Standards and Guidelines for Suboptimal Imaging

Summary for Use of Contrast Agents

With Extracts from:

IAC Standards and Guidelines for Adult Echocardiography Accreditation
Contents

This document includes all material related to the use of contrast agents as found in IAC's Standards and Guidelines for Adult Echocardiography Accreditation, and retains the original nomenclature. In addition, it includes a written protocol template for the use of contrast agents in laboratories and other facilities, which is called for in the IAC Guidelines but for which no template is provided.

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Section 3A: Examination Reports and Records

3.4A  **Adult Transthoracic Echocardiogram Report Components**

3.4.1A The report must accurately reflect the content and results of the study. The report must include, but may not be limited to:

3.4.1.3A Report text must include comments on:

i. left ventricle (LV size, ejection fraction and regional dysfunction, if present)
   (See Guidelines on Page 16 for further recommendations);

ii. right ventricle (size and function);

iii. right atrium;

iv. left atrium;

v. mitral valve;

vi. aortic valve;

vii. tricuspid valve;

viii. pulmonic valve;

ix. pericardium; and

x. aorta.

Comment: If any structure is not well visualized this must be noted. The overall assessment and the report text must be consistent with the quantitative data. Where appropriate, this must include localization and quantification of abnormal findings.
Section 1B: Adult Transthoracic Echocardiography Testing

STANDARD - Components of the Transthoracic Echocardiogram

1.6B Transthoracic echocardiograms must be comprehensive and include standard components.

1.6.3B Use of Contrast for Suboptimal Image Quality - Contrast is indicated for use when two contiguous segments are not visualized in any three of the apical views (poor endocardial border definition) as it provides greater accuracy in determining left ventricular function.

If contrast is used, there must be a written policy for the use of contrast agents. (See protocol template below.)

If contrast is not able to be used there must be a policy for alternative imaging.

Comment: Poor endocardial border definition is defined as the inability to detect two or more contiguous segments in any three of the apical views.

Section 1B: Adult Transthoracic Echocardiography Testing

Guidelines

1.1.1B Cardiac Ultrasound Systems

Instrument settings to enable optimization of ultrasound contrast agents. There should be a system setting to display low frequency Doppler filtering for tissue Doppler display.

1.2B A facility should perform a minimum of 600 echocardiograms annually. Each member of the medical staff should interpret a minimum of 300 studies annually. Each member of the technical staff should perform a minimum of 300 studies annually. The total volume of studies interpreted and performed by each staff member may be combined from sources other than the applicant facility. Lower volumes than those recommended here, however, should not dissuade a facility that is otherwise compliant with the IAC Echocardiography Standards from applying for accreditation.

1.4.3B A routine study on an inpatient should be performed on the same working day as ordered, unless otherwise specified. Outpatient studies should be assigned priority as defined by the referring physician and/or the indication of the study.
1.6.1B For all imaging protocols, if any required view or Doppler signal cannot be adequately obtained, it should be recorded and labeled in order to demonstrate that it was attempted.

1.6.2.3B Doppler flow evaluations:

Tissue Doppler, strain, strain-rate are optional Doppler studies
Contrast studies are not required but should be considered when patients are technically difficult
LV diastolic function should be evaluated through a combination of PW and tissue Doppler techniques.

1.6.3B Contrast should be used in the presence of poor endocardial border definition for quantification of chamber dimensions, volumes, ejection fraction and assessment of regional wall motion.

Contrast should also be used to assess conditions such as hypertrophic cardiomyopathy or when left ventricular thrombus is suspected.

Section 2B: Adult Transesophageal Echocardiography Testing

**STANDARD - Components of Transesophageal Echocardiograms**

2.8.7B The complete examination must include the following standard views while allowing for patient tolerance and safety:

2.8.7.8 in cases of suspected cardiac source of emboli, appropriate use of contrast methods to evaluate for the presence of intracardiac shunting;

Section 3B: Adult Stress Echocardiography Testing

**STANDARD - Indications, Ordering Process and Scheduling**

3.5.2B Definition of Procedure Types
3.5.2.5B Contrast agents may be used in conjunction with treadmill, bicycle, pacing or pharmacological stress to optimize endocardial border definition or enhance Doppler signals.

STANDARD - Techniques

3.7B Examination performance must include proper technique.

2.7.1B Elements of study performance include, but are not limited to:

2.7.1.5B Contrast is indicated for use when two contiguous segments are not visualized as it provides greater accuracy in determining left ventricular function. Contrast must be used if this is not accomplished with harmonic optimal imaging;

STANDARD - Stress Echocardiogram Components

3.9B Stress echocardiograms must be comprehensive and include standard components.

3.9.1B Components of the Examination - Separate protocols must be in place that defines the components of each type of stress echocardiograms performed in the facility. Indications for the performance of a pharmacologic stress echocardiogram and/or a standard exercise stress echocardiogram must be included.

Comment: Alternate views may be obtained if contrast is used.

3.9.1.4B Contrast Stress Echo: Facilities using contrast must have a written protocol for use of contrast agents for stress echocardiography (See template below.)

Section 3B: Adult Stress Echocardiography Testing

Guidelines

3.1.1B Cardiac Ultrasound Systems

Instrument settings to enable optimization of ultrasound contrast agents. There should be a system setting to display low frequency Doppler filtering for issue Doppler display.
Protocol for the Use of Contrast Agents

In accordance with IAC Standards and Guidelines for Adult Echocardiography, sonography laboratories and other facilities administering contrast agents are required to maintain a written protocol for their use.

The following is a generic template for a written protocol. Procedures for administering the contrast agents, Definity and Optison vary slightly and full details may be viewed at the links provided below.

Draft informed consent forms for Intravenous Contrast Administration and Stress Echo procedures are also included below.

Hospital Cardiovascular Ultrasound Laboratory

Optison/Definity Protocol Template

Subject: Echocardiography Definity/Optison Policy and Procedure

Scope: Definity/Optison Contrast Echocardiography impacts:

Cardiovascular Services – Sonographers and Nurses

Cardiologists

Purpose: Cardiac imaging, ultrasound — Contrast-enhanced imaging utilizing Definity or Optison microsphere preparations are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and improve the delineation of the left ventricular endocardial borders and can be used during Exercise Stress, Dobutamine Stress, Resting Echocardiograms and Transesophageal Echocardiograms

Policy:

Criteria for Optison/Definity Usage

Basic Criteria may include, but are not limited to the following:

1. Transthoracic echo with suboptimal image quality; where two or more contiguous segments are not visualized in any of the three apical windows, and to provide greater accuracy in determining left ventricular function.

2. Transthoracic echocardiogram to assess hypertrophic cardiomyopathy or when left ventricular thrombus is suspected.

3. Stress echocardiogram either exercise or pharmacologic may be used to optimize endocardial border definition.
4. **Contraindications:** Definity/Optison should not be administered to patients with the following:

- Known hypersensitivity to Perflutren (Definity/Optison) blood, blood products or albumin
- Patients with known or suspected cardiac shunts
- By direct intra-arterial injection

5. **Comments:**

Pregnant or Nursing - Definity/Optison should be used during pregnancy only if clearly needed and the potential benefit justifies the potential risk to the fetus. Because many drugs are excreted in human milk, caution should be exercised when administered to a nursing woman, and nursing mothers should pump and discard breast milk once after treatment.

Should the sonographer or nurse have any question regarding the use of Definity/Optison, they should contact the cardiologist prior to using ultrasound contrast agents.

**Procedure:**

**Supplies:**

- 1 vial of Definity/Optison
- 2, 10 cc syringes prefilled with bacteriostatic 0.9% saline solution
- Alcohol prep pads
- 2 #16 gauge needles
- If necessary, start IV kit with 20 gauge needle or larger.

1. The sonographer will need to communicate the reason for the need for contrast ultrasound agents. The patient may refuse the use of these enhancement agents.

2. The sonographer or RN will wash their hands prior to preparing the Definity/Optison.
3. The RN will start IV access if necessary. If the patient has IV access, flush with saline to check for patency.

4. The sonographer or RN will remove the vial of Definity or Optison from the refrigerator. For Definity the vial is to be placed in the Vialmix mechanical agitator to suspend the microspheres. For Optison, the vial should be gently rolled between the hands for 10-15 seconds until the vial is white appearing.

5. Insert one 16 gauge needle into the vial of Definity to vent.

6. Open one of the 10 cc syringes and waste 2 cc of saline solution. Attach a 16 gauge needle to the syringe.

7. Wipe the top of the Definity/Optison vial with an alcohol prep pad and draw up the full vial.

8. Use the alcohol prep pad to scrub the hub of the IV access.

9. Gently rotate and invert the Definity/Optison solution if necessary to re-suspend the microspheres.

10. Attach the syringe containing the Definity/Optison to the IV hub. Slowly push approximately 2-3 cc of the Definity/Optison at a rate of approximately 1 cc per 20-30 seconds. Dose to be determined by the sonographer.

11. The sonographer will acquire appropriate images. Repeat contrast administration at the sonographer’s discretion.

12. When all images have been captured, flush the IV using the other syringe of saline.

13. When complete, dispose of the Definity/Optison solution syringe in the black sharps container and dispose of the saline syringe in the red sharps container.

References:
1. INTRAVENOUS CONTRAST ADMINISTRATION WITH *(name of contrast agent to be used)* INFORMED CONSENT FORM

Your doctor has scheduled you for an echocardiogram. This test may require an injection of a contrast agent. The contrast agent, *(product name)* is necessary to address specific questions and help the cardiologist interpret your study.

*(Contrast agent name)* is FDA approved. It is different from x-ray contrast agents and does not contain iodine. Common side effects include transient lower back discomfort or flushing that resolve within minutes. Rarely, a more serious reaction may occur (1 out of 10,000 injections). The healthcare providers working with you today are trained and equipped to assist you promptly should any problem occur. The physicians at Cardiovascular Consultants are aware of the very small risk of complication and feel that the diagnostic information to be obtained outweighs any potential risk. We take every precaution to follow the guidelines for use set forth by the FDA to ensure safety.

I, ________________________________, have read and understand the above and give consent to have an injection of *(contrast agent name)* as part of my echocardiogram evaluation.

__________________________________________  Date
Signature of Patient

__________________________________________  Date
Signature of Witness

CC MRN_________________________
I hereby voluntarily consent to engage in a monitored dobutamine stress test to determine the state of my heart and circulation. This test will be performed through IV administration of dobutamine, preceded and followed by echocardiographic imaging of my heart. I am informed that symptoms such as flushing, shortness of breath, dizziness, headache, nausea, vomiting, or chest discomfort may occur. As part of that exam, an injection of an ultrasound contrast agent may be required. The contrast agents, Definity or Optison may be necessary to address specific questions and help the cardiologist interpret your study.

Definity and Optison are FDA approved. These imaging agents differ from x-ray contrast agents and do not contain iodine. Common side effects include transient lower back discomfort or flushing that resolve within minutes. Rarely, a more serious reaction may occur (1 out of 10,000 injections). The physicians are aware of the very small risk of complication and feel that the diagnostic information to be obtained outweighs any potential risk and take every precaution to follow the guidelines for use set forth by the FDA to ensure safety.

During the test, my pulse, blood pressure, electrocardiogram and symptoms will be monitored. If I feel any discomfort, I will inform the staff immediately.

The possibility exists that certain changes may occur during the test. They include abnormal blood pressure, fainting, disturbances of heart rhythm, and very rare instances of heart attack or death. Every effort will be made to minimize these risks by the preliminary examination and by observation during the test. Emergency equipment and trained personnel are available to deal with unusual situations, should they arise.

The information that is obtained will be treated as privileged and confidential and will not be released to any person without expressed written consent. The information obtained, however, may be used for a statistical or scientific purpose with my right of privacy retained.

I have read the foregoing and I understand the procedures involved. All questions have been answered to my satisfaction.

____________________________________________________________
Signature of Patient                                      Date

____________________________________________________________________________________
Signature of Witness                                      Date
1. **DEFINITY**

The full DEFINITY dosing and administration document may be found at:

   [http://www.definityimaging.com/how-administration.html](http://www.definityimaging.com/how-administration.html)

2. **OPTISON**

The full OPTISON Protocol and Optimization Manual may be found at:
