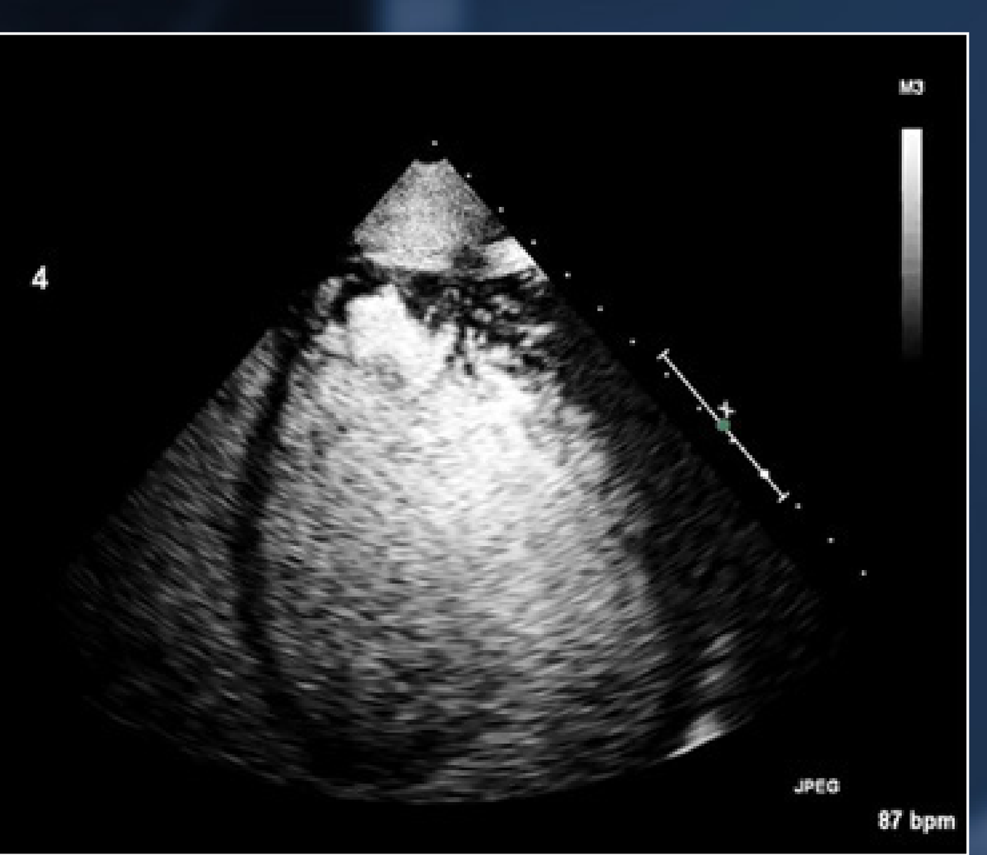
OPTISON™

(Perflutren Protein-Type A Microspheres Injectable Suspension, USP)



A clear path forward™

Please see Important Safety Information including Boxed Warning at the bottom of this piece.

Echocardiography remains central to the assessment and management of cardiac disease; however, many scans may be suboptimal[1-3]

Estimated incidence of incomplete endocardial resolution:

10-15% of routine echocardiograms[2]

25-30% of echocardiograms performed in the ICU[3]

Suboptimal echocardiograms may affect patient care through:

- Diminished diagnostic accuracy[4]
- Changes in clinical management[5]
- Additional testing[5]

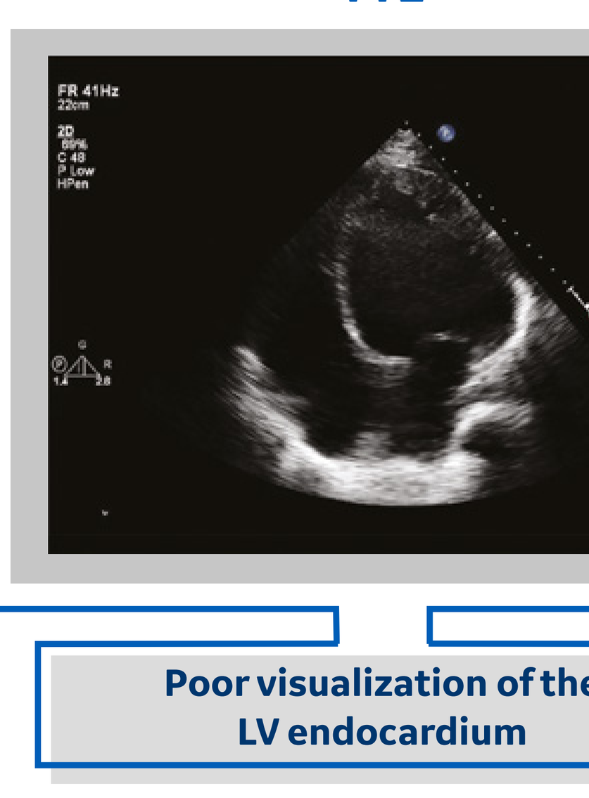
BY USING A UEA,
75-90%
OF SUBOPTIMAL ECHOCARDIOGRAMS CAN BE MADE INTERPRETABLE[4]

By enhancing image quality and workplace efficiency, Optison helps provide a clear path forward in left ventricle image enhancement

Quality

Optison can help improve visualization of the left ventricle by creating an echogenic contrast effect in the blood[6,7]

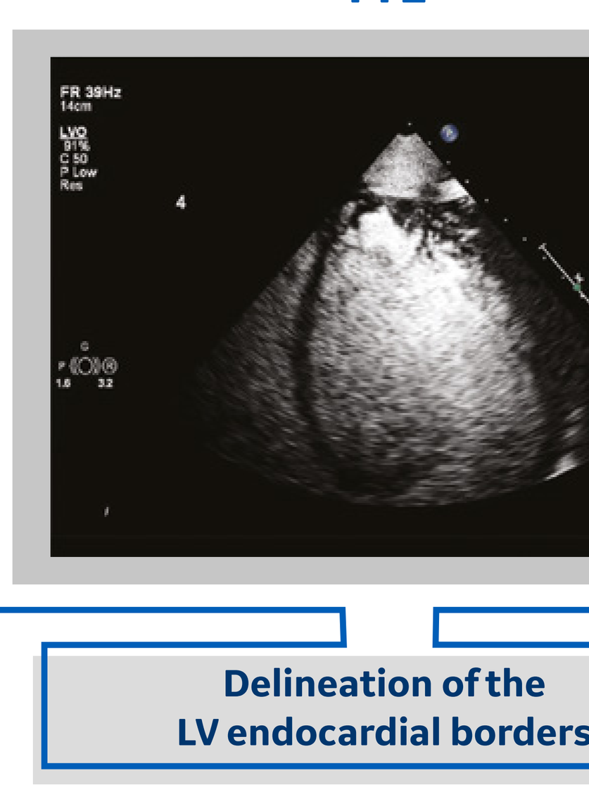
Unenhanced TTE



Poor visualization of the LV endocardium

VS

Optison-enhanced TTE



Delineation of the LV endocardial borders

By producing clear delineation of the endocardial borders, Optison may allow evaluation of LV wall motion and function and help improve diagnostic confidence[6]

Safety

Optison has a well-established safety profile with over 20 years of clinical use across multiple care settings

Most common AEs during treatment with Optison[7]

(N=279)

Optison has a boxed warning about Serious Cardiopulmonary Reactions. See full Prescribing Information for details

Headache	Nausea and/or vomiting	Warm sensation or flushing	Dizziness
5.4%	4.3%	4.3%	2.5%

<0.5% of patients who received Optison reported back pain as an AE[7]

PEG is frequently used in pharmaceutical products but may be associated with potentially life-threatening hypersensitivity reactions[8,9]

Optison is the only PEG-free UEA available in the US

Optison's safety profile is supported by multiple post-marketing clinical trials

No clinically important pulmonary hemodynamic effects in patients with normal or elevated baseline PASP[12] (N=30)

No increase in mortality in critically ill patients administered Optison vs control patients[11] (N=2,900)

No serious AEs and deaths in >1000 patients administered Optison in routine clinical practice[10] (N=1,039)

Please see Important Safety Information including Boxed Warning at the bottom of this piece.

Efficiency

Optison is portable, easily stored, and takes less than one minute from suspension to injection

Prepare – Rotate the vial in your hands for 10 seconds

Check – Inspect the vial for complete resuspension*

Load – Vent the vial, withdraw, and prepare to inject

Administer – Administer within 60 seconds of suspension

No vial mixer or special equipment required to resuspend

Optison is stable at room temperature for up to 24 hours

If unopened, Optison can be returned safely to the refrigerator for later use

*Do not use Optison after resuspension if the solution appears clear rather than opaque milky-white. Failure to adequately resuspend Optison may cause an underdelivery of the microspheres, and may result in inadequate contrast.

Support

Optison is backed by a team of sonographers, always on hand to offer clinical and commercial support

- Product inquiries
- Product trials
- CE programs
- Formulary kit
- Machine settings
- Image optimization
- Guideline recommendations
- Educational programs with insights on policies and procedures
- Reimbursement or payment questions

For medical affairs inquiries, please contact medical information at 800 654 0118 or medical.affairs@ge.com

A clear path forward

1 Quality
2 Safety
3 Efficiency
4 Support

To learn more about Optison:

Visit us online | Contact us directly

References:

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Abbreviations:

AE, adverse event
CE, continuing education
ICU, intensive care unit
LV, left ventricular
PASP, pulmonary artery systolic pressure
PEG, polyethylene glycol
TTE, transthoracic echocardiogram
UEA, ultrasound enhancing agent

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INDICATIONS AND USAGE

OPTISON (Perflutren Protein-Type A Microspheres Injectable Suspension, USP) is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and to improve the delineation of the left ventricular endocardial borders.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration
- **Assess all patients for the presence of any condition that precludes OPTISON administration**
- **Always have resuscitation equipment and trained personnel readily available**

- **CONTRAINDICATION:** Do not administer OPTISON to patients with known or suspected hypersensitivity to perflutren or albumin.
- **WARNINGS AND PRECAUTIONS:** Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following administration. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias).
- Serious anaphylactic reactions have been observed during or shortly following perflutren-containing microsphere administration, including shock, hypersensitivity, bronchospasm, throat tightness, angioedema, edema (pharyngeal,palatal, mouth, peripheral, localized), swelling (face, eye, lip, tongue, upper airway), facial hypoesthesia, rash, urticaria, pruritus, flushing, and erythema have occurred in patients with no prior exposure to perflutren-containing microsphere products.
- When administering OPTISON to patients with a cardiac shunt, microspheres can bypass filtering of the lungs and enter the arterial circulation. Assess patients with shunts for embolic phenomena following OPTISON administration.
- High ultrasound mechanical index values may cause microsphere rupture and lead to ventricular arrhythmias. Additionally, end-systolic triggering with high mechanical indices has been reported to cause ventricular arrhythmias. OPTISON is not recommended for use at mechanical indices greater than 0.8.
- This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral disease.
- **ADVERSE EVENTS:** The most frequently reported adverse reactions in clinical trials were headache, nausea and/or vomiting, warm sensation or flushing and dizziness. Cardiac arrests and other serious but nonfatal adverse reactions were uncommonly reported in post-approval use. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions.

Please see the full Prescribing Information here, including Boxed Warning, for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch