved in your clinical decision-making will then perform bedside ultrasound. During the examination you will remain in a semi-recumbent position. Both the left and right diaphragm will be measured, and all images will be stored and reviewed again by an expert team.

Important note on grouping: this is an observational study. For analysis, you will be classified according to the respiratory-support status already in use before measurement: (i) invasive ventilation group (patients intubated or tracheostomized and connected to a ventilator); or (ii) non-invasive group (patients receiving non-invasive mask ventilation, conventional oxygen therapy, or in a tracheostomy weaning state). Grouping is for data analysis only and will not change any of your current treatment.

3.3 How long will participation last? The overall study is expected to last about 2 years. For you personally, participation will last about 30 minutes. You may withdraw at any time without losing any benefits to which you are otherwise entitled. However, if you decide to withdraw during the study, we encourage you to discuss it first with your doctor. If a serious adverse event occurs, or if your study doctor believes continued participation is not in your best interest, he or she may decide to withdraw you from the study. The sponsor or regulatory authorities may also terminate the study during its course. Your withdrawal will not affect your normal medical care or rights.

3.4 Biological samples: this study does not involve collection of biological samples.

4. Risks and Benefits

4.1 What are the risks of participating? Ultrasound examination in this study is a routine clinical procedure. The widespread use of ultrasound in medicine is based on its controllable risk profile. Diagnostic ultrasound uses very low energy, and decades of application have demonstrated its safety even in pregnant women and fetuses. Therapeutic ultrasound uses higher energy in controlled settings, but this study involves only diagnostic ultrasound. In summary, when performed by trained professionals under proper standards, the risks of ultrasound are known and controllable, and its safety profile is favorable compared with many other physical or chemical methods.

If you experience any discomfort, any new change in your condition, or any unexpected event during the study, whether or not it is related to the study procedure, you should notify your doctor promptly so that appropriate evaluation and treatment can be provided.

4.2 What are the benefits of participating? Direct benefit: participation may allow direct monitoring of your breathing effort and may help clinicians identify appropriate training or prevent excessive respiratory fatigue earlier, although this cannot be guaranteed. Potential benefit: the information obtained from your participation may help you or other patients with similar conditions in the future.

5. Alternative Options

This study only collects your information and examination data. You may choose not to undergo ultrasound for research purposes and instead use other examinations such as CT or electromyography as alternative clinical options, if appropriate.

6. Confidentiality of Personal Information

During the study, the research team may need to access your medical history and collect necessary prior medical records and test results for study purposes. By signing this informed consent form, you authorize the research team to contact other healthcare providers involved in your care to obtain necessary medical information related to services they provided to you. Only members of the research team will have access to your medical information and be able to identify you. Without violating confidentiality principles and applicable regulations, the ethics committee and health or drug regulatory authorities may review your original medical records to verify the study.

During the study, we will collect your medical history, laboratory and imaging results, and follow-up information. To protect your privacy, part of your information will be coded; personal identifiers such as your name, date of birth, and address will be replaced with a unique study code so that others cannot identify you. Personal information collected or generated during the study and the study data will be stored in coded form and kept at Zhongshan Hospital, Fudan University for 5 years before destruction. If the study results are published in medical journals or presented at scientific meetings, no information that could identify you will be disclosed.

You may withdraw your authorization for the use and sharing of your personal information at any time by contacting your study doctor. If you do so, you will no longer be able to remain in the study. After that point, investigators will not collect any new identifiable health data from you. However, health data already collected may continue to be used and shared with other researchers as described in this form. To ensure scientific integrity and reliability, you may not be able to review some study-related records until the study is completed. After the study ends, you may ask the study doctor to review the health data collected during the study and may request correction of any errors in your personal information.

Your information will not be reused for purposes beyond this study.

7. Feedback of Study Results

The results of the standard and modified measurements of diaphragmatic excursion will be fed back to the patient regarding their correlation. The overall study results, without your personal information, will be made publicly available after study completion on the Chinese Clinical Trial Registry website. You may search for them yourself.

8. Costs and Compensation

8.1 Cost of study procedures: Participation in this clinical study will not create any extra out-of-pocket expenses for you. The respiratory support you receive is part of routine clinical care and its cost is borne by you in the usual way. Any additional ultrasound procedures required by the study will be provided at no cost to you. Treatment and examinations for other coexisting diseases are not included in this free-of-charge scope.

8.2 Compensation for participation: This study does not impose additional burden on you; therefore, no financial compensation will be provided.

8.3 Compensation for injury: If any study-related injury occurs, you may receive free treatment from Zhongshan Hospital, Fudan University or compensation in accordance with applicable Chinese laws.

9. Participant Rights and Important Notes

9.1 Your rights: Your participation is voluntary throughout the entire study. If you decide not to participate, it will not affect any other treatment you should receive. If you choose to participate, you will be asked to sign this written informed consent form. You have the right to withdraw from the study at any stage without discrimination or unfair treatment, and your medical care and rights will not be affected. If updated information arises that may affect your rights or safety, you will be asked to sign an updated version of the informed consent form to acknowledge receipt of the new information.

9.2 Important notes: As a participant, you need to provide truthful information about your medical history and current health status; report any discomfort discovered during the study; avoid taking any drugs or foods that the doctor has told you are restricted; and inform the study doctor whether you have recently participated in another study or are currently participating in another study.

10. Contact Information

If any important new information arises during the study that may affect your willingness to continue participation, your doctor will inform you promptly. If you have any questions about your study data, or if after the study you would like to know the findings, you may raise questions at any time and receive appropriate answers. Please contact Yaxiarjiang Muhetar at 15021891200.

The study has been reviewed and approved by the Ethics Committee. If you have any questions related to your rights and interests, wish to report difficulties, dissatisfaction, or concerns encountered during participation, or would like to provide comments or suggestions about the study, please contact the Medical Ethics Committee of Zhongshan Hospital, Fudan University, telephone: 021-31587871; email: ec@zs-hospital.sh.cn.

Signature Page

Consent Statement: I have been informed of the purpose, background, procedures, risks, and potential benefits of this study. I have had sufficient time and opportunity to ask questions, and I am satisfied with the answers. I have also been informed whom to contact if I have questions, wish to report difficulties or concerns, provide suggestions about the study, seek further information, or offer assistance to the study.

I have read this informed consent form and agree to participate in this study. I understand that I may choose not to participate, or I may withdraw from the study at any time during participation without giving any reason.

I understand that if my condition worsens, if I experience a serious adverse event, or if my study doctor believes continued participation is not in my best interest, he or she may decide to withdraw me from the study. The sponsor or regulatory authorities may also terminate the study during its course without my additional consent. If that happens, the study doctor will inform me promptly and discuss other options with me.

I will receive a copy of this informed consent form containing my signature and the investigator's signature. I understand that participation requires the use of my personal information, and I agree to its use and processing for the purposes described in this informed consent form.

Agree **Disagree (cannot participate in this study).**

Participant signature: _____ Date: _____

Guardian signature: _____ Relationship to participant: ( ) Date: _____

(Applicable when the participant lacks or has limited capacity for civil conduct.)

Impartial witness signature: _____ Date: _____

(Applicable when the participant cannot read this informed consent form. The witness confirms that the investigator has explained all contents of the informed consent form to the participant, that the participant has expressed willingness to participate, and that the witness signs and dates accordingly.)

Investigator signature: _____ Date: _____

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