

CHAPTER 11 VASCULAR FUNCTION CORE: IMAGE ANALYSIS AND DATA INTERPRETATION

11.1 Personnel and Contact Information

The HFM Study Vascular Function Core is located at Boston University under the direction of Joseph A. Vita, M.D. The Technologist for the Vascular Function Core is Mai-Ann Duess, B.A.

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Address for Mailing FMD/NMD Ultrasound Images by Overnight Courier:

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Fill in Recipient Information as follows:

c/o Mai-Ann Duess, B.A.
Boston University Medical Center
Section of Cardiology
88 East Newton Street, C-818
Boston, MA 02118

- Service Type: Priority Overnight
- Package Type: FedEx Pack
- No of Packages: 1
- Weight:

- Declared Value: \$0
- Bill transportation to: **Third Party**
- Account number: 151716687
- Your reference: HFM Study
- Email Notification: Set up to send “Ship” email to mduess@bu.edu

11.2 Feedback from the DCC to the Clinical Center

The Vascular Function Core will alert the DCC if any of the FMD/NMD ultrasound images are unreadable, and the DCC will alert the Clinical Center. The first 5 ultrasound studies from each Clinical Center will be read as soon as they are received so that feedback can be provided early in the course of the study and technical issues can be resolved.

11.3 FMD / NMD Image Analysis and Data Transmission to DCC

The Vascular Function Core will read the FMD/NMD ultrasound images obtained at the Clinical Centers. The following data will be transmitted by the Vascular Function Core to the DCC for each FMD/NMD study:

1. Baseline brachial artery diameter
2. Post-occlusion brachial artery diameter
3. Baseline nitroglycerin diameter
(see appendix 1 – example of drug dispensation log)
4. Post nitroglycerin brachial artery diameter
5. Baseline Flow and Velocity
6. Hyperemic Flow and Velocity

FMD will be expressed as the post-ischemia percentage increase in brachial artery diameter.

NMD will be expressed as the post-nitroglycerin percentage increase in brachial artery diameter.

The formula for PRE Velocity is:

Average PRE-Cuff FBF/((FMD PRE Diameter*FMD PRE Diameter)*0.471)

The formula for POST Velocity is:

Average Post-Cuff FBF/((FMD Post Diameter*FMD Post Diameter)*0.471)

11.4 Interpretation of Venous Occlusion Plethysmography Data

Using the data entered by the Clinical Centers onto **Form 211**, the DCC will generate linear regression equations for the relationship between the venous pressure (20, 30, 40, 50, and 60 mm Hg) and the change in forearm volume (% increase in ml). The slope of the linear regression line will be an indicator of the venous capacitance (expressed as % increase in volume per mm Hg).

The Vascular Function Core will participate in the interpretation of the venous capacitance measurements. If necessary, (e.g., if the transmitted data does not generate linear volume/pressure relationships), the Vascular Function Core will assist the DCC in evaluating direct output from the Hokanson EC6 maintained at the Clinical Centers.

The acceptable range for maximal venous outflow (MVO) is 0.01-500. A value of “0” is usually patient related or a technical problem. A “0” value often can be corrected after re-positioning the patient's arm. Negative MVO's always reflect a problem with positioning and should not be used. If the Center feels that there is a valid value of “0” for the MVO, the Vascular Core should be contacted as soon as possible. If the plethysmography is found to be valid before the 2-week follow-up ultrasound, the patient can continue to be followed. Otherwise, the patient will need to be dropped from the study if the other two vascular function tests (FMD/NMD and arterial pulse wave velocity) were not successfully performed.

11.5 Interpretation of SphygmoCor PWV Data

The SphygmoCor device will generate carotid-radial and carotid-femoral artery pulse wave velocities as well as other indicators of arterial stiffness (augmentation index, central pressures, and pulse pressure).