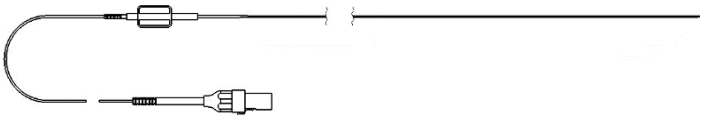
# NES Reprocessed .014 IVUS Product Famiy

**REF # R-014R .014 IVUS**
**REF # R-85900P Eagle Eye Platinum Long Tip**
**REF # R-85900PST Eagle Eye Platinum Short Tip**

# INSTRUCTIONS FOR USE



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Waterbury, CT 06704
203-756-2111
www.smarthealth-care.com

**Manufacturer:**
**Northeast Scientific, Inc.**
**2142 Thomaston Avenue**
**Waterbury, CT 06704 U.S.A.**

## CAUTION:

**1. U.S. Federal Law restricts this device to sale by or on the order of a physician.**
**2. Prior to use, read this entire package insert. For Symbol Glossary, visit www.smarthealth-care.com.**

**⚠WARNING: This product can expose you to chemicals, including Ethylene Oxide which is known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.**

## INDICATIONS FOR USE:

The Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.
The Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

## DESCRIPTION·

The Catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.
The Catheter utilizes an internal lumen that allows the catheter to track over the 0.014'' (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system. Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.
The Catheter may only be used with the Volcano s5 Series or CORE Series of Systems Operator's Manual. This catheter will not operate if connected to any other imaging system.

## CONTRAINDICATIONS·

The Catheter is generally contraindicated in situations presenting a reasonable probability of tissue or organ damage. This device is not currently indicated for use in cerebral vessels.

## ADVERSE EFFECTS:

Possible adverse effects include, but are not limited to, the following: myocardial infarction; occlusion; coronary vessel dissection; perforation, rupture or injury; restenosis; hemorrhage or hematoma; unstable angina; arrhythmias; drug reactions; allergic reaction to contrast medium; hypo/hypertension; infection; vessel spasm; arteriovenous fistula; embolism; entry puncture site bleeding; vascular wall injury; vessel thrombosis; pseudoaneurysm (at site of catheter insertion); renal failure; coronary aneurysm; vessel trauma requiring surgical repair or intervention, death.

## WARNINGS:

- Use of the Catheter should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended.
- The product is supplied sterile; if the pouch is opened or damaged compromising the sterile barrier, please discard the product. This product cannot be re-sterilized or re-used.
- The Catheter is designed for single use only.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including re-sterilization of unused product may result in, but is not limited, to the following:
    - Potential critical harm to patient due to Device Separation, Material Deformation or Infection/Sepsis
    - Failure to Image or other device malfunctions
- The catheter transducer is a delicate electronic assembly, deliberate misuse by bending, twisting or any other severe physical manipulation will void the warranty.
- Do not use the device for purposes other than those indicated.
- The device may not be safe in those patients who cannot be properly anticoagulated or who cannot receive anti-platelet or anti-coagulation therapies.

## PRECAUTIONS:

The Catheter is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

- Prior to use, carefully inspect the scanner and catheter body for bends, kinks or other damage. Do not use a damaged or suspected damaged catheter.
- Protect the catheter tip from impact and excessive force.
- Do not cut, crease, knot, or otherwise damage the catheter.
- Protect the electrical connections from exposure to fluid.
- Do not handle the transducer.
- The outside diameter along the entire length of the guide wire should not exceed the maximum specified
- During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.
- Clean guide wire and flush catheter thoroughly with heparinized saline before and after each insertion.
- When inserting the guide wire both catheter and wire must be straight with no bends or kinks, or damage to inner lumen may occur.
- Do not advance the guide wire against significant resistance. If binding occurs between the catheter and the guide wire while inside the patient, CAREFULLY REMOVE BOTH the wire and catheter and do not use. If binding occurs outside of the patient, remove the catheter and do not use.
- The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- During the procedure, provide appropriate anticoagulation to the patient as needed.

- When advancing or re-advancing the catheter over a guide wire and through a stented vessel, in the event that the stent is not fully apposed against the vessel wall, the guide wire and/or catheter may become entangled in the stent between the junction of the catheter and guide wire or within one or more stent struts. This may result in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation. Never use force to advance the catheter.
- Use caution when re-advancing a catheter over a guide wire and into a stented vessel. Forceful advancement of the IVUS catheter could cause entanglement between the catheter and the stent(s) resulting in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation.
- Use caution when removing the catheter over the guide wire from a stented vessel to minimize patient risk.
- If resistance is encountered during pull bade, remove the entire system (guide wire, IVUS catheter, sheath/guide catheter) at the same time.

## INSTRUCTIONS FOR USE:

- The Catheter may be introduced into the vascular system percutaneously or surgically and advanced to the desired location. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.
- Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
- If using VH IVUS, review the Volcano Imaging System Operator's Manual prior to use.
- Remove the Catheter from its sterile packaging when in a sterile field.
- Remove the stylet.
- Attach the flushing device to a 10 cc or larger syringe filled with heparinized normal saline. Insert the distal tip of the catheter into the device. Inject the saline into the lumen. Fluid should be observed flowing out of the Guide Wire Exit Port.
- Remove the clear/white cap from the PIM connector (if applicable).
- Connect the PIM connector of the Catheter to the Patient Interface Module as described in the Volcano Imaging System Operator's Manual. Verify that the device is imaging.
- Place the Catheter onto the intravascular guide wire which has been previously positioned into the artery. A guide wire of 0.014# (0.36 mm) or smaller can be used.
- Advance the catheter over the guide wire to the site of the vasculature to be imaged.
- Check the Monitor for an image. Once the image has been obtained, the catheter can be advanced over the guide wire to image additional segments of vasculature.
- If an image is not obtained or is not satisfactory, consult the Volcano s51M Series or CORE™ Series of Systems Operator's Manual.
- When the procedure is completed, remove and discard the catheter in accordance with local regulations.

## STORAGE AND HANDLING:

Products should be stored in a dry, dark, cool place in their original packaging.

## PRODUCT SPECIFICATIONS:

All Models-

| | |
|---|---|
| Crossing profile at transducer | Catheter 3.5F (0.046", 1.17 mm) |
| Maximum guide wire | 0.014" (0.36 mm) |
| Minimum guide catheter O.D. | 5F (0.066", 1.67 mm) |
| Minimum guide catheter I.D. | 0.056", 1.42 mm |
| Usable length | 150 cm |

| Acoustic Output Parameter | B-Mode | Chromaflo |
|---|---|---|
| $I_{SPTA.3}$ (mW/cm$^2$)* | 2.93 x $10^{-3}$ | 7.98 x $10^{-2}$ |
| $I_{SPPA.3}$ (W/cm$^2$)* | 7.5 x $10^{-3}$ | 175.0 x $10^{-3}$ |
| Pr.3 (MPa) | 20.0 x $10^{-3}$ | 81.5 x $10^{-3}$ |
| PD (µs) | 161.0 x $10^{-3}$ | 125.0 x $10^{-3}$ |
| PRF (Hz) | 53760 | 75368 |
| Center Freq (MHz) | 18.6 | 17.9 |
| MI** | 4.5 x $10^{-3}$ | 1.92 x $10^{-2}$ |
| TI** | 2.06 x $10^{-5}$ | 1.56 x $10^{-4}$ |

* Maximum overall uncertainty +33.9% / -30.5%

** As estimated in tissue

| | |
|---|---|
| **TI:** | **Thermal Index defined as TI = ($W_{01x1fc}$)/210** |
| **$W_{01x1}$:** | **Bounded-square Output (mW)** |
| **fc:** | **Center Frequency (MHz)** |
| **MI:** | **Mechanical Index defined as MI=Pr.3/($fc^{1/2}$)** |
| **$I_{SPPA.3}$:** | **Derated Intensity, Spatial Peak Pulse Average (W/cm$^2$)** |
| **$I_{SPTA.3}$:** | **Derated Intensity, Spatial Peak Temporal Average (mW/cm$^2$)** |
| **Pr.3:** | **Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)** |
| **Wo:** | **Total Power (mW)** |
| **PD:** | **Pulse Duration (µs)** |
| **PRF:** | **Pulse Repetition Frequency (Hz)** |