



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)
FOLDER: K083691 - 255 pages (FOI:11002064)
COMPANY: MICROMRI, INC. (MICROMRI)
PRODUCT: SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)
SUMMARY: Product: BONEVUE

DATE REQUESTED: Jul 27, 2011

DATE PRINTED: Aug 10, 2011

Note: Releasable Version



1083691

XII. 510(k) SUMMARY

FEB 25 2009

This 510(K) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter's Information:

Manufacturer: MicroMRI, Inc.
580 Middletown Boulevard
Suite D-150
Langhorne, PA 19047

Contact: Richard Elrath
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.

Phone: 267 212-1119
Facsimile: 267 212-1101
Email: relrath@micromri.com

Trade Name, Common Name and Classification:

Trade Name: BoneVue
Common Names: Image processing software
Classification Name: System, Image Processing, Radiological
Product Code: LLZ

Predicate Devices:

510k Reference No. & Date	Device Name	Manufacturer
K070831 May 22, 2007	Voxar 3D™	Barco View MIS 2 Anderson Place Edinburgh, EH6 5NP, UK
K011142 May 8, 2001	Aquarius Workstation™	TeraRecon, Inc. 2955 Campus Drive, Suite 325 San Mateo, CA 94403
K053281 September 3, 2004	EVMS™ Enterprise Visual Medical System	Emageon UV, Inc. 131 Wilson Street Suite 700 Madison, WI 53703
K071331 May 25, 2007	Vitreia® Version 4.0 Medical Image Processing Software	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343

Device Description:

BoneVue evaluates high-resolution MRI datasets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

The following cortical measurements are reported: average cortical inner diameter, average cortical outer diameter, and average cortical thickness.

The following trabecular measurements are reported: average measures of bone volume/total volume, trabecular thickness, trabecular number, and trabecular separation.

The 3D visualization module is used to display a high resolution 3D model of the trabecular bone and its micro-architecture. The 3D visualization helps a trained physician make a qualitative assessment of bone micro-architecture, which may be viewed from different angles. BoneVue allows standard surface rendering views as well as standard maximum intensity projection views.

Additionally, BoneVue offers the display of a standard "bone plug", a surface rendering of a central cylinder of trabecular tissue, as a representative sample of the bone micro-architecture.

Indications for Use:

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Technological Characteristics:

BoneVue software does not control image acquisition and can be used with a variety of commercially available pulse sequences and imaging coils. BoneVue does not contact the patient, nor does it control any life sustaining devices. A trained physician interprets the data and information being displayed.

Performance Testing:

BoneVue has been successfully tested and has met acceptance criteria previously established in accordance with documented procedures.

Conclusion:

The 510(k) Pre-Market Notification contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices. BoneVue has been developed, and will be manufactured in accordance with the MicroMRI's established Quality Policy Manual, which meets all of the requirements of 21 CFR Part 820, Quality System Regulation and ISO 13485, Medical Devices – Quality Management Systems – Requirements for regulatory purposes. The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "Minor".



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2009

Mr. Richard Elrath
Manager of Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
580 Middletown Boulevard, Suite D-150
LANGHORNE PA 19047

Re: K083691

Trade/Device Name: BoneVue
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 8, 2008
Received: December 15, 2008

Dear Mr. Elrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

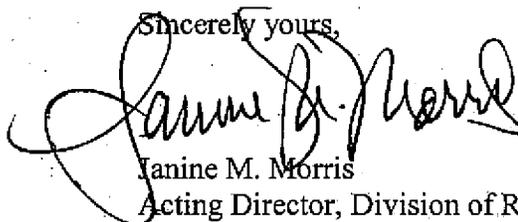
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry.support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XIII. STATEMENT of INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): N/A K083691

Device Name: BoneVue

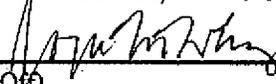
Indications for Use:

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K083691



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2009

Mr. Richard Elrath
Manager of Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
580 Middletown Boulevard, Suite D-150
LANGHORNE PA 19047

Re: K083691

Trade/Device Name: BoneVue
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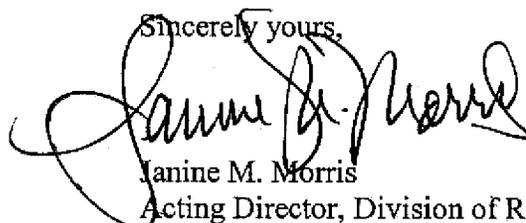
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21 CFR 892.xxx	(Radiology)	(240) 276-0120
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Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XIII. STATEMENT of INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): N/A K083691

Device Name: BoneVue

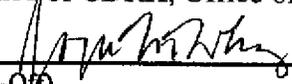
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BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K083691



December 16, 2008

MICROMRI, INC.
580 MIDDLETOWN BLVD. SUITE D-150
LANGHORNE, PENNSYLVANIA 19047
UNITED STATES
ATTN: RICHARD ELRATH

510k Number: K083691
Received: 12/15/2008
Product: BONEVUE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 12, 2008

MICROMRI, INC.
580 MIDDLETOWN BLVD. SUITE D-150
LANGHORNE, PENNSYLVANIA 19047
UNITED STATES
ATTN: RICHARD ELRATH

510k Number: K083691
Received: 12/12/2008
User Fee ID Number: 6040245
Product: BONEVUE

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K083691

MicroMRI bone micro-architecture	580 Middletown Boulevard Suite D-150 Langhorne, PA 19407	Telephone: 267 212-1100 Facsimile: 267 212-1101 Website: www.micromri.com
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December 8, 2008

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center HFZ-401
 9200 Corporate Boulevard
 Rockville Maryland 20850
 510(k) Notification

FDA CDRH DMC
 DEC 12 2008
 Received

Dear Sir or Madam:

This letter is to notify the Food and Drug Administration that MicroMRI, Inc.; FDA Registration Number 3005871119, is submitting this Traditional 510(k) Premarket Notification of intent to market the device BoneVue Software, as required by 21 CFR § 807.90(e). Enclosed please find two copies of this 510(k) submission, one hard copy and one electronic copy (CD) for review.

The following information pertaining to BoneVue software is included as recommended by the FDA guidance on 510(k) cover letters:

- Device Common Name: Medical Image Processing Software
- Classification Regulation Number: 21 CFR 892.2050
- Classification Regulation Name: Picture archiving and communication system
- Regulatory Class: II
- Classification Panel Number: 892
- Classification Product Code: LLZ
- Classification Product Code Name: Image Processing System

BoneVue evaluates high-resolution MRI datasets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

Some of the material in this submission may be a trade secret, confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. The Company therefore asks to be consulted with as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

Please let me know if you have any questions concerning the enclosed 510(k) document. I would be happy to answer any questions you might have.

Sincerely,



Richard Elrath
 Manager of Quality Assurance and Regulatory Affairs
 MicroMRI, Inc.
 580 Middletown Boulevard, Suite D-150
 Langhorne, PA 19047
 Telephone : 267 212-1119
 Email : relrath@micromri.com

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MICROMRI INC 580 Middletown Boulevard, D-150 Langhorne PA 19047 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Richard Elrath 2.1 E-MAIL ADDRESS relrath@micromri.com 2.2 TELEPHONE NUMBER (include Area code) 267-212-1119 2.3 FACSIMILE (FAX) NUMBER (include Area code) 267-212-1101	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD098250		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		10-Dec-2008

Form FDA 3601 (01/2007)

[Close Window](#) [Print Cover sheet](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission 12/08/2008	User Fee Payment ID Number 50005257-09106730	FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 90-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information
Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-HDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):			
Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):			
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name MicroMRI, Inc.		Establishment Registration Number (if known) 3005871119	
Division Name (if applicable)		Phone Number (including area code) (267) 212-1100	
Street Address 580 Middletown Boulevard		FAX Number (including area code) (267) 212-1101	
City Langhorne	State / Province PA	ZIP/Postal Code 19047	Country USA
Contact Name Richard Elrath			
Contact Title Manager of Quality Assurance and Regulatory Affairs		Contact E-mail Address relrath@micromri.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

FDA Form 3514 (9/07) (2007) 11

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 LLZ	2 LLZ	3 LLZ	4 LLZ	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)		
510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K070831	Voxar 3D Enterprise	Barco View MIS
2 K011142	Aqualus Workstation	TeraRcon, Inc.
3 K053281	EVMS Enterprise Visual Medical System	Emageon UV, inc.
4 K071331	Vitrea Medical Image Processing Software	Vital Images, Inc.
5		
6		

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Image Processing Software

Trade or Proprietary or Model Name for This Device	Model Number
1 BoneVue	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LLZ	C.F.R. Section (if applicable) 892.1000	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel 892		

Indications (from labeling)
 BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	
Contact E-mail Address			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	
Contact E-mail Address			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	
Contact E-mail Address			

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

MicroMRI bone-micro-architecture	580 Middletown Boulevard Suite D-150 Langhorne, PA 19407	Telephone: 267 212-1100 Facsimile: 267 212-1101 Website: www.micromri.com
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December 8, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center HFZ-401
9200 Corporate Boulevard
Rockville Maryland 20850
510(k) Notification

Dear Sir or Madam:

This letter is to notify the Food and Drug Administration that MicroMRI, Inc.; FDA Registration Number 3005871119, is submitting this Traditional 510(k) Premarket Notification of intent to market the device BoneVue Software, as required by 21 CFR § 807.90(e). Enclosed please find two copies of this 510(k) submission, one hard copy and one electronic copy (CD) for review.

The following information pertaining to BoneVue software is included as recommended by the FDA guidance on 510(k) cover letters:

Device Common Name: Medical Image Processing Software
Classification Regulation Number: 21 CFR 892.2050
Classification Regulation Name: Picture archiving and communication system
Regulatory Class: II
Classification Panel Number: 892
Classification Product Code: LLZ
Classification Product Code Name: Image Processing System

BoneVue evaluates high-resolution MRI datasets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

Some of the material in this submission may be a trade secret, confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. The Company therefore asks to be consulted with as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

Please let me know if you have any questions concerning the enclosed 510(k) document, I would be happy to answer any questions you might have.

Sincerely,



Richard Elrath
Manager of Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
580 Middletown Boulevard, Suite D-150
Langhorne, PA 19047
Telephone : 267 212-1119
Email : relrath@micromri.com

510(k) PREMARKET NOTIFICATION CHECKLIST

<u>ITEM</u>	<u>COMMENT</u>
1. Device trade or proprietary name	<u>See section I, page 3</u>
2. Device common or usual name or classification name	<u>See section I, page 3</u>
3. Establishment registration number (only applies if establishment is registered)	<u>See section II, page 3</u>
4. Class into which the device is classified	<u>See section III, page 3</u>
5. Classification Panel	<u>See section III, page 3</u>
6. Action taken to comply with Section 514 of the Act	Not applicable as no performance standards have been developed and no applicable special controls apply.
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	<u>See Attachment 1</u>
8. A 510(k) Summary or a 510(k) Statement	<u>See section XII, page 38</u>
9. For class III devices only, a class III certification and a class III summary	Not applicable - this is a class II device
10. Photographs and engineering drawings of the device	Not applicable – this is a software only product.

- | | |
|--|--|
| 11. The marketed device(s) to which equivalence is claimed including labeling and description of the device - Predicate Device Materials | <u>See section VII, page 12</u>
<u>See Attachment 3</u> |
| 12. Statement of similarities and/or differences with marketed devices(s) - Chart of Substantial Equivalence | <u>See section VII, page 12</u>
<u>See Attachment 2</u> |
| 13. Data to show consequences and effects of a modified device | Not Applicable |
| 14. Submitter's name and address | <u>See section X, page 38</u> |
| 15. Contact person, telephone number and fax number | <u>See Section XI, page 38</u> |
| 16. Representative/Consultant if applicable | Not Applicable |
| 17. Table of Contents with page information | <u>See Table of Contents, page 2</u> |
| 18. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s) | <u>See section X, page 38</u> |
| 19. Comparison table of the new device to the marketed device(s) - Chart of Substantial Equivalence | <u>See Attachment 2</u> |
| 20. Action taken to comply with voluntary standards | <u>See section IV, page 3</u> |
| 21. Performance data | |
| a. Marketed Device | |
| 1. bench testing | Not applicable |
| 2. animal testing | Not applicable |

3. clinical data	Not Applicable
b. New Device	
1. bench testing	Not applicable
2. animal testing	Not applicable
3. clinical data	Not applicable
22. Sterilization information	Not Applicable
23. Software Information	<u>See section VIII, page 27</u>
24. Hardware information	Not applicable
25. Is this device subject to issues that have been addressed in specific guidance document(s)?	Not Applicable
26. Indications for Use Statement	<u>See section XIII, page 41</u>
27. Truthful and Accurate Statement	<u>See section XIV, page 42</u>
28. Derivation of Algorithm	Not Applicable

**MicroMRI Inc.
580 Middletown Boulevard
D-150
Langhorne, PA 19047**

510 (k) Premarket Notification

BoneVue™ Software v1

Table of Contents

I. NAME OF DEVICE	3
II. ESTABLISHMENT REGISTRATION NUMBER.....	3
III. DEVICE CLASSIFICATION/CLASSIFICATION PANEL	3
IV. PERFORMANCE STANDARDS	3
V. LABELING.....	4
VI. DEVICE DESCRIPTION.....	4
VII. SUBSTANTIAL EQUIVALENCE	12
VIII. SOFTWARE INFORMATION.....	27
IX. CONFIDENTIALITY	38
X. SUBMITTER'S NAME AND ADDRESS	38
XI. CONTACT PERSON.....	38
XII. 510(k) SUMMARY.....	38
XIII. STATEMENT of INDICATIONS FOR USE	42
XIV. TRUTHFUL AND ACCURATE STATEMENT.....	43
XV. BIBLIOGRAPHY	44
ATTACHMENT 1	46
ATTACHMENT 2	74
ATTACHMENT 3	77
ATTACHMENT 4	104
ATTACHMENT 5	122
ATTACHMENT 6	161
ATTACHMENT 7	174

December 11, 2008

The following information is provided as required by 21 C.F.R. § 807.87 (1997) for MicroMRI and its BoneVue Software 510(k) Premarket Notification.

I. NAME OF DEVICE

Trade Name: BoneVue

Common Names: Image processing software

Classification Name: System, Image Processing, Radiological

II. ESTABLISHMENT REGISTRATION NUMBER

MicroMRI, Inc.
580 Middletown Boulevard
Suite D-150
Langhorne, PA 19047
FDA Registration number: 3005871119

III. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

The FDA has classified Magnetic Resonance image processing software devices as Class II in 21 CFR 892.1000. The panel number is 892. The product code is LLZ.

IV. PERFORMANCE STANDARDS

No performance standards or special controls have been developed under Section 514 of the Food, Drug and Cosmetic Act for image processing software. No special controls apply. The product is designed to comply with the applicable standards administered by CDRH and appropriate submissions will be forwarded as required by the Code of Federal Regulations.

Image processing software and the related hardware are subject to the following voluntary standards: Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., and the Society of Motion Picture and Television Engineers (SMPTE) Test Pattern.

BoneVue is 3D visualization software that has been designed to conform to the DICOM 3.0 standard and the JPEG standard. The use of BoneVue is compatible with various off-the-shelf hardware components. Those monitors recommended by the Company will meet the SMPTE test pattern standard.

V. LABELING

A draft of the Operator's Manual for the BoneVue post processing software, along with a draft of the product data sheet, are provided in **Attachment 1** of this submission.

VI. DEVICE DESCRIPTION

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

BoneVue software is a 3D visualization tool similar to what is used in other MRI post-processing applications, such as 3D visualization of blood vessels. BoneVue has been adapted to fulfill the particular needs for visualization and measurement of bone tissue.

The software is designed to operate on a PC running Windows XP (Microsoft Corp.). The development languages used are IDL (ITT Visual Information Solutions) and C++.

Magnetic Resonance Imaging (MRI) machines use imaging coils to capture the signal coming from the human body and then reconstruct images. BoneVue can be used in combination with datasets acquired with a variety of different commercially available coils that provide high signal-to-noise ratio for high-resolution bone MRI examinations, including a "bird cage" wrist coil developed by MicroMRI (K 073131).

In addition to a coil, MRI of the bone requires a pulse sequence capable of acquiring high-resolution images in tissue with magnetic susceptibility effects. BoneVue can process data from a variety of commercially available pulse sequences. Typically, two pulse sequences are used, a first sequence for volumetric imaging of cortical bone and a second sequence for volumetric imaging of trabecular bone. The image data (DICOM format) from the cortical scan and the raw (k-space) data (or image data in DICOM format) from the trabecular scan are stored on CD. The CD is then transferred to the PC on which the BoneVue software is installed and the files are read in for further processing. Alternatively, secure electronic transfer between networked PCs can be used in lieu of data transfer using CD.

A more detailed diagram of the BoneVue data and processing flow is illustrated in the chart and further explained below. BoneVue processing can be run either in automated mode or in manual mode, in which the user can manually adjust parameters affecting the segmentation boundaries for cortical and trabecular bone, as described in the following sections.

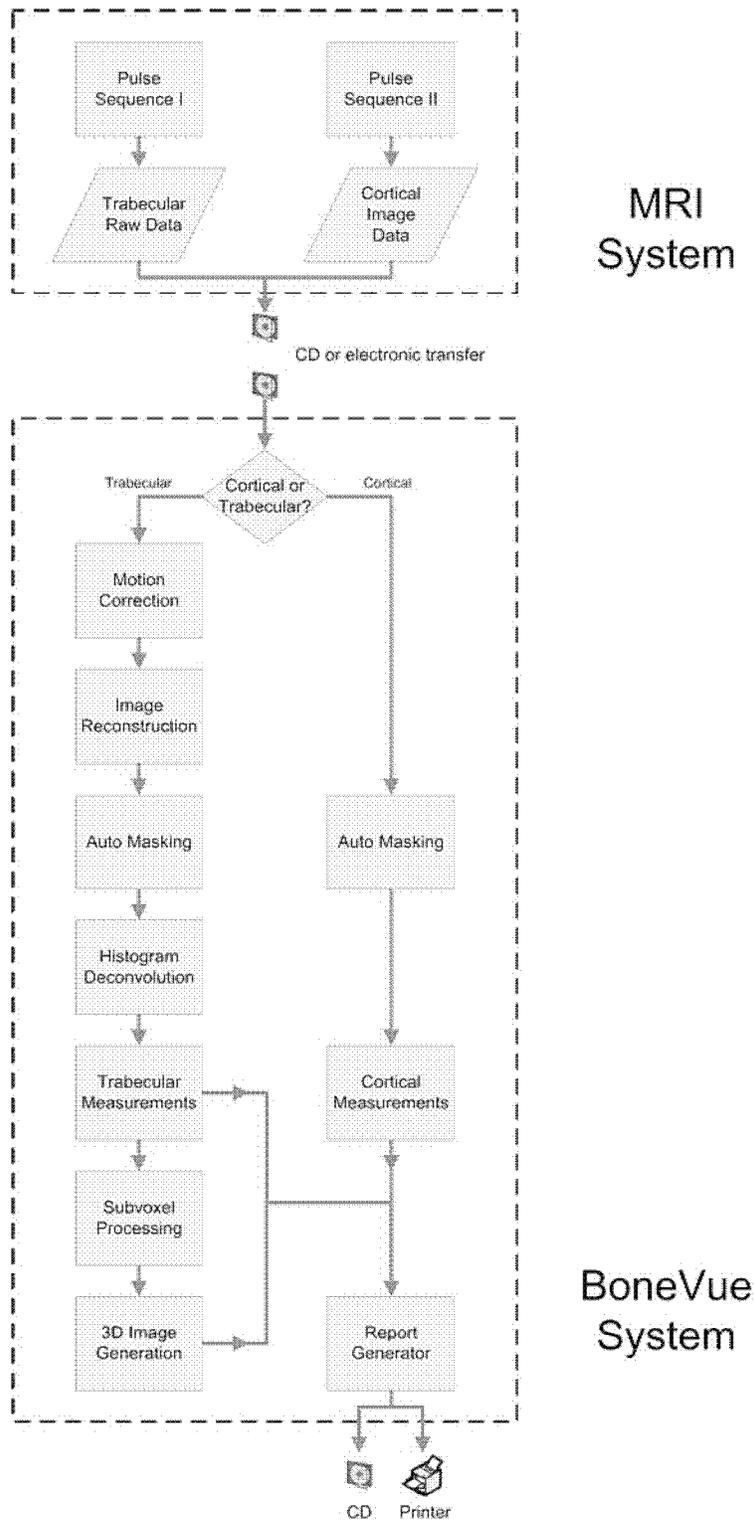


Figure 1 - BoneVue Flow Chart

In general, an evaluation of MRI bone datasets involves assessment of both cortical and trabecular bone. The first step in the processing is to distinguish between cortical and trabecular datasets since they follow different processing paths. These processing paths are separately described below.

1. CORTICAL DATA PROCESSING FLOW

The scan protocol generates a volumetric set of a number of slices of cortical bone. The cortical image data are then stored on a CD in DICOM format, or transferred electronically to the PC running the BoneVue software.

a. Auto-Masking and Segmentation Module

The first step in processing the cortical images is to perform segmentation to isolate the cortical bone from the rest of the image and define the trabecular/marrow region on a

(b)(4)

(b)(4)

b. Cortical Measurements Module

The initial estimate of the endosteal boundary (output of step 1.a.) is then inputted to the Cortical Measurements Module. First, (b)(4)

(b)(4)

Once the (b)(4) lines are established, the cortex is then segmented by detecting the (b)(4)

(b)(4)

(b)(4)

For each cortical slice, the following measurement steps are performed:

1. (b)(4)
- 2.
- 3.

After performing the above operations for each slice, the final values of Cortical Inner Diameter (Cr.ID), Cortical Outer Diameter (Cr.OD), and Cortical Thickness (Cr.Th.) are calculated, as further described below. These parameters are presented to the user as part of the final report and may be stored on CD or printed to hardcopy using the report generator module.

Cr.ID The average inner diameter of the cortical shell is calculated as the average of (b)(4)

Cr.OD The average outer diameter of the cortical shell is calculated as the average of (b)(4)

Cr.Th The average thickness of the cortical shell is calculated as the average of the (b)(4)

It should be noted that the measurements of Cr.Th, Cr.ID, and Cr.OD can also be performed manually by a user visually inspecting the images. The user can examine

(b)(4)

(b)(4)

2. TRABECULAR BONE PROCESSING FLOW

The scan protocol generates a volumetric set of a number of slices of trabecular bone. The trabecular bone processing begins with a DICOM image or raw k-space data stored on CD or transferred electronically from the MRI scanner.

a. Motion Correction Module

Patient movement during the scan, even on a sub-millimeter scale, can introduce image artifacts. Since involuntary patient movement cannot completely be prevented, even when using immobilization techniques, retrospective motion correction is beneficial.

The software corrects for translation movement in the x-y plane. (b)(4)

(b)(4)

(b)(4)

The maximum displacements in both x and y directions are monitored. (b)(4)

(b)(4)

The motion correction step is optional in BoneVue, and if no navigator echoes are available, DICOM images can be used and inputted directly into step 2.c. below.

b. Image Reconstruction Module

Following motion correction, a 3D Fourier Transform is applied to the k-space data to generate motion corrected reconstructed images. The image reconstruction step incorporates well known and standard filtering techniques, such as an apodizing filter to avoid Gibbs artifacts.

c. Auto-Masking and Segmentation Module

In the trabecular data flow, the Auto-Masking Module operates on trabecular data in a similar fashion to step 1.a. to delineate the trabecular Volume of Interest (VOI) for further processing.

d. Histogram Deconvolution Module

The inputs to this module are trabecular images, either the non-motion corrected ones extracted directly from the DICOM files, or the motion-corrected output of step 2.b., and the VOI mask of step 2.c. Only tissue inside the VOI mask, i.e., only the trabecular-marrow region inside the cortical shell, is used in this and subsequent steps.

The Histogram Deconvolution Module operates on a slice-by-slice basis to produce a Bone Volume Fraction (BVF) map, as explained below, correcting for intensity variations across the image due to spatial variations in the signal sensitivity of the coil. The module also de-convolves the image to remove the effects of acquisition noise.

This module exploits the fact that the trabecular region is bi-phasic, containing only marrow, which produces a large MRI signal due to its fatty content, or bone, which produces virtually no MRI signal. Indeed, the trabecular region consists mostly of

marrow, with a small overall fill factor of bone (typically ~10%). The intensity of any given voxel is determined by the Marrow Volume Fraction (MVF), which is the proportion of the voxel that contains marrow. Since the voxels contain only bone and marrow, BVF is easily calculated:

$$BVF = 1 - MVF$$

To calculate MVF, the effects of spatial variations in signal sensitivity must first be removed. Since the maximum voxel intensity corresponds to MVF = 1, the local maximum intensity is calculated for each voxel in a given slice by examining the histogram of above-average MRI signal intensities in a region up to (b)(4) in size, centered on the given voxel. The mode (most likely value) of the histogram corresponds to the local value for a voxel containing only marrow (MVF = 1). In this fashion, for each slice, a marrow intensity map is created which stores the spatial variation in signal intensity across the image.

Since trabecular bone structures are smaller than the voxel size, voxel signal intensity is influenced by partial volume effects. Instead of a bimodal distribution, the histogram of voxel intensity values has a broad maximum (mono-modal), which is further broadened by the effects of noise. Therefore, the next step in calculating the BVF map for each slice is to remove the effects of noise and recover the actual intensity values.

It is well known that since the acquisition noise in the MRI signal in the x and y channels is Gaussian with standard deviation σ , the noise in the measured voxel intensity is characterized by a Rician distribution:

$$P(I_{measured} | I_{actual}) = \frac{I_{measured}}{\sigma^2} e^{-(I_{measured}^2 + I_{actual}^2)/2\sigma^2} I_0\left(\frac{I_{measured} I_{actual}}{\sigma^2}\right)$$

Where $I_0()$ is the modified zeroth-order Bessel function. The measured intensity values are given by the actual intensity values convolved with the Rician distribution function above.

The histogram deconvolution module makes an initial assumption of the actual intensity distribution, adjusts it to reflect the marrow intensity map, and then convolves it with the Rician noise distribution function referenced above to calculate an estimated measured intensity distribution. The estimated measured intensity distribution is then compared to the true measured intensity distribution. The estimation error, which is the difference between the estimated and true measured intensity distributions, is then distributed back through the Rician function and used to update the actual intensity distribution. This process is repeated iteratively until the estimation error is minimized.

In order to produce a noise-free BVF map of the trabecular region, the actual intensity distribution calculated by the iterative histogram deconvolution method is then used to

reassign voxel intensity values in the image based on the measured (noisy) intensity values and connectivity logic, which exploits the fact that bone tends to connect with other bone. This step removes (non-physical) islands of bone. The BVF map contains values ranging from 0-100 corresponding to the percent of bone occupancy in each voxel.

The entire iterative process is repeated during a second pass in which the marrow intensity map is refined using the BVF map result from the first pass.

e. Trabecular Measurements Module

This module uses the BVF maps to calculate average measures of bone volume/total volume (BV/TV), trabecular thickness (Tb.Th), trabecular number (Tb.N), and trabecular separation (Tr.Sp), as further described below.

BV/TV The ratio of bone volume to total volume is calculated by computing the average value of BVF over the entire multi-slice volume of the trabecular region.

Tb.Th The average trabecular thickness for each slice is calculated by first summing

(b)(4)

(b)(4)

Tb.N The linear density of trabecular structures, expressed in units of 1/distance is given by the quantity $(BV/TV)/(Tb.Th)$.

Tb.Sp The average separation between trabecular structures, given by $1/(Tb.N)$.

It should be noted that the bone volume fraction and other trabecular measurements can also be performed manually by a user visually inspecting the images. The user can examine each slice and carefully trace the trabecular patterns in a defined representative area, and then count and measure the total trabecular area and total length of the trabecular segments. BoneVue performs these steps automatically, avoiding the tedium of manual measurement and saving the user time.

f. Subvoxel Processing Module

The main purpose of this module is to increase the pixel resolution of the BVF map to display or print a high resolution 3D model of the trabecular bone micro-architecture.

Subvoxel processing converts each original voxel into an array of smaller subvoxels.

Subvoxel processing is an iterative process. During the first pass the BVF from the

(b)(4)

(b)(4)

3. 3D Image Visualization Module

In this module standard 3D visualization algorithms are used to display a high resolution 3D model of the trabecular bone. The 3D visualization helps a trained physician make a qualitative assessment of bone micro-architecture, which may be viewed from different angles and using different visualization modes. BoneVue allows standard surface rendering views as well as standard maximum intensity projection views. Additionally, BoneVue allows rotating the 3D dataset with viewing from different angles.

In general, voxels with higher BVF appear brighter. Depth queuing may be used to modify the intensity of distant regions relative to regions closer to the viewer. In addition, an opacity matrix determines how “rays” from inner voxels propagate to the outer surface. If all inner rays are blocked, the view will appear as a standard surface rendering.

To further facilitate visualization of the 3D bone structure, the BVF map is binarized (bone and non-bone voxels) so that only voxels exceeding a threshold value for bone volume fraction are displayed. In addition, connectivity logic is used to isolate and display the trabecular bone network.

Additionally, BoneVue offers the display of a standard “bone plug”, a surface rendering of a cylinder of central trabecular tissue, as a representative sample of the bone micro-architecture. This “bone plug” is a representation of the trabecular morphology from a sample area in the center of the bone. It is for representation only. All quantitative calculations are based on the entire imaged volume. No calculations are based solely on the “bone plug” area alone.

4. Measurements and Reports

The fixed outputs of the BoneVue 3D visualization software consist of the following images and automatically calculated measurements:

Images:

3D graphic visualization of the trabecular bone using surface rendering (“bone plug”)

Trabecular parameters:

- BV/TV Ratio of bone volume to total volume
- Tb.Th Average trabecular thickness
- Tb.N Average linear density of trabecular structures
- Tb.Sp Average separation between trabecular structures

Cortical parameters:

- Cr.ID Average inner diameter of the cortical shell
- Cr.OD Average outer diameter of the cortical shell
- Cr.Th Average thickness of the cortical shell

It should be noted that all measurements of cortical or trabecular parameters can also be performed manually by a user visually inspecting the images. Although the user has the option of making manual measurements, BoneVue allows these steps to be performed automatically, avoiding the tedium of manual measurement and saving the user time.

The trabecular and cortical parameters are purely descriptive of the morphology of the bone micro-architecture displayed in the MRI images.

These outputs are presented in a report, which is created by the report generator and may be printed to hardcopy. The outputs may also be stored on CD for later review.

VII. SUBSTANTIAL EQUIVALENCE

BoneVue 3D visualization software is substantially equivalent to other legally marketed MR image 3D visualization software tools. Specifically, BoneVue is substantially equivalent to:

510k Reference No. & Date	Device Name	Manufacturer
K070831 May 22, 2007	Voxar 3D™	Barco View MIS

K011142 May 8, 2001	Aquarius Workstation™	TeraRecon, Inc.
K053281 September 3, 2004	EVMS™ Enterprise Visual Medical System	Emageon UV, Inc.
K071331 May 25, 2007	Vitrea® Version 4.0 Medical Image Processing Software	Vital Images, Inc.

BoneVue has the same intended use, principles of operation, and characteristics as the previously cleared predicate devices. Each of the predicate devices named above is used to display the 3D nature of morphology contained in MRI and/or CT datasets in a variety of formats. Additionally, all the predicate devices named above allow the measurement of descriptive parameters related to the displayed morphology or tissue. Although there are differences in the details of the types of images processed by BoneVue and its predicate devices, those differences relate to the particular anatomic region of interest addressed by each individual software package. The analysis performed and the information displayed by BoneVue does not raise new questions of safety or efficacy relative to the predicate devices.

Description of Barco View MIS Voxar 3D™

The indications of use for Voxar 3D™ in the K070831 approval letter by the FDA are listed as following:

The Voxar product family is a suite of products that is intended to provide tools for reading and review of a DICOM compliant series of medical images which can be interpreted as representing a volume of data. These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data. The Voxar 3D product family provides several levels of functionality:

- a. Basic analysis tools used on a daily basis, such as 2D review, orthogonal Multi Planar Reconstructions (MPRs), oblique MPRs, curved/cross-curved MPRs, slab MPRs, AveIP, MIP, measurements, annotations, reporting, and distribution.
- b. Tools for in-depth analysis, such as regional segmentation of anatomical structures within the image data, endoscopic review, color volume rendering of the finite thickness data cross-sections, 3D review of data volumes, path definition through vascular and other tubular structures and boundary detection.
- c. Specialist tools and workflow enhancements for specific clinical applications which provide directed workflows, custom User Interfaces, and special measurement and reporting functions optimized for the specific clinical applications. Specialized clinical applications include:
 - Colon Screening (which is intended for the screening of patients for colonic polyps, tumors and other lesions using tomographic Colonography),
 - Vessel Analysis (which is intended for the qualitative and quantitative analysis of tomographic angiographic studies to evaluate occlusive and aneurismal diseases and the effectiveness of stents and stent grafts),
 - Coronary Artery Analysis (which is intended for the qualitative and quantitative analysis of coronary arteries to evaluate occlusive and aneurismal disease),
 - Functional Cardiac Analysis (which is intended to evaluate the functional characteristics of the heart),
 - PET-CT Reading (which is intended for the analysis of lesions using FDG imaging from hybrid PET-CT scanners).

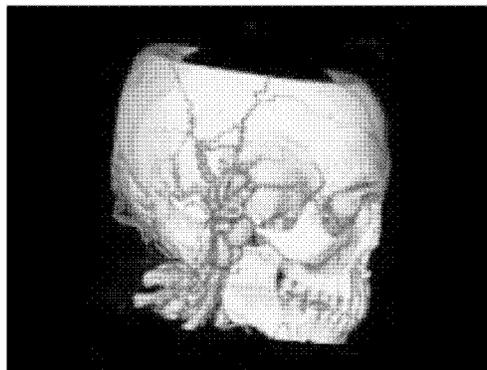
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The following illustrations have been taken from the Barco web site (www.barco.com) and illustrates the features and the use of Voxar 3D™.

Voxar 3D Workstation

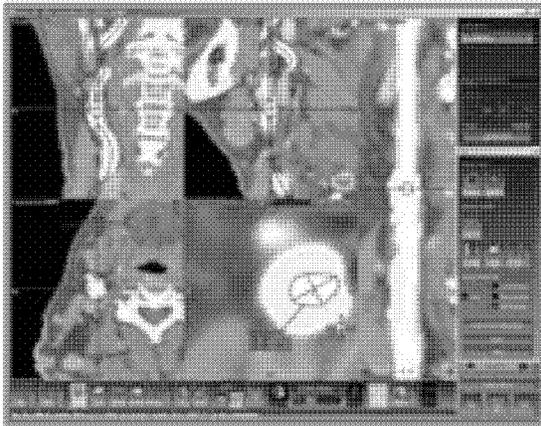
Suite of advanced visualization tools including MIP, MPR, 3D, segmentation and bone removal

Voxar 3D offers a full suite of advanced visualization and analysis tools optimized to deliver productivity and high-quality multimedia reports. With Voxar 3D you can read large volumetric datasets more efficiently, in any plane, at any thickness without compromising on image quality, speed and ease-of-use.



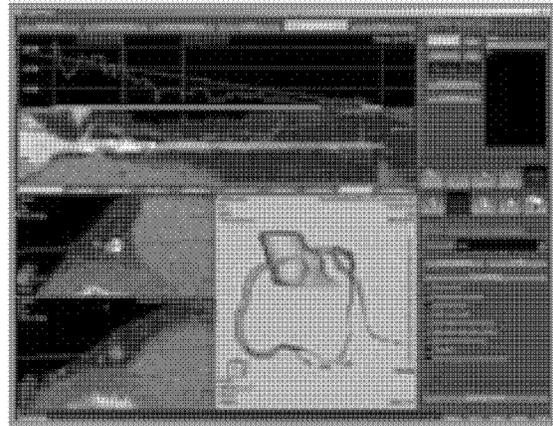
VOXAR 3D VESSELMETRIX

Delivers all the tools you need for quantitative vascular analysis and stent-graft planning of CTA and MRA studies on one easy screen.



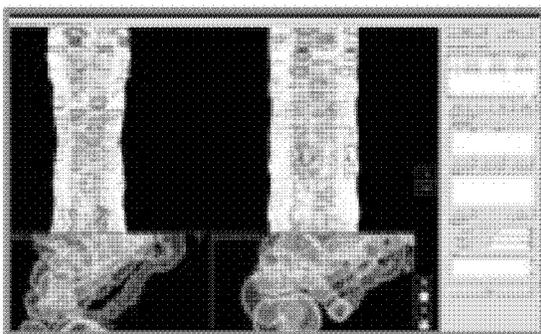
VOXAR 3D CARDIAMETRIX

Analyzes multi-phase cardiac CT studies and provides 2D, 3D and 4D visualization for quantitative evaluation of cardiac anatomy and function.



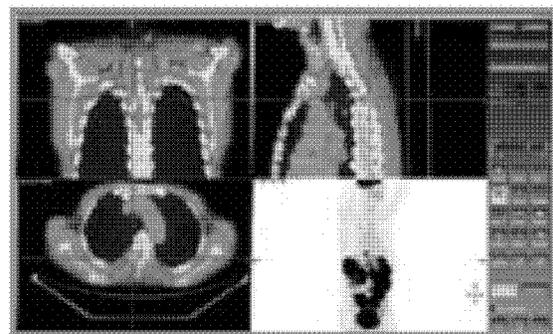
VOXAR 3D COLONMETRIX

Optimized to visualize supine and prone image studies simultaneously in 2D and 3D. DICOM reports are automatically generated on-the-fly as you diagnose.



VOXAR 3D PET/CT FUSION

Supports the effective interpretation of whole body FDG oncology studies and provides real-time interaction with PET/CT images.



Description of TeraRecon, Inc. Aquarius Workstation™

The indications of use for Aquarius Workstation™ in the K011142 approval letter by the FDA are listed as following:

To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. The software supports post-processing based on CT or MR images continuously acquired to aid in the assessment of time-dependent behavior of the image density or dimension of certain regions of interest. Calcium Scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

The following illustrations have been taken from the TeraRecon, Inc. web site (www.terarecon.com) and illustrates the features and the use of Aquarius Workstation™.

Designed For Modern Multi-Slice CT & MR Scanners

Aquarius enables real-time diagnostic review of 2D, 3D, and 4D images from almost all modalities, and incorporates workflow-enhancing tools with an intuitive user interface. Aquarius is designed to manage the most demanding volumetric datasets acquired from modern multi-slice CT and MR scanners. It offers a comprehensive suite of clinical application modules and has been carefully designed for streamlined workflow and ease-of-use.

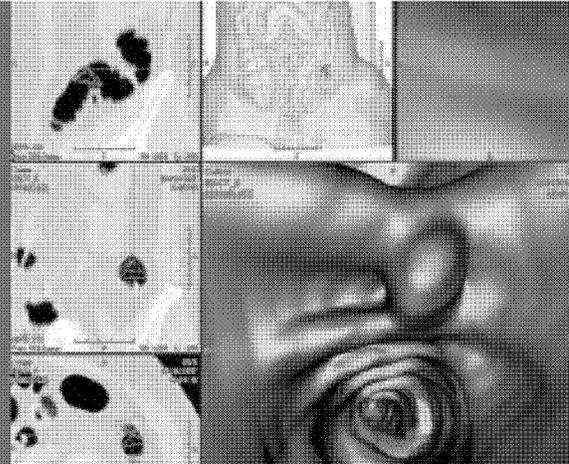


Oncology

Oncology—Tumor characterization with volume measurements and detailed evaluation of vascular supply.

Lung—Solitary pulmonary nodule assessment with auto segmentation and volume measurements.

Colonography—Integrated 2D/3D and side-by-side review. Rapid auto-navigation with endoluminal analysis.



Clinical Analysis Tools

SAT: Segmentation-Analysis Tracking for analyzing and tracking volumes.
[e.g. soft-tissue masses or solitary pulmonary nodules.]

TDA: Time-Density Analysis for studying time-dependence of contrast enhancement.
[e.g. Enhancement of brain tissue due to perfusion with contrast enhanced blood.]

TVA: Time-Volume Analysis for analyzing changes in volume over time.
[e.g. change in volume of left ventricle during the cardiac cycle.]

VAT: Vascular Analysis Tool for analyzing thrombus, calcifications, and endoleaks.

Calcium Scoring Analysis to detect and quantify atherosclerotic plaque burden in the coronary and other arteries.

Advanced Segmentation, Measuring, and Editing Tools.

Automated Templates load cases directly to the clinically appropriate 3D and/or reformatted views.

Quick Cubic Viewing is a quick examination tool to visualize volume regions of interest from the inside and outside.

Advanced 3D measurement tools allow for angle and distance measurements relative to fiducial markers.

Region growing includes erosion, dilation, and masking.

Description of Emageon UV, Inc. EVMS™ Enterprise Visual Medical System

The indications of use for EVMS™ in the K053281 approval letter by the FDA are listed as following:

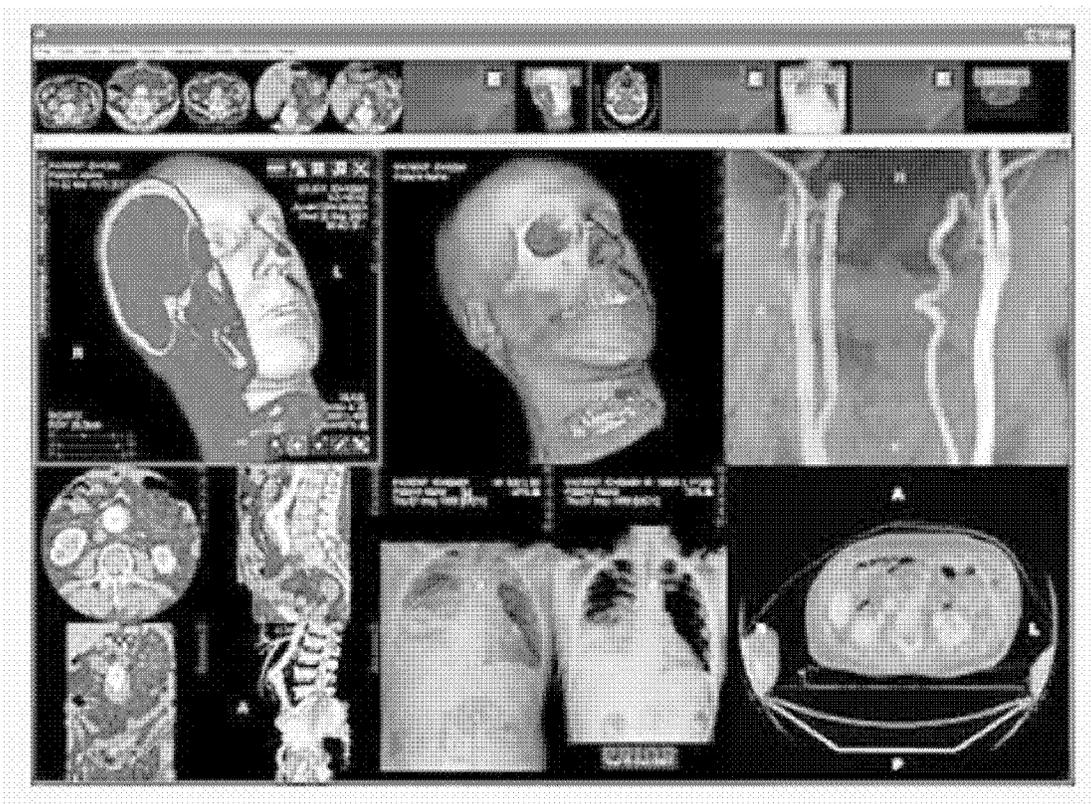
The Enterprise Visual Medical System™ is classified as a picture archive and communications systems. It is a software only solution developed by Emageon Inc., combined with other 3rd party off-the-shelf software, standard computer workstations and standard storage devices that allow authorized physicians and authorized health care professionals to manage, access, visualize and store digital medical images, visualization tools, clinical content management and clinical work flow through a graphical user interface. Advanced Visualization (Image Viewing) includes: Full featured 2D imaging, 3D surface and volume rendering, Real-time Multi-Planar Reformatting (MPR), Real-time Streaming, JPEG and Key Image Note export, Presentation States, Annotation and study management, softcopy viewing of digital mammography images provided that only 5 MP monitors with a cleared 510(k) are used and that digitized secondary captures of these images are not viewed for assisting in diagnosis, utilization of third party electronic orthopedic templates, the display of Standard Uptake Value, recording voice reports using third party, plug-in software, and user configurable setting for viewing digital medical images and corresponding data.

The following illustrations have been taken from the Emageon UV, Inc. web site (www.emageon.com) and illustrates the features and the use of EVMS™ Enterprise Visual Medical System.

Advanced Visualization Tools

Emageon's advanced visualization software shows how images can be displayed using native features that enable Body Transparency™ all in one system, even on one screen. Images can be displayed in any configuration or format the user specifies and can be configured to be associated with that specific user's profile. All display protocols and user configurable settings follow the user throughout the enterprise.

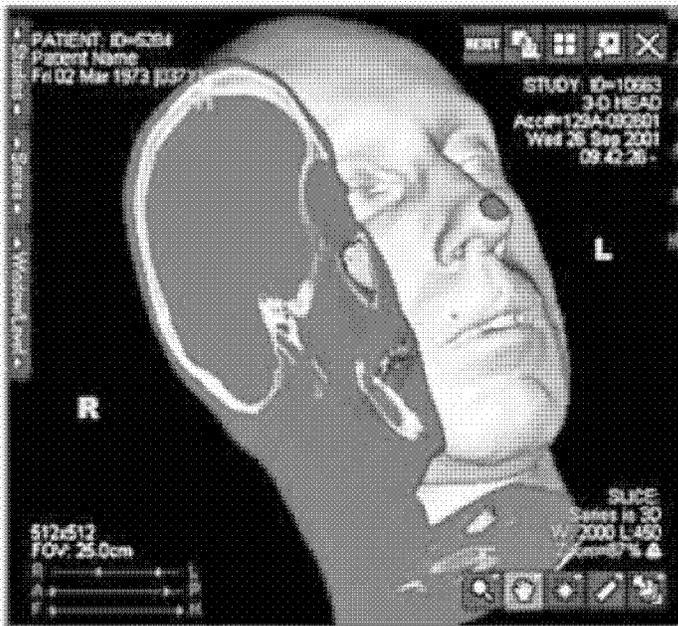
The features that are depicted by the six viewports (image viewing areas) below represent Emageon's native functionality.



Advanced Visualization Tools

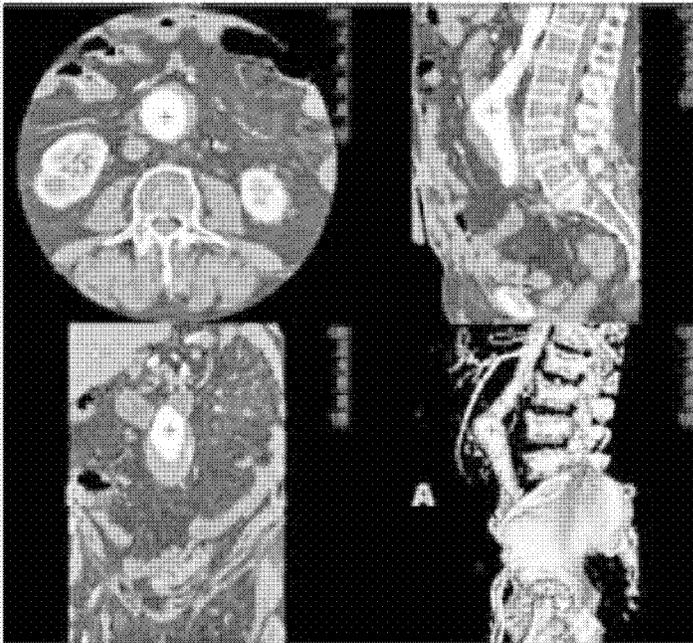
3D Surface Rendering

3D surface rendering is native to the software and accessible from the current viewport. This tool is used to render large volumes of data to produce a 3D model of the study data to enable quicker care response. This image also shows how one can slice (segment) through the volume of data to view the data not only from the surface, but through the body part as well. This allows the physician to review the entire data set as a volume rather than scrolling through thousands of images.



MPR of a CT

Multi-planar reconstruction (MPR) is an advanced functionality that is native to the software and accessible from the current viewport. MPR shows all three viewing planes: Axial, Sagittal and Coronal. The physician can use the localizer line (yellow line seen in Viewport Five) to oblique any MPR view. Emageon provides the ability to do double obliques by utilizing displayed localizer lines from multiple viewing planes represented. 3D surface rendering of the AAA (abdominal aortic aneurysm) also depicted.



Description of Vital Images, Inc. Vitrea® Medical Image Processing Software

The indications of use for Vitrea® Medical Image Processing Software in the K071331 approval letter by the FDA are listed as following:

Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography. In addition Vitrea Version 4.0 has the following addition indication:

- Cardiac EP Planning is a post-processing advanced visualization application that is intended to be used for the analysis and assessment of the heart including the atria, pulmonary veins, and coronary sinus. The application provides analysis tools which include a number of display, quantitative measurement and 3D model export capabilities for use with the St. Jude Ensite System. The application can be used to aid trained physicians in the visualization and assessment of cardiac anatomy.
- The SUREPlaque™ software application is intended to assist trained physicians in the stratification of patients identified to have atherosclerosis. This software post processes images obtained using a multidetector CT. The package provides tools for the measurement and visualization (color coded maps) of arterial vessels.
- The Vessel Probe option is intended for viewing the anatomy and pathology of a patient's peripheral arteries. Clinicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotate-able curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Cross-sectional measurements can be obtained using standard Vitrea software measuring tools. Clinicians can semi-automatically determine contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit or signal intensity statistics. Clinicians can also manually measure vessel length along the centerline in standard curved MPR views.

The following illustrations have been taken from the Vital Images, Inc. web site (www.vitalimages.com) and illustrates the features and the use of Voxar 3D™.

Vitrear® Software

Vitrear® software is Vital Images' advanced visualization solution that creates 2D, 3D and 4D images of human anatomy from CT (computed tomography) and MR (magnetic resonance) image data. With this productivity-enhancing tool, physicians can easily navigate within these images to better understand disease conditions. The Vitrear product addresses specialists' needs through various software options for cardiac, colon, vessel probe and other applications. In addition, Vitrear software utilizes an intuitive clinical workflow and automatic settings to improve speed and simplicity. Other capabilities and partnerships with PACS (picture archiving and communications systems) providers expand physicians' access to Vitrear software throughout an enterprise.

Coronary

- Zero-click vessel tree segmentation
- Easy vessel management across multiple phases
- Right-click tool palettes
- Easy vessel management & labeling
- Easy centerline editing
- Comprehensive reporting with auto population of findings
- 3D tool access through click and pause

Vascular

- Lesion tool and SUREPlaque™ for carotids, renals and peripherals
- Curved/cath view and optimized layouts for all vessels Electrophysiology (EP)
- Automatic left atrium and pulmonary vein segmentation
- Easy measurements of the left atrium and the pulmonary vein ostia diameter
- Identifies the location of the esophagus
- Export 3D images to St. Jude Medical EnSite® Workstation

Colon

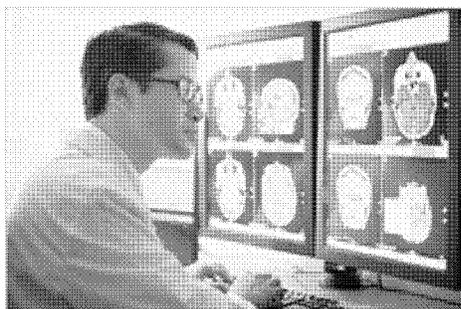
- Polyp probe for easy characterization of potential polyps
- Easy polyp management
- CAD integration for easy and comprehensive read
- Automatic Prone/Supine registration
- Improved fly-through for smooth traversal

Neuro

- Automatic artery and vein selection
- Motion correction
- Simultaneous multi-slice computation for 4D motion perfusion
- Greater control of display parameters
- Singular Value Decomposition (SVD) deconvolution

Radiology

Vital Images' "complexity made simple" approach provides radiologists with fast and powerful solutions that increase efficiency and provide powerful clinical tools. The company's solutions set the standard for ease of use with its intuitive tools. And, its combined workstation and Web-client solution enables a streamlined workflow designed to improve efficiency. Check out our full solution today.

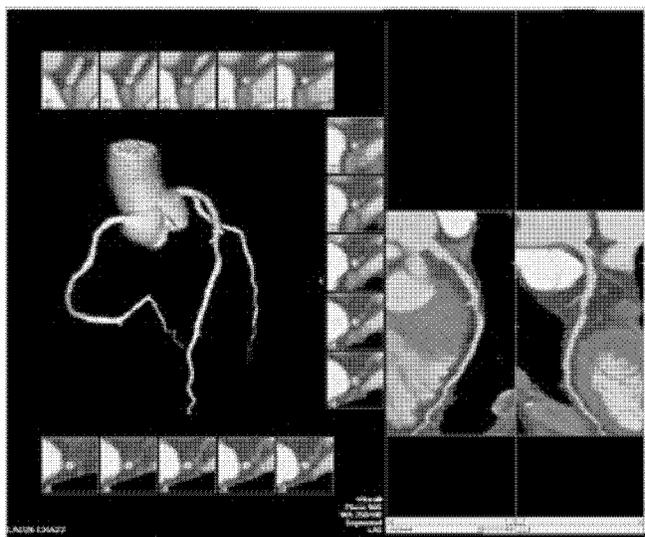


Vessel Probe™

Vessel Probe is a fast and easy-to-use tool for identifying and segmenting particular vessels of interest. This tool allows users to examine multiple vessels and easily calculate stenosis measurements.

Highlights of Vessel Probe include:

- Vessel segmentation
- Highlighted vessel view in 3D viewer
- Automatic centerline generation
- Multi-planar reformats
- Automatic orthogonal cross-sections
- Synchronized cross-hair tracking



Summary of Equivalence Findings

BoneVue has the same intended use and principles of operation and characteristics as the previously cleared predicate devices. BoneVue and each of the predicate devices named are used to process and display, in a variety of formats (including 3D Visualization), the information contained in MR (and/or CT) datasets, and allow both manual and automated measurements.

Although there are differences in the details of the types of images processed by BoneVue and its predicate devices, those differences relate to the particular anatomic region of interest addressed by each individual software package. The analysis performed and the information displayed by BoneVue does not raise new questions of safety or efficacy relative to the predicate devices.

See Attachment 2 for a substantial equivalence chart comparing the similarities and differences between BoneVue and the predicate devices named above.

See Attachment 3 for promotional information regarding each of the predicate devices.

VIII. SOFTWARE INFORMATION

A. Level of Concern

As discussed in greater detail below, BoneVue presents a “minor” level of concern as defined in FDA’s *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005). According to the *Guidance Document*, software has a “minor” level of concern when “failures or latent design flaws [in the software] would not be expected to result in any injury to the patient and/or operator.” Clearly, this is the case with the BoneVue, since the software does not in any way control a device which acts as a monitor or administers medication to a patient. Further, in the FDA’s *Guidance for the Submission of Premarket Notifications for Magnetic Resonance Devices* (November 14, 1998), it specifically states “software for MR devices that is used to perform image reconstruction or image processing is considered to be of minor level of concern.”

Using the FDA’s “Approach to Deciding Level of Concern” as detailed in the *Guidance Document*, the BoneVue has a minor level of concern for the following reasons:

BoneVue is not a life supporting or life sustaining device; thus, a failure or latent design flaw in its software will not result in the termination of life support or life sustaining activities;

BoneVue does not control the delivery of any potentially harmful energy that could cause death or serious injury;

BoneVue is not used for diagnostic purposes or to control or deliver a treatment system that can cause death or serious injury; rather, BoneVue provides information to be used by medical personnel for visualizing bone morphology; and

BoneVue is not intended to monitor vital signs or sound alarms for potentially life threatening situations in which intervention is necessary.

Conclusion: Based upon the Hazard Analysis (See [Attachment 4](#)) and the *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*, as well as the *Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, the Level of Concern for BoneVue software is determined to be “**Minor**”.

B. Software Description

BoneVue is a software only device. The device description in [Section VI](#) provides a detailed summary overview of the features and operating environment of BoneVue software.

C. Device Hazard Analysis

BoneVue Hazard Analysis document (See [Attachment 4](#)) was developed in accordance with EN-001.000, SOP on Design Control and EN-002.001, SOP on Hazard Analysis and approved on October 28, 2008. A signed and dated copy of the document is included in the Design History File.

D. Software Requirements Specification

BoneVue System Requirement Specification (See [Attachment 5](#)) was developed in accordance with EN-001.000, SOP on Design Control. A signed and dated copy of the document is included in the Design History File. The text below is an appendix from the System Requirement Specification which provides a summary of the functional requirements.

Introduction

This appendix captures the foreseen, chief use cases for the *BoneVue* application, as it will be utilized in a clinical setting. While the use cases were used to drive the BoneVue system requirements, which are presented in the main document, they **are not** in themselves requirements, but rather general term guidelines to the structuring of the application, provided in a flow-oriented format. It is therefore expected that the fine details of the use cases may change during the system's design, though in concept they remain valid. The ultimate usage of the application will be captured in the BoneVue User Manual.

The use cases given here include the system-level interactions between the User and the BoneVue User Application (referred to simply as BoneVue in the use cases), as well as the internal communication between the application and its underlying components, primarily, the Bone Processing Software (BPS). The details of the processing flow within BPS are outside the scope of this document aside from the flow's impact on the manual QC procedures. Note also that use cases for the technical user relating to system configuration and maintenance were not developed at this time.

Use Cases

UC-1 Input Handling

1.1 Prerequisites

1.1.1 A dataset is available on one of the file system's drives.

1.2 Trigger

1.2.1 The user wishes to load a dataset for processing.

1.3 Main flow (success-oriented)

1.3.1 The user opens an input selection screen.

1.3.2 BoneVue opens a file browser.

1.3.3 The user browses through the file system to the input dataset's location.

1.3.4 The user selects the input dataset.

1.3.5 BoneVue displays and stores the path to the input dataset.

1.3.6 BoneVue displays key information, such as patient name/ID, age, scan date/time, and referring physician, which is extracted from the dataset's header.

1.4 Comments

1.4.1 The user may copy the dataset from an optical drive, received from the scanner, to any folder on the local system.

1.4.2 The selection GUI will allow folder selection for cortical bone processing input and file or folder selection for trabecular bone processing input.

1.5 Success conditions

1.5.1 The requested dataset is available for processing.

1.6 Failure conditions¹

1.6.1 None

1.7 Alternative flows

1.7.1 None

UC-2 User-Initiated Automatic Processing

2.1 Prerequisites

2.1.1 A dataset is available in the local file system.

2.1.2 The system is not set to *Manual QC* mode (i.e., without user interaction).

2.2 Trigger

2.2.1 The user wishes to process a dataset.

2.3 Main flow (success-oriented)

2.3.1 The user selects the series (single or pair) for which processing is needed (see UC-1).

2.3.2 BoneVue passes the dataset's path to BPS.

2.3.3 BoneVue launches a progress bar (or similar mechanism) to indicate which dataset is being processed and the status of processing.

2.3.4 BPS generates the required outputs.

2.3.5 BPS generates a *processing successfully completed* event.

2.3.6 BoneVue marks the dataset as *processed*.

2.3.7 BoneVue indicates to the user that the dataset was successfully processed.

2.3.8 BoneVue launches the results viewer.

2.4 Comments

2.4.1 Currently available processing flows include Trabecular Bone Processing (TBP) and Cortical Bone Processing (CBP), each requiring dedicated data acquisition.

¹ Structural failures, such as an optical media corruption, are ignored throughout this document.

- 2.4.2 In the typical case where a study includes both a TBP and CBP series, BoneVue will display in step 2.3.8 the results of both flows in a combined view, so as to facilitate an integrated report.

2.5 Success conditions

- 2.5.1 The required results are stored.
- 2.5.2 The dataset is labeled as *processed*.

2.6 Failure conditions

- 2.6.1 The user selects two series, each pertaining to a different study (step 2.3.1)
 - 2.6.1.1 BoneVue alerts the user to the mismatch and suggests processing each series separately.
 - 2.6.1.2 BoneVue terminates the flow.
- 2.6.2 The user selects an input folder with more than one valid series (step 2.3.1)
 - 2.6.2.1 BoneVue alerts the user to the multiplicity and suggests copying the dataset to a new location.
 - 2.6.2.2 BoneVue terminates the flow.
- 2.6.3 BPS is unable to process the dataset, for example, due to an unsupported file format or type, or excessive motion (step 2.3.4)
 - 2.6.3.1 BPS generates a *failure* event for the relevant processing step.
 - 2.6.3.2 BoneVue indicates processing failure in the processing progress view.
 - 2.6.3.3 BoneVue marks the dataset as *processing failed* and logs the reason for failure.
 - 2.6.3.4 If the other series (TBP/CBP) can be successfully processed, BPS will do so. On step 2.3.8, BoneVue will utilize the available results.
- 2.6.4 The user aborts processing (step 2.3.4).
 - 2.6.4.1 BoneVue marks the dataset as *partial processing* and logs the reason for failure.

2.7 Alternative flows

- 2.7.1 Both series selected by the user had already been processed in the automated mode (step 2.3.1)
 - 2.7.1.1 BoneVue displays the results viewer.
- 2.7.2 One of two series selected by the user had already been processed in the automated mode (step 2.3.1)
 - 2.7.2.1 BoneVue passes to BPS only the dataset ID for the not-yet-processed series.

- 2.7.2.2 The procedure follows the main flow given above from step 2.3.3.
- 2.7.2.3 If a combined display is required on step 2.3.8, BoneVue will utilize the pre-existing results for the relevant processing flow.
- 2.7.3 Restart processing - the user selects a series, which is marked *partial processing* (step 2.3.1)
 - 2.7.3.1 The procedure follows the main flow.
 - 2.7.3.2 On step 2.3.8, BPS will utilize all available outputs and resume processing from the relevant stage.
- 2.7.4 A series selected by the user had already been processed in the manual QC mode (step 2.3.1)
 - 2.7.4.1 BoneVue alerts the user that all the output files for this exam will be deleted, including the final report.
 - 2.7.4.2 If the user approves, BoneVue requests BPS to clear the output folder of all files and deletes the report file.
 - 2.7.4.3 BoneVue performs the main flow.

2.8 Use case diagram

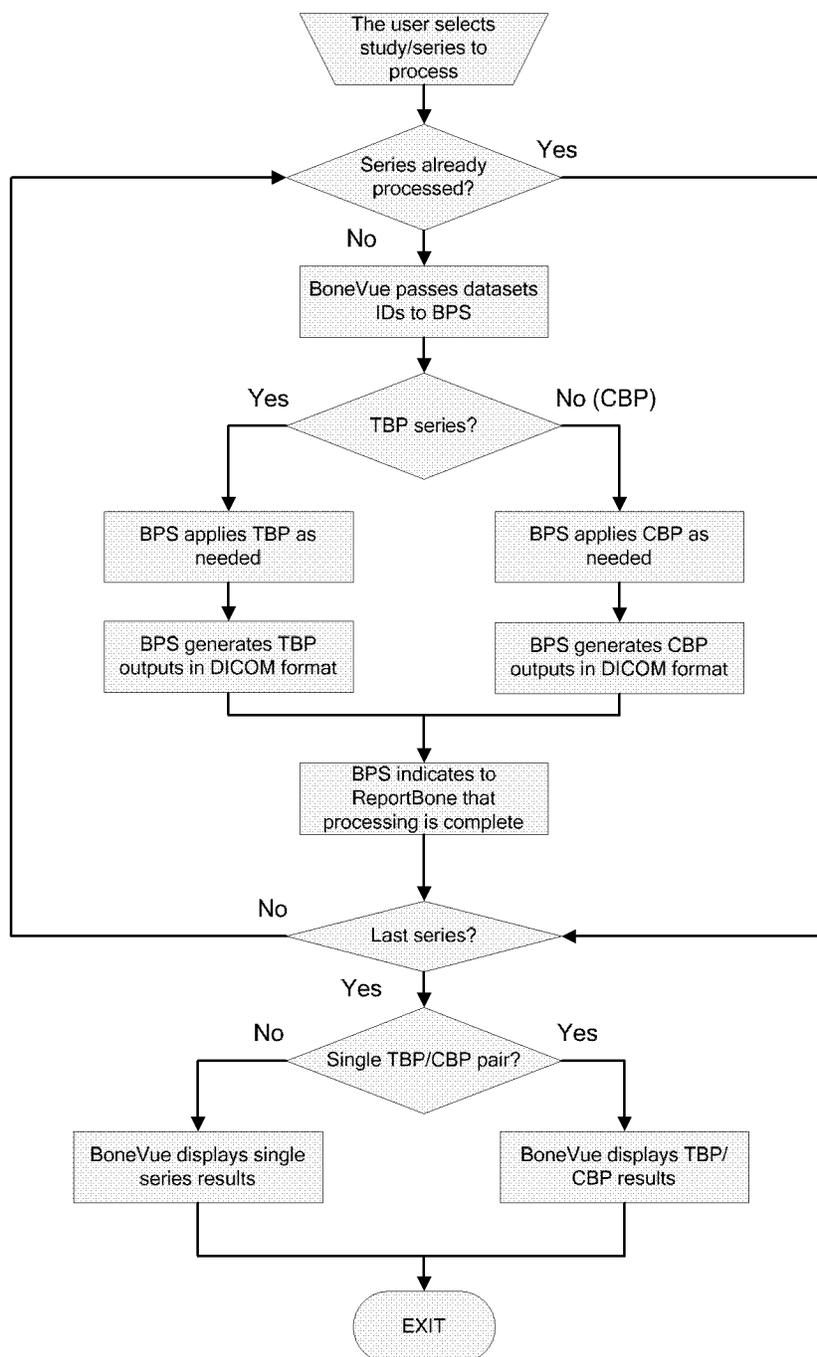


Figure 2: User-initiated automatic processing of a single study. The diagram covers the main flow as well as the alternative flows pertaining to previously processed data (in the current mode) and single series processing.

UC-3 User-Initiated Manual Processing

3.1 Prerequisites

- 3.1.1 A dataset is available in the local file system.
- 3.1.2 The system is set to *QC* mode.

3.2 Trigger

- 3.2.1 The user wishes to process a study, verifying the results at key intermediary steps (and editing the results as needed).

3.3 Main flow (success-oriented)

- 3.3.1 The user selects the series (single or pair) for which processing is needed (see UC-1).
- 3.3.2 BoneVue passes the dataset ID to BPS, requesting a controlled process.
- 3.3.3 BPS reads the CBP series and generates the 3D mask, which initializes the endosteal boundary for cortical segmentation.
- 3.3.4 BPS indicates to BoneVue that CBP has been initialized.
- 3.3.5 BoneVue displays to the user the automatically-generated 3D mask in a stack view, where each slice of the mask is represented by a contour overlaid on the corresponding image slice.
- 3.3.6 The user approves the mask.
- 3.3.7 BoneVue orders BPS to resume processing.
- 3.3.8 BPS performs cortical segmentation.
- 3.3.9 BPS indicates to BoneVue that cortical segmentation is done.
- 3.3.10 BPS displays to the user the automatically-generated cortical boundaries in a stack view, where the corresponding boundaries are represented as overlaid colored contours on each image slice.
- 3.3.11 The user approves the detected boundaries.
- 3.3.12 BoneVue orders BPS to resume processing.
- 3.3.13 BPS completes CBP, storing the required outputs.
- 3.3.14 BPS indicates to BoneVue the completion of CBP.
- 3.3.15 BoneVue marks the series as *processed*.
- 3.3.16 BPS reads the TBP series and performs motion correction.
- 3.3.17 BPS indicates to BoneVue that motion correction is done.
- 3.3.18 BoneVue displays the motion-corrected image and/or motion graphs to the user.

- 3.3.19 The user approves that the image is fit to be processed.
- 3.3.20 BoneVue orders BPS to resume processing.
- 3.3.21 BPS generates the ROI mask.
- 3.3.22 BPS indicates to BoneVue that the automatic ROI generation is done for TBP.
- 3.3.23 BoneVue displays to the user the automatically-generated 3D mask (ROI) in a stack view, where each slice of the mask is represented by a contour overlaid on the corresponding image slice.
- 3.3.24 The user approves the ROI.
- 3.3.25 BoneVue orders BPS to resume processing.
- 3.3.26 BPS processes the dataset, generating a *successful completion* event at the end of each processing step.
- 3.3.27 BoneVue updates the processing status in the processing progress view.
- 3.3.28 BPS generates the required outputs.
- 3.3.29 BPS indicates to BoneVue the completion of TBP.
- 3.3.30 BoneVue marks the series as *processed*.
- 3.3.31 BoneVue indicates to the user that the study was successfully processed.
- 3.3.32 BoneVue launches the results viewer, displaying the results of both flows.

3.4 Comments

- 3.4.1 None.

3.5 Success conditions

- 3.5.1 The required results are in the database.
- 3.5.2 The dataset(s) is labeled as *processed*.

3.6 Failure conditions

- 3.6.1 The user rejects CBP initialization (step 3.3.6) or the cortical boundaries (step 3.3.11)
 - 3.6.1.1 The user enters or selects a rejection reason.
 - 3.6.1.2 BoneVue terminates CBP (it may continue to TBP if the relevant input is available).
 - 3.6.1.3 BoneVue marks the CBP series as *rejected by user* and logs the reason.
- 3.6.2 BPS is unable to process a CBP series, for example, due to an unsupported file format or type (steps 3.3.3, 3.3.8, 3.3.13)

- 3.6.2.1 BPS generates a *failure* event for the relevant processing step.
- 3.6.2.2 BoneVue indicates processing failure in the processing progress view.
- 3.6.2.3 BoneVue marks the CBP series as *processing failed* and logs the reason.
- 3.6.2.4 The procedure continues from step 3.3.16 (TBP).
- 3.6.2.5 Only TBP results will be shown on step 3.3.32.
- 3.6.3 The user rejects the motion correction results (step 3.3.19) or the ROI mask (step 3.3.24)
 - 3.6.3.1 The user enters or selects a rejection reason.
 - 3.6.3.2 BoneVue marks the TBP series as *rejected by user* and logs the reason.
 - 3.6.3.3 Only CBP results will be shown on step 3.3.32.
- 3.6.4 BPS is unable to process a TBP series, for example, due to an unsupported file format or type (steps 3.3.16, 3.3.21, 3.3.26)
 - 3.6.4.1 BPS generates a *failure* event for the relevant processing step.
 - 3.6.4.2 BoneVue indicates processing failure in the processing progress view.
 - 3.6.4.3 BoneVue marks the TBP series as *processing failed* and logs the reason.
 - 3.6.4.4 Only CBP results will be shown on step 3.3.32.
- 3.6.5 The user aborts the process midway or selects to cancel processing at any of the QC steps (steps 3.3.6, 3.3.11, 3.3.19, 3.3.24)
 - 3.6.5.1 BoneVue/BPS stores all the output available at this point.
 - 3.6.5.2 BoneVue ensures the appropriate dataset is marked *partial processing*.
 - 3.6.5.3 BoneVue terminates the procedure.
- 3.6.6 The user selects an input folder with more than one valid series (step 3.3.1)
 - 3.6.6.1 BoneVue alerts the user to the multiplicity and suggests copying the dataset to a new location.
 - 3.6.6.2 BoneVue terminates the flow.
- 3.6.7 BPS detects that the SNR is lower than the recommended threshold.
 - 3.6.7.1 BPS generates a *failure* event for the relevant processing step.
 - 3.6.7.2 BoneVue indicates a low SNR instance.
 - 3.6.7.3 The user may approve processing nevertheless – the main flow is resumed; the user may choose to reject the dataset – see 3.6.3; the user may choose to cancel processing altogether – see 3.6.5.

3.7 Alternative flows

- 3.7.1 The user selects to process a single dataset (step 3.3.1)
 - 3.7.1.1 Main flow steps 3.3.3-3.3.15 or 3.3.16-3.3.30 are skipped, depending on the dataset's type.
 - 3.7.1.2 On step 3.3.32, BoneVue will display single series results.
- 3.7.2 Restart processing - the user selects a series, which is marked *partial processing* (step 3.3.1)
 - 3.7.2.1 The procedure is handled as reprocessing with partial data (see 3.7.4).
- 3.7.3 The user wishes to edit the automatically generated results (steps 3.3.6, 3.3.11, or 3.3.24) – see UC-7.
 - 3.7.3.1 The procedure continues with the edited mask.
- 3.7.4 A series selected by the user had already been processed (step 3.3.1)
 - 3.7.4.1 The flow will go from one QC step to the other until the user decides to change the existing data on steps 3.3.6, 3.3.11, or 3.3.24 (or the required data does not exist in the case of a partially processed dataset as input).
 - 3.7.4.2 Once the user changes the existing data, BoneVue alerts the user that all the output files for this and subsequent processing steps, including the final report, will be deleted.
 - 3.7.4.3 If the user approves, BoneVue requests BPS to clear the output folder of all relevant files and deletes the report file.
 - 3.7.4.4 BoneVue will resume the main flow from the appropriate step until the results are displayed.

E. Traceability Analysis

BoneVue Traceability Matrix (See [Attachment 6](#)) was developed in accordance with EN-001.000, SOP on Design Control and is included in the Design History File.

F. Verification and Validation Documentation

The Software Functional Test Plan, including pass fail criteria and results are included in [Attachment 7](#). This document is a subset of the Design Verification and Validation Plan required by EN-001.000, SOP on Design Control, and part of the Design History File.

G. Revision Level History

This is the initial release of BoneVue Software. Revision History Logs of all required documents are maintained as part of the Design History File.

IX. CONFIDENTIALITY

MicroMRI, Inc. considers its intent to market the BoneVue as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken.

Some of the material in this application may be a trade secret, confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. The Company therefore asks to be consulted with as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

X. SUBMITTER'S NAME AND ADDRESS

MicroMRI, Inc.
580 Middletown Boulevard
Suite D-150
Langhorne, PA 19047
Phone: 267 212-1100
Facsimile: 267 212-1101

XI. CONTACT PERSON

Richard Elrath, CMQ/OE
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
580 Middletown Boulevard
Suite D-150
Langhorne, PA 19047
Phone: 267 212-1119
Facsimile: 267 212-1101
Email: relrath@micromri.com

XII. 510(k) SUMMARY

This 510(K) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter's Information:

Manufacturer:	MicroMRI, Inc. 580 Middletown Boulevard Suite D-150
---------------	---

Langhorne, PA 19047

Contact: Richard Elrath
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
Phone: 267 212-1119
Facsimile: 267 212-1101
Email: relrath@micromri.com

Trade Name, Common Name and Classification:

Trade Name: BoneVue
Common Names: Image processing software
Classification Name: System, Image Processing, Radiological
Product Code: LLZ

Predicate Devices:

510k Reference No. & Date	Device Name	Manufacturer
K070831 May 22, 2007	Voxar 3D™	Barco View MIS 2 Anderson Place Edinburgh, EH6 5NP, UK
K011142 May 8, 2001	Aquarius Workstation™	TeraRecon, Inc. 2955 Campus Drive, Suite 325 San Mateo, CA 94403
K053281 September 3, 2004	EVMS™ Enterprise Visual Medical System	Emageon UV, Inc. 131 Wilson Street Suite 700 Madison, WI 53703
K071331 May 25, 2007	Vitreá® Version 4.0 Medical Image Processing Software	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343

Device Description:

BoneVue evaluates high-resolution MRI datasets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

The following cortical measurements are reported: average cortical inner diameter, average cortical outer diameter, and average cortical thickness.

The following trabecular measurements are reported: average measures of bone volume/total volume, trabecular thickness, trabecular number, and trabecular separation.

The 3D visualization module is used to display a high resolution 3D model of the trabecular bone and its micro-architecture. The 3D visualization helps a trained physician make a qualitative assessment of bone micro-architecture, which may be viewed from different angles. BoneVue allows standard surface rendering views as well as standard maximum intensity projection views.

Additionally, BoneVue offers the display of a standard “bone plug”, a surface rendering of a central cylinder of trabecular tissue, as a representative sample of the bone micro-architecture.

Indications for Use:

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Technological Characteristics:

BoneVue software does not control image acquisition and can be used with a variety of commercially available pulse sequences and imaging coils. BoneVue does not contact the patient, nor does it control any life sustaining devices. A trained physician interprets the data and information being displayed.

Performance Testing:

BoneVue has been successfully tested and has met acceptance criteria previously established in accordance with documented procedures.

Conclusion:

The 510(k) Pre-Market Notification contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices. BoneVue has been developed, and will be manufactured in accordance with the MicroMRI's established Quality Policy Manual, which meets all of the requirements of 21 CFR Part 820, Quality System Regulation and ISO 13485, Medical Devices – Quality Management Systems – Requirements for regulatory purposes. The submission contains the results of a hazard analysis and the “Level of Concern” for potential hazards has been classified as “Minor”.

XIII. STATEMENT of INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): N/A

Device Name: BoneVue

Indications for Use:

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

December 11, 2008

XIV. TRUTHFUL AND ACCURATE STATEMENT

December 11, 2008

XIV. TRUTHFUL AND ACCURATE STATEMENT

(As required by 21 C.F.R. § 807.87(j))

I certify that, in my capacity as President and Chief Executive Officer of MicroMRI, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the BoneVue are truthful and accurate and that no material fact has been omitted.

December 11, 2008



Andreas Muehler, MD, MBA

President and CEO

MicroMRI, Inc.

XV. BIBLIOGRAPHY

Clinical Trial Publications:

Maria Benito, MD; Branimir Vasilic, Ph.D; Felix W Wehrli, Ph.D; Ben Bunker; B.A.; Michael Wald; B.A.; Bryon Gomberg, Ph.D; Alexander C Wright, Ph.D; Babette Zemel, Ph.D; Andrew Cucchiara, Ph.D; PeterJ. Snyder, MD, Effect of Testosterone Replacement on Trabecular Architecture In Hypogonadal Men, Journal of Bone and Mineral Research. 20(10), 2005.

Gomberg BR, Wehrli FW, Vasilic B, Weening RH, Saha PK, Song HK, and Wright AC, Reproducibility and error sources of Micro-MRI-based trabecular bone structural parameters of the distal radius and tibia, Bone 35 (2004) 266– 276.

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Wehrli FW, Gomberg BR, Saha PK, Song HK, Hwang SN, Snyder PJ, Digital Topological Analysis of In Vivo Magnetic Resonance Microimages of Trabecular Bone Reveals Structural Implications of Osteoporosis, Journal of Bone & Mineral Research. 16(8):1520-31, 2001 Aug.

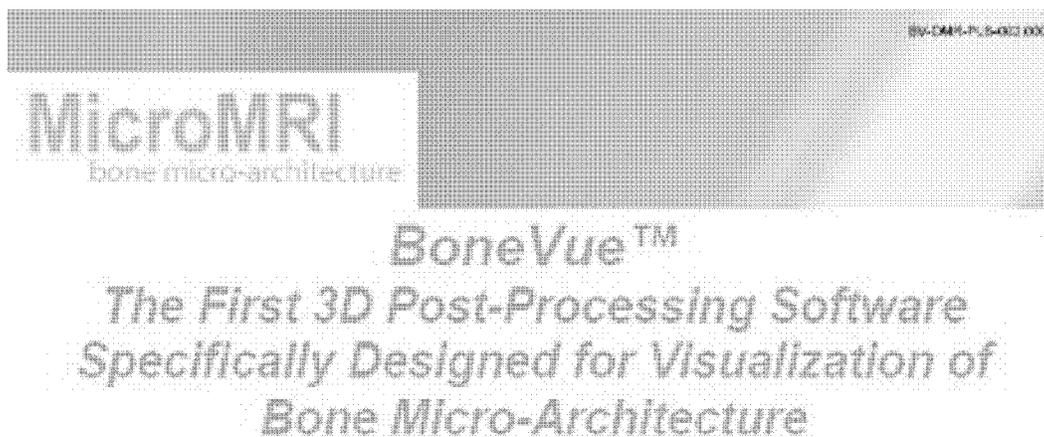
Technical Publications:

Gomberg BR, Saha PK, Wehrli FW, Method for cortical bone structural analysis from magnetic resonance images, Academic Radiology. 12:1320-1332, 2005.

Wehrli, F. W., K. P. Saha, Bryon R. Gomberg, Hee Kwon Song, Peter J. Snyder, Maria Benito, Alex Wright, Richard Weening, Role of Magnetic Resonance for Assessing Structure and Function of Trabecular Bone, Topics in Magnetic Resonance Imaging 13(5): 335-355.

Bryon R. Gomberg, Punam K. Saha, Scott N. Hwang, Hee Kwon Song, and Felix W. Wehrli, >Integrated Processing System for In Vivo MR Images of Trabecular Bone Networks, ISMRM 9th Meeting and Exhibition, Glasgow, Scotland, 2001.

ATTACHMENT 1
Labeling
Product Marketing Brochure



Post-processing software tool:

- 3D visualization of bone micro-architecture
- Operates on high-resolution MRI datasets
- Choice of manual or automated measurements
- Includes cortical and trabecular morphometry

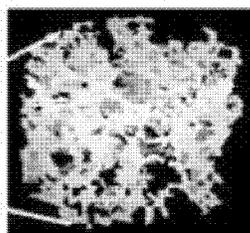
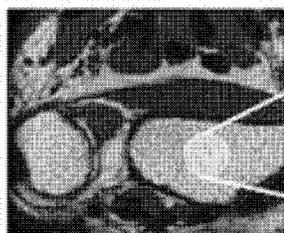


Image display of original MR image and 3D rendering of trabecular micro-architecture using BoneVue™

Tabulation of quantitative descriptive parameters available through BoneVue™ using manual or automated measurements of trabecular and cortical morphometry

Morphometric Measurements		
Name	Units	Description
Cr ID	mm	Cortical Inside Diameter
Cr OD	mm	Cortical Outside Diameter
Cr Th	mm	Cortical Thickness
BWTV	%	Bone Volume
Tb Th	µm	Trabecular Thickness
Tb N	mm ⁻³	Trabecular Number
Tb Sp	µm	Trabecular Separation

CAUTION: Investigational Device. Limited by US Federal Law to Investigational Use Only.

MicroMRI, Inc.
580 Middletown Boulevard, Suite D-150
Langhorne, PA 19047

Tel: 267-212-8100
Fax: 267-212-8101
www.micromri.com



BoneVue™ Operator's Manual

MR Image Post-Processing Software

MicroMRI
580 Middletown Blvd
Suite D-150
Langhorne, PA 19047
Tel: (267) 212-1100
Fax: (267) 212-1101
www.micromri.com

BV-DMR-LEL-001-000-03



ABOUT THIS DOCUMENT

Disclaimer

MicroMRI is not responsible for any issues arising from changes made to the computer hardware or operating system after the delivery of the software or for problems that occur as a result of the use of the BoneVue™ software in conjunction with non-MicroMRI software other than that explicitly covered in this documentation. For a complete description of warranty, please refer to the End User License Agreement (EULA) provided with the MicroMRI BoneVue™ software product.

Caution

For optimal results, the BoneVue™ software should be used to analyze images captured on a magnetic resonance imaging device of 1.5 Tesla or greater. The results of a BoneVue™ analysis are displayed on the computer monitor. BoneVue™ image sets and numeric output should be interpreted by trained physicians only.

The BoneVue™ software is compatible with all Magnetic Resonance Imaging systems that are Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and can run on Windows-based operating systems. No additional software is required. Please confirm that your system has all the required prerequisites for this software application. Please call MicroMRI at 267-212-1100 or e-mail info@micromri.com for more information.

For more information about DICOM, please refer to the National Electrical Manufacturer's Association (NEMA) at: <http://www.nema.org/prod/med/dicom.cfm>.

Regulatory Notices

The MicroMRI Quality Management System complies with the requirements of ISO 13485:2003 entitled Medical devices — Quality management systems — Requirements for regulatory purposes, FDA 21 CFR Part 820 entitled Quality System Regulation (QSR or cGMP), European Medical Device Directive 93/42/EEC, and Medical Device Vigilance System MEDDEV 2.12/1- Canadian Medical Device Regulations (CMDR) Registration SOR/98-282 Food and Drugs Act.

Feedback

As part of our commitment to provide the highest quality products and services, we encourage feedback on the quality of this documentation. Please send questions or suggestions to info@micromri.com and include this Operator's Manual identifier BV-DMR-PLB-001.000-03.



Table of Contents

About this document	2
Disclaimer	2
Caution.....	2
Regulatory Notices	2
Feedback	2
Document Conventions	5
Intended Purpose	6
Introduction	7
Related Documents	7
Prerequisites	7
Software Requirements.....	7
Hardware Requirements.....	7
Operating System Requirements.....	7
Product Overview - Indications for use	8
Software Operation	9
Basic Operation.....	9
Software Installation and Setup	9
Setting Facility Information.....	10
Transferring MRI Datasets.....	10
Starting and Exiting BoneVue™.....	11
Menu Bar	11
Automatic Mode.....	12
Inputs.....	12
Localizer.....	13
Processing.....	13
Output	14
Manual QC Mode.....	15
Cortical Segmentation.....	15
Cortical Boundaries.....	17
Motion Correction.....	18
Trabecular ROI Masking.....	20
Results Screen.....	21
Report Generator.....	23
Key User Alerts.....	24
Processing Exception	24

MicroMRI
(bone micro-architecture)

Low SNR 26
Indeterminate Cortical Boundary 26
Indeterminate Trabecular Boundary 26
Reprocessing Scan Data 26

Appendix 27

Uninstall 27
 Troubleshooting 27
 Support Resources 27



DOCUMENT CONVENTIONS

When you read this Operator's Manual, you will see that certain words are represented in different fonts, typefaces, sizes and weights. This highlighting is systematic; different words are represented in the same style to indicate their inclusion in a specific directory. The types of words that are represented this way include the following:

command (Courier New font)

Windows DOS or command-prompt commands are represented using the Courier New font. This style indicates that you can type the word or phrase on the command line and press [Enter] to invoke a command.

For example: `winver.exe`

APPLICATION

This style in bold all CAPS type should indicate that the program named is an end-user application (as opposed to a program that is part of MicroMRI BoneVue™ software suite).

[key]

A key on the keyboard is shown in this style.

For example: press [Enter]

[key]-[combination]

A combination of keystrokes is represented this way.

For example: press [Ctrl]-[Alt]-[Delete] will invoke the Task Manager program.

Text found on GUI interface

A title, word, or phrase found on a GUI interface screen or window will be shown in this style.

For example: Select the **Polygon** radio button in **ROI Tools**.

"button" on a GUI screen

This text indicates that the enclosed text will be found on a clickable button on a GUI screen.

For example: Click "Next" to proceed with the installation.

Sequence → of → Commands

This indicates a series of commands or buttons to be clicked.

For example: Click **Start** → **All Programs** → **MicroMRI**



This symbol indicates an important instruction for proper usage of BoneVue™ software or proper interpretation of its outputs.



INTENDED PURPOSE

This Operator's Manual focuses on how to use BoneVue™ software and is ideal for radiologists or PACS administrators who want to install, configure and operate this system. This document will help you configure your system, guide you through the basic operational steps, and assist in troubleshooting the software in case of problems.



INTRODUCTION

This Operator's Manual describes how to install and operate the MicroMRI BoneVue™ software.

Related Documents

MicroMRI DICOM CONFORMANCE STATEMENT

PREREQUISITES

Software Requirements

BoneVue™ runs on Microsoft Windows XP Professional Edition. The OS should be patched with the latest Windows Service Packs and Windows hot fixes.

Hardware Requirements

MicroMRI recommends the following minimum computer hardware specifications:

- 1.4 GHz processor speed
- 512 Megabytes of RAM
- 10 Gigabytes available space on primary hard drive
- 19" or higher LCD display monitor

Operating System Requirements

The account on which the BoneVue™ will run should have 'administrator'-level privileges and permissions. The account should have both read and write access to Windows Services, registries and Scheduled Tasks. Additionally, the account should have full access to the files and folders in which the DICOM images will be stored.



PRODUCT OVERVIEW – INDICATIONS FOR USE

The MicroMRI BoneVue™ medical imaging post-processing software provides the most sophisticated tool available for 3D visualization of bone micro-architecture using high resolution MRI datasets. MicroMRI revolutionizes the clinical radiology experience with an easy to-use software application that provides interactive 3D visualization of the trabecular bone as well as automated measurements of descriptive parameters regarding the cortical and trabecular bone.

BoneVue™ processes the MR data and provides the following measurements:

Name	Units	Description
BV/TV	%	Ratio of bone volume to total volume
Tb.Th	µm	Mean trabecular thickness
Tb.Sp	µm	Mean separation between trabecular plates
Tb.N	1/mm	Mean linear density (pitch) of trabecular plates
Cr.OD	mm	Mean outer diameter of cortical shell
Cr.ID	mm	Mean inner diameter of cortical shell
Cr.Th	mm	Mean thickness of cortical shell

A coil with high signal-to-noise (SNR) for generating high resolution images, such as the birdcage MicroMRI Wrist Coil, is recommended for use with BoneVue™ post-processing software.

In addition to a suitable coil, MR imaging of bone micro-architecture requires use of a pulse sequence capable of acquiring high-resolution images in tissue with magnetic susceptibility effects. BoneVue™ can process data from a variety of commercially available pulse sequences. Generally, two pulse sequences are used, a first sequence for volumetric imaging of cortical bone and a second sequence for volumetric imaging of trabecular bone. The image data in DICOM format from the cortical and trabecular scans (or, alternatively, the raw k-space data from the trabecular scan) are transferred to the PC running BoneVue™ via a network connection or by reading data sets stored on a CD.

Typically, the cortical data are acquired with a Spin Echo pulse sequence and the high resolution trabecular data are acquired with a Fast Large Angle Spin Echo (FLASE) pulse sequence. Please refer to your MRI system's Operator's Manual for information how to set up pulse sequences.

MicroMRI BoneVue™ provides the user with two processing modes. In Automatic Mode, the user selects the data sets to be processed and BoneVue™ then automatically processes the entire study, including both the cortical and trabecular data series, and displays the results. The user can save and print a clinical report, and then select another study for processing.

Alternatively, in Manual QC Mode, the user interacts with BoneVue™ during the processing. At four different stages, intermediary results are displayed, which the



user may accept or reject, or, in the case of ROI boundaries, modify. The Manual QC Mode is recommended for users who want to inspect and have the option to modify the intermediary results of individual processing steps.

The MicroMRI BoneVue™ software license permits installation on a single PC. Installation by the user on more than one PC is strictly prohibited.

SOFTWARE OPERATION

Basic Operation

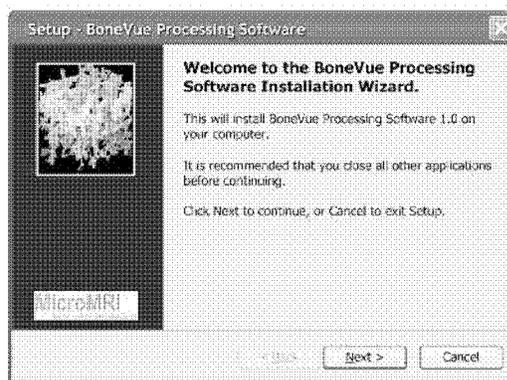
BoneVue™ software interacts with the user in a way that is standard among computer applications. The basic objects the user will see and interact with are windows, buttons, tabs, and menus. Hence, the user input to the program will be reduced mostly to mouse clicks on windows, buttons, and menu selections.

Buttons work in a standard way throughout the product. You must click with the left mouse button on the displayed button to invoke the associated action. Buttons have a generic grey color and are operated with the single click of the left mouse button.

Please refer to the **Document Conventions** section above for a description how buttons, windows, clicks and menu options are referenced in this Operator's Manual.

Software Installation and Setup

1. Log on to Windows® as an administrator.
2. Close all open applications.
3. Insert the BoneVue™ CD-ROM in the CD drive.
4. Click 'Next' on the BoneVue™ installation screen shown below.
5. Follow the displayed instructions.





Setting Facility Information

During the installation process, you will be asked to enter identification information about your MRI facility as shown on the screen below. This information will be automatically incorporated into the reports generated by BoneVue™.

Facility Information	
Facility Name	North Shore Diagnostic Imaging
Address	123 Main Street
Address2	Suite 1040
City	Yorhtown
State	OH
Zip	39464
Telephone	767-555-9000
Fax	767-555-9001
e-mail	radiology@nsdi.com
Logo	c:\forms\logo\nsdi_logo.jpg

Save
Cancel
Close

You may access and revise this information at any time by clicking on **Tools** → **Settings** on the menu bar.

Transferring MRI Datasets



Before starting the BoneVue™ application, you should transfer the MRI cortical and trabecular datasets to be processed to file folders accessible to the PC on which BoneVue™ is installed. By default, BoneVue™ expects the datasets to be located in the local drive in the following directories:

c:\MMRI_Input\Cortical\
c:\MMRI_Input\Trabecular\



Datasets can be transferred by CD or via a network connection, if available. The trabecular and cortical series are multi-slice studies. When transferring DICOM image files, be sure to transfer all the DICOM image files to the BoneVue™ input file folder. Missing DICOM image files in the middle of a multi-slice study will cause BoneVue™ to abort the image processing.



In general, there will be a single study for a given patient on a given date. However, if the study was repeated, for example, due to excess patient motion, there may be multiple studies for a particular patient on the same date. It is important to ensure that the trabecular and cortical datasets be acquired from the same study. Attempting to process two series from different studies will cause BoneVue™ to abort the image processing.



Starting and Exiting BoneVue™

Before starting the application, check to make sure there is sufficient free space available on the hard drive to accommodate the data processing. One Gigabyte of free space on the hard drive is sufficient for processing up to 2,000 studies. If there is insufficient free space on the hard drive, the user must delete files no longer needed until there is sufficient free space.

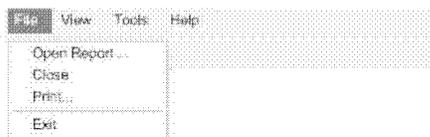
From the Windows® desktop, click on **Start → All Programs → MicroMRI → BoneVue**. The application will be automatically launched in Automatic Mode.

Upon completion of a working session, BoneVue™ may be closed by clicking on **File → Exit** on the menu bar in the BoneVue™ application.

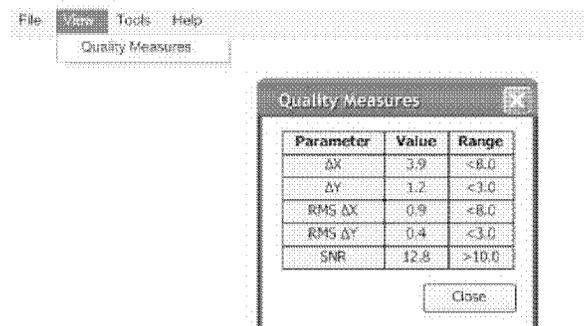
Menu Bar

The menu bar provides access to several important functions.

Clicking on **File** opens a drop down menu that allows the user to open previously saved Reports, print or close the current Report, or to exit from the application.



Clicking on **View** pops up a display of Quality Measures for the last study processed during the current session. The quality parameters are explained further in the Results Screen section below.



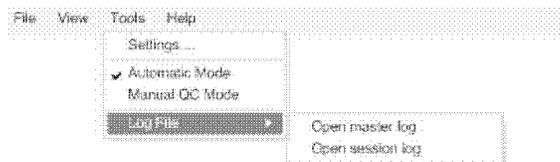
Clicking on **Tools** opens a dropdown menu that provides access to several useful capabilities.

Clicking on **Settings** allows the user to change the facility information settings as described in Software Installation and Setup above.



In the **Tools** dropdown menu the user can select either Automatic Mode or Manual QC Mode for processing the image data, as further described below.

In addition, the user can access the Master Log File and the Session Log File to aid in troubleshooting, if needed.



Clicking on **Help** will display software version information and also allows the user to view a PDF version of this Operator's Manual.

Automatic Mode

In Automatic Mode, the user selects a study for processing and clicks the **"Start"** button. No further user interaction is required to complete the processing and display the results.

While in Automatic Mode, the message "BoneVue Mode: Automatic:" is displayed in the status bar at the bottom of the screen.

When operating in the Automatic Mode, it is recommended that the user inspect the quality of the images displayed on the Results Screen before saving and printing a Report.

The BoneVue™ Processing display screen is organized into 4 sections, as further described below.

- Inputs
- Localizer
- Processing
- Output

Inputs

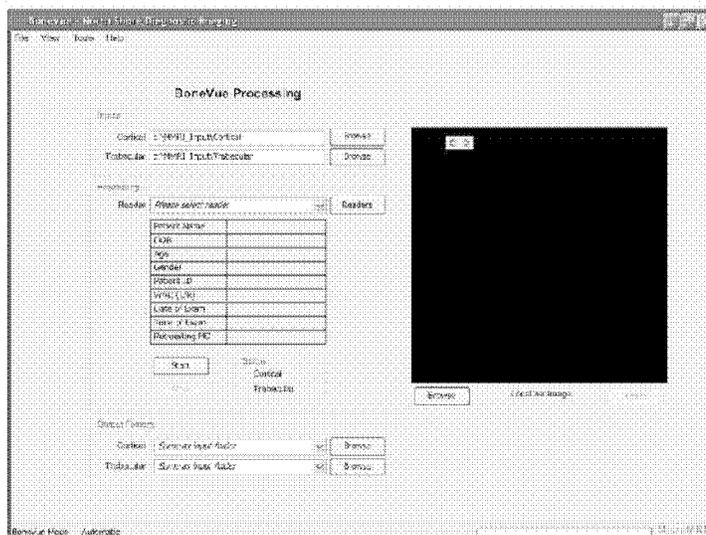
The default folders, where the cortical and trabecular scan data are expected to be stored, are:

```
c:\MMR1_Input\Cortical\  
c:\MMR1_Input\Trabecular\  

```

You may optionally change the input folders, either by typing the path in the text box, or by clicking on the **"Browse"** buttons to select the folders containing the scan data. The cortical and trabecular scan data must be from the same study and for the same patient.

After selecting the input scan data, the table in the Processing area on the display screen will be automatically populated with patient demographic data.



If scan data are available for only trabecular or cortical, then delete the text identifying the path for the unavailable scan data. In this case, only the available scan data will be processed.

Localizer



The user has the option of displaying a localizer image by clicking the "Browse" button below the localizer window and selecting one of the localizer images from the current study. The user may scroll through and view other localizer images acquired in the study by clicking the spinner button on the localizer image window.

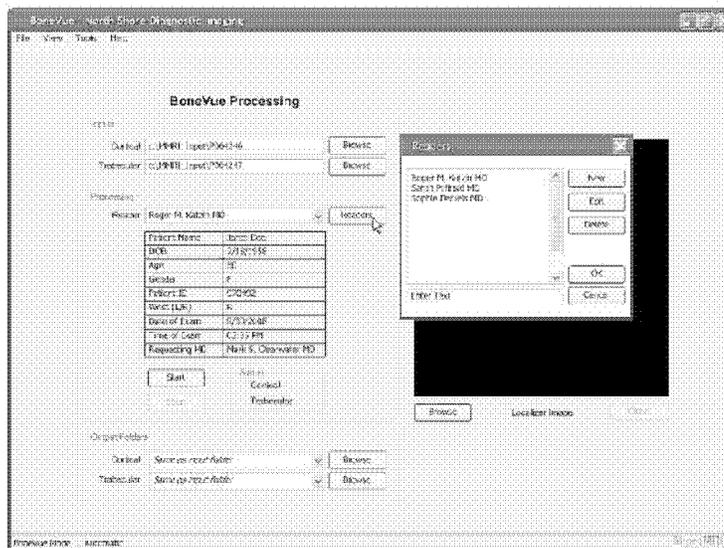


Note that while BoneVue™ processing of trabecular and cortical data sets does not require viewing the localizer image, it is highly recommended that the user perform this step to check that the trabecular and cortical scans were acquired at the proper anatomical locations.

Processing

The user should select the appropriate name from the **Readers** combo box in the Processing section. The selected Reader Name will be entered into the Reports generated by BoneVue™.

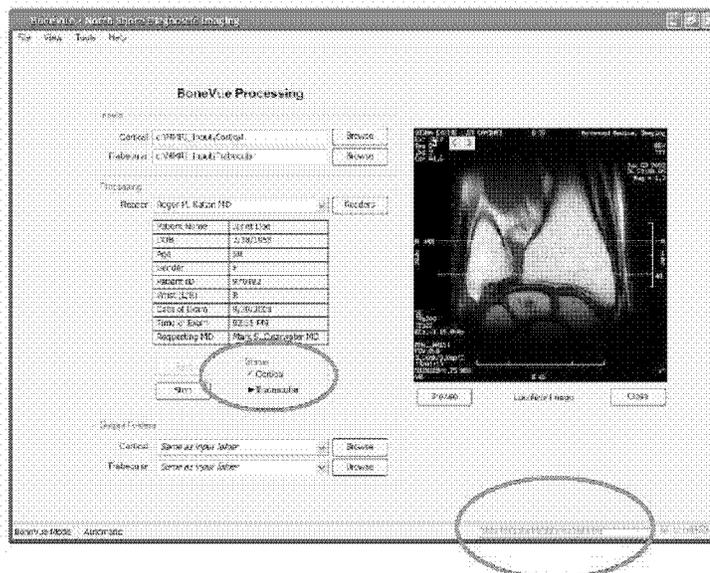
The list of readers may be edited by clicking on the "Readers" button, as shown below. New names may be added, and existing names may be edited or deleted.



Output

The user may optionally select folders for storing the output files generated by BoneVue™. If no selection is made, by default the output folders will be the same as the input folders.

To begin processing, the user clicks the “Start” button.





While processing in Automatic Mode, a progress bar is displayed on the right side of the status bar at the bottom of the display screen. In addition, the **Status** box inside the Processing group informs the user which part of the study (cortical or trabecular) is currently being processed.

Processing a data set that includes both cortical and trabecular scans takes about 40 minutes on a PC with a 1.6 GHz CPU. The user may halt the processing at any time by clicking the "Stop" button.

After completion of processing, the Results screen is displayed, as explained in the Results Screen section on page 21 below.

Manual QC Mode

While processing in Automatic Mode will provide satisfactory results in most cases, Manual QC Mode gives the user the option to visually inspect, and to accept, modify, or reject the automatically generated results at intermediary processing stages. This mode is recommended for users who prefer to visually inspect and exercise a greater degree of control over the post-processing.

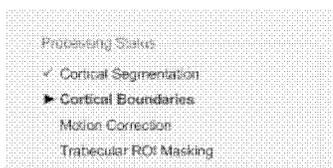
To switch from Automatic Mode to Manual QC Mode, click on **Tools** → **Manual QC Mode** on the menu bar.

While in Manual QC Mode, the message "BoneVue Mode: Manual QC:" is displayed in the status bar at the bottom of the screen.

Following the same steps as described in the Automatic Mode section, the user should select input and output folders, set the Reader name, and display a localizer image.

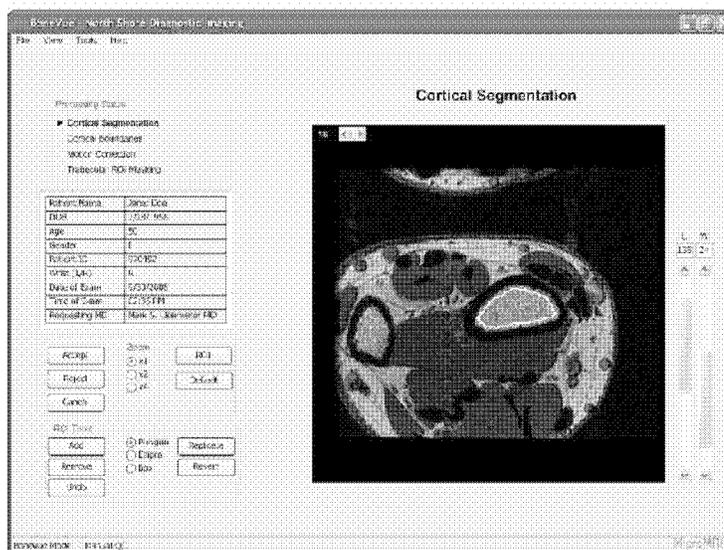
After checking to ensure proper positioning on the localizer image, the user clicks "Start". The first step in the processing chain is cortical segmentation.

The progress of each processing step is displayed in a progress bar at the bottom of the display screen. In addition, the overall Processing Status, including the current processing stage and which stages have already been completed, is displayed, as shown in the example below:



Cortical Segmentation

In this first processing step, the first cortical image of the multi-slice stack of cortical images is displayed. A white contour is displayed as an overlay on the image. This is an exclusion contour, meaning that the cortical boundaries subsequently calculated exclude any pixels inside an exclusion contour.



The user may click on the "ROI" button to toggle on/off the exclusion contour. The user can control the degree of image enlargement by selecting x1, x2, or x4 magnification in the zoom box. When the image is magnified to a size larger than the display size, vertical and horizontal scroll bars are automatically displayed to enable the user to pan to the desired location on the image.

At any time, the user may change window and level settings by adjusting the scroll bars to the right of the image or by entering numerical values into the text boxes above the scroll bars.

The user may scroll through the stack of axial cortical images to view the exclusion contour on other images slices by clicking on the spinner button on the upper left corner of the displayed image.

The user should verify that the exclusion contour circumscribes the trabecular/marrow region while remaining inside the true inner cortical boundary and that its deviation from the true inner cortical boundary does not exceed 2 or 3 pixels.

If the user is satisfied with the exclusion contour on all axial slices, he may click **Accept** and the next processing step will be initiated.

The user may increase or decrease the size of the cortical boundary on a given image by clicking "Add" or "Remove" button, respectively, in the ROI Tools box. The user can select an **Ellipse** or **Box** drawing shape and then left-click and drag the mouse on the image to set the position and size of the shape. In the **Add** mode, the ROI will be adjusted to add the area of the ellipse or box to the original ROI, thus expanding its area. In the **Remove** mode, area common to the original ROI and the ellipse or box will be removed from the original ROI, thus shrinking its area. Clicking "Undo" undoes the last step.



If the **Polygon** shape is selected, the process is similar except that the user makes a series of left mouse clicks on the image to define the polygon-shaped ROI.

Clicking the **Revert** button will cause the ROI to revert to its initial state.

Clicking the **Default** button will cause the ROI to revert to its initial state and also reset the window/level and zoom settings to their initial state.

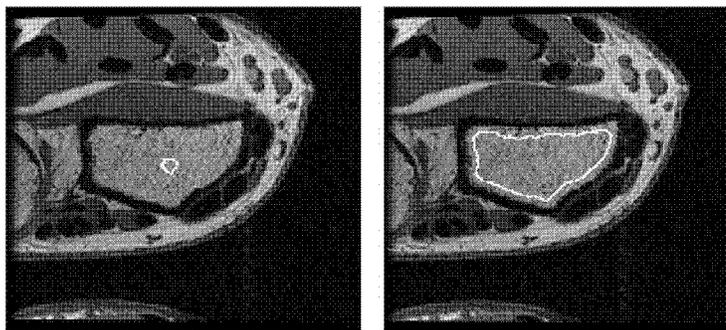
Clicking the **Replicate** button will replace the ROI with the ROI from the previous slice in the cortical stack.

Clicking the **Accept** button confirms that the cortical segmentation is acceptable as displayed. BoneVue™ continues on to the next processing step.

Clicking the **Cancel** button returns the user to the BoneVue™ Processing display screen where he may reprocess the current study from the start.

Clicking the **Reject** button aborts the current processing (e.g. cortical) but will continue to process the other portion of the study (e.g. trabecular) if that data set is available.

In the before and after example below, the **Polygon** ROI tool has been used on the left image to enlarge the initial exclusion ROI (incorrectly clustered in the center) to just inside the cortical boundary as shown on the right image.



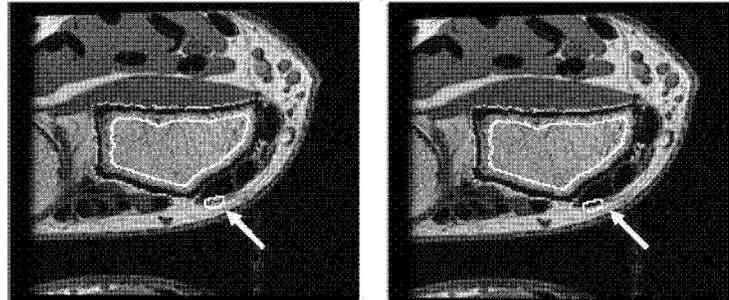
Cortical Boundaries

In the second intermediary processing step, the first cortical slice in the multi-slice cortical study is displayed with two ROIs marking the inner and outer cortical boundaries.

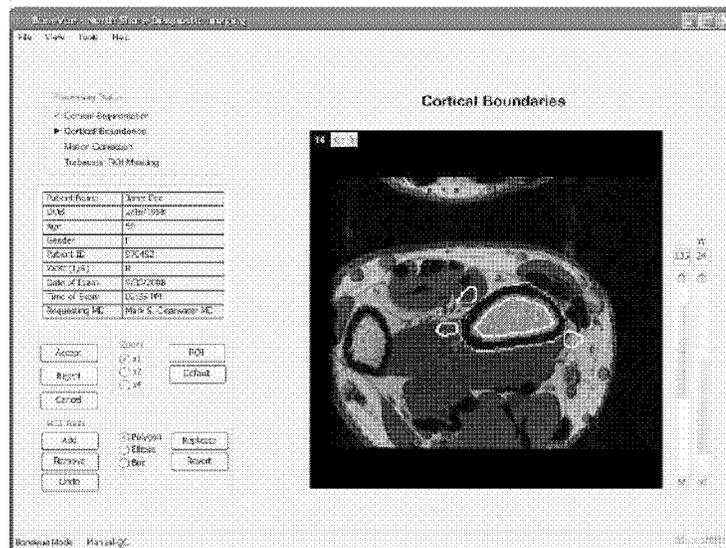
If there are outlier points for displayed for either the inner or outer cortical boundaries, the user may exclude these by clicking the **Add** button and drawing an ROI using the **ROI Tools** to circumscribe the outlier points. This process may be performed repeatedly until all outlier points have been circumscribed for subsequent exclusion.



In the example below, a group of green points that are outliers on the external cortical boundary are circumscribed in an exclusion ROI by clicking the "Add" button and using the Polygon drawing tool. As shown on the right, these points are automatically removed from the cortical boundary (yellow arrow).



In a second example below, there were three clusters of outlier points that were excluded from consideration as cortical boundary points by circumscribing them in three separate exclusion ROI contours.



Upon completing this step, the user clicks either the "Accept", "Reject", or "Cancel" button. The actions taken are the same as described above in the previous processing stage.

This step completes the user interaction with processing of the cortical scan data.

Motion Correction

The third processing step performs motion correction on the trabecular data.



Despite immobilization of the patient's limb during the scan, patient movement can not be eliminated completely. The high resolution MRI scan is sensitive to small amounts of patient motion. When enabled, the extent of motion is measured and its effects are mitigated in this processing step.

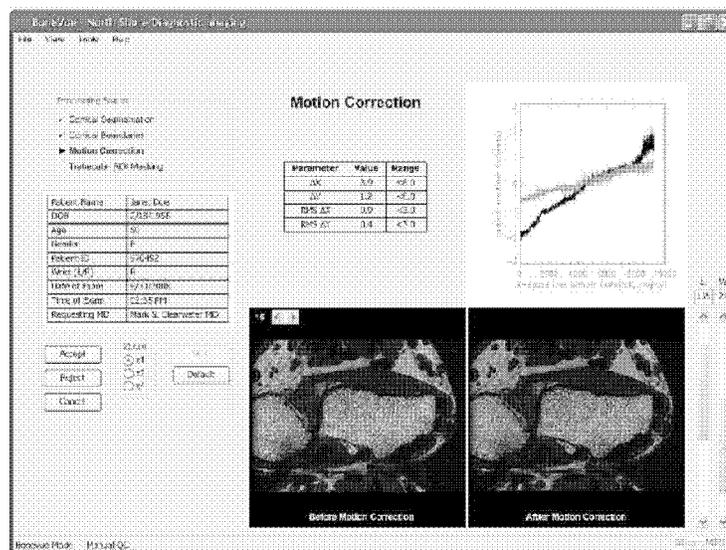
Upon completion of this processing step, a trabecular image from the mid-point of the image stack is displayed before and after motion correction. This comparison allows the user to visually judge the presence of motion in the original image and the extent of its mitigation by the motion correction algorithm.

In addition, a graph is displayed which tracks the amount of motion that occurred during the scan in the horizontal and vertical (x and y) directions.

Finally, a table is displayed that displays the maximum and RMS (root mean square) movement in the x and y directions, along with the acceptable range for each of these parameters. A parameter exceeding its acceptable range is highlighted and the user should carefully judge the image quality of the motion corrected images before deciding whether to accept or reject the study. The other trabecular slices in the study may be displayed by clicking on the spinner button.

Window/level and pan/zoom controls are provided and function in the same manner as previously described.

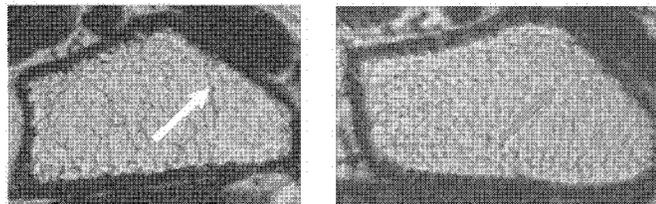
Upon completing this step, the user clicks the "Accept", "Reject", or "Cancel" button. The actions taken are the same as previously described.



An example of a clean image without motion artifact is shown below on the left. Note the sharp dark lines representing the trabecular bone (white arrow). In comparison, an image with excessive motion artifact, which should be rejected



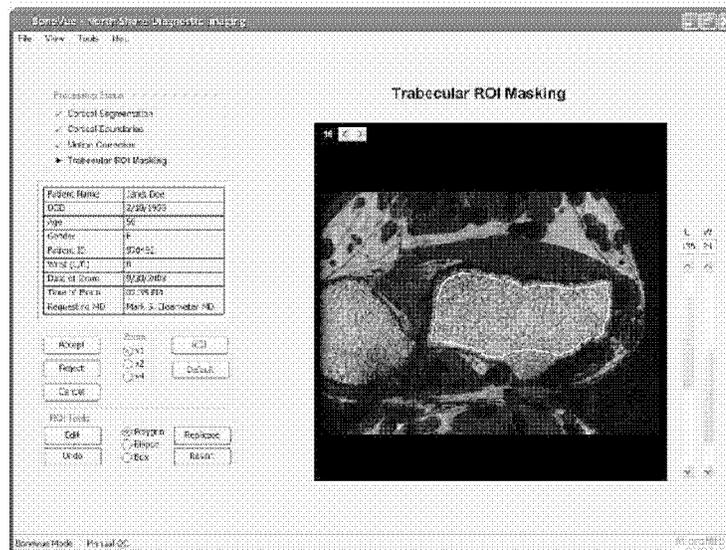
from further analysis, is shown below. Note the absence of clear trabecular structure (red arrow).



Trabecular ROI Masking

The fourth and final processing step calculates and displays a boundary around the trabecular/marrow space. The slice from the mid-point of the image stack is initially displayed. The user may view other slices by clicking the spinner button.

The user may toggle on and off the boundary by clicking the "ROI" button.



Window level/width and pan/zoom controls are provided and function in the same manner as previously described.

The user may view other slices in the image stack by clicking on the spinner button.

The user may view and modify the ROI boundary on individual slices by using the ROI Tools as previously described.

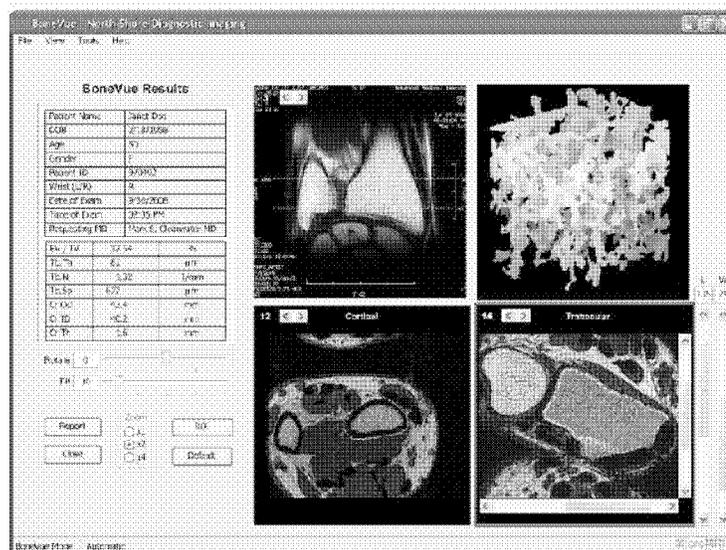
Upon completing this step, the user clicks the "Accept", "Reject", or "Cancel" button. The actions taken are the same as previously described.



If the user clicks "Accept", the processing will continue. When the processing is completed, the Results Screen will be displayed.

Results Screen

Upon completion of processing in either the Automatic Mode or the Manual QC Mode, the Results Screen is displayed, as shown below:



On the left side of the screen, patient and study information are displayed along with a table presenting the cortical and trabecular bone measurement results. The table includes the following measurements:

Name	Units	Description
BV/TV	%	Ratio of bone volume to total volume (BVF)
Tb.Th	µm	Mean trabecular thickness
Tb.Sp	µm	Mean separation between trabecular plates
Tb.N	1/mm	Mean linear density (pitch) of trabecular plates
Cr.OD	mm	Mean outer diameter of cortical shell
Cr.ID	mm	Mean inner diameter of cortical shell
Cr.Th	mm	Mean thickness of cortical shell



The 3D visualization, further described below, is a representative sample from the trabecular volume. However, the bone parameters in the table above are calculated based on the entire imaged volume of cortical and trabecular bone that is contained inside the respective cortical and trabecular ROI boundaries.



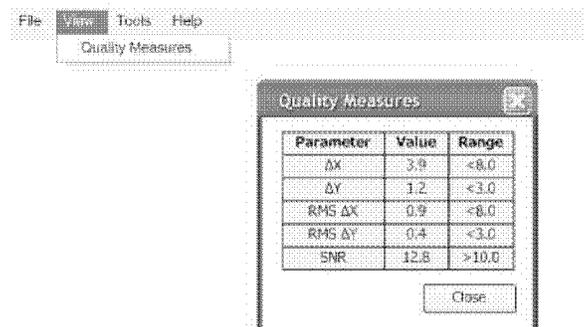
On the right side of the screen four images are displayed in clockwise order starting in the upper left corner:

1. **A localizer image**, if one was selected before processing began. If no localizer was selected, a "Browse" button is displayed and the user may select a localizer image for display. Other localizer images may be selected for display by clicking the spinner button.
2. **A surface rendered projection of a 3D visualization** of a representative sample of the trabecular bone. The projection image may be tilted and/or rotated by adjusting the sliders on the left side of the screen or by typing different numeric values into the adjacent text boxes. The numeric values correspond to angular degrees of tilt and rotation.
3. **A trabecular slice**. Different trabecular slices may be selected by clicking on the spinner control. The slice number is displayed to the left of the spinner control.
4. **A cortical slice**. Different cortical slices may be selected by clicking on the spinner control. The slice number is displayed to the left of the spinner control.

Individual images may be selected by left-clicking the mouse. When an image is selected it will be surrounded by a red frame. The window level/width and pan/zoom controls are active only for the selected image.

Upon selecting the trabecular or cortical image, the trabecular/marrow or cortical boundaries may be toggled on and off by clicking the "ROI" button. When the ROI is displayed, the voxel values inside the ROI on the trabecular image display a gray scale that corresponds with the calculated values of bone volume fraction (BVF), which is defined as the ratio of bone volume to total volume. These values range from zero to 100%.

The user may check the results of motion correction and signal-to-noise (SNR) in the trabecular series by clicking **View → Quality Measures** on the menu bar.



Clicking on the "Default" button will return the window level/width and pan/zoom settings and the rotate and tilt settings for the 3D view to their initial values.

When satisfied with the results of the BoneVue™ processing, the user may save and print a report by clicking "Report".



Report Generator

Clicking **Report** saves the report and displays a preview of the final report and a dialog box with print controls. In the dialog box, the user may select any available printer and the number of copies to print.

Clicking **OK** in the dialog box will cause the report to be printed. Clicking **Cancel** will close the report screen without saving or printing the report.

A message on the status bar notifies the user that report has been saved.

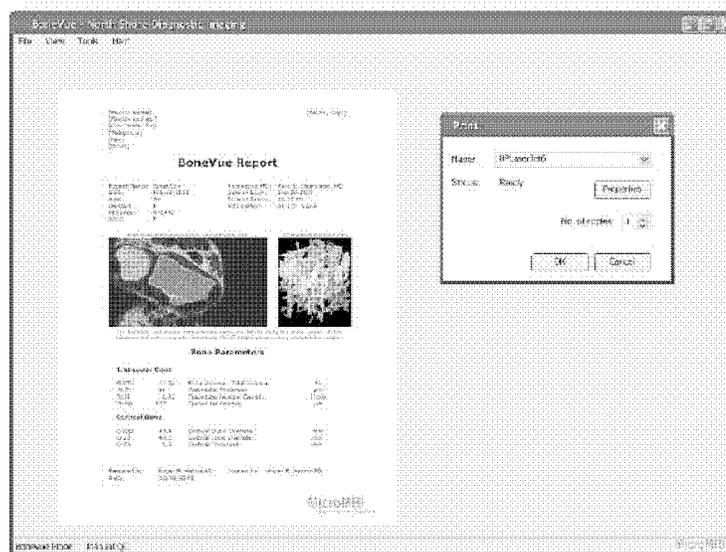


The report includes the following information:

- Facility identification information
- Patient and exam information
- An axial image of the trabecular bone
- A 3D visualization of a representative sample of the trabecular volume
- Table of measurement results of trabecular and cortical bone
- Name of person preparing/signing the report
- Report date

Reports are saved as PDF files using a standardized convention for file naming to facilitate future retrieval, if needed:

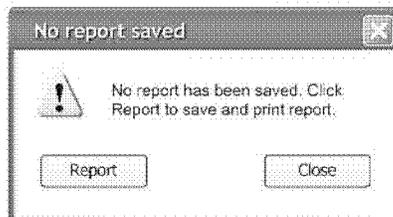
YYYYMMDD_LastName_FirstName.pdf





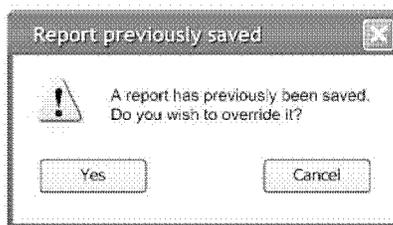
YYYYMMDD is the exam date expressed as year, month, day; and LastName and FirstName are the patient's family and first names.

If the user attempts to close the Results or Report screen without first saving the report, the following warning message will pop up:



The user may print and save the report or confirm his/her intentions to not print/save the report by clicking "Close".

If a user has processed a study that was previously processed saved, the following warning message will pop up upon clicking the "Report" button:



Clicking "Yes" will cause the previously saved report to be overwritten. Clicking "Cancel" will retain the previously saved report.

Key User Alerts

BoneVue™ alerts the user of processing exceptions and conditions that require user decisions. Some of the key user alerts are described in this section.

Processing Exception

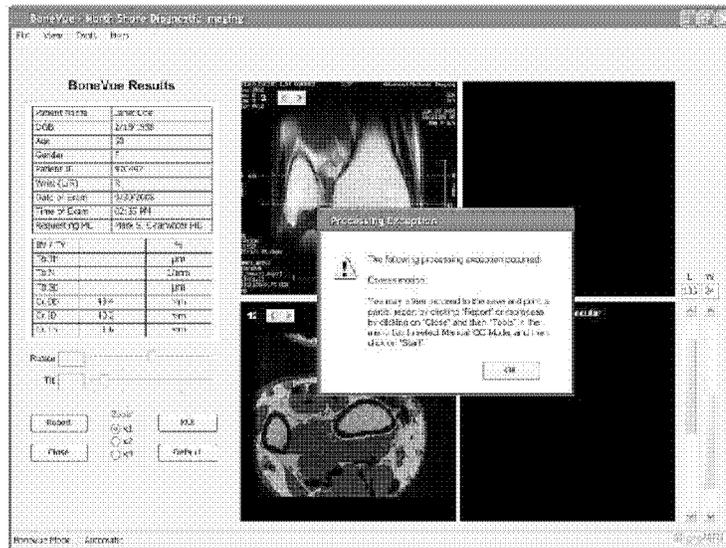
Processing exceptions can occur when processing in Automatic Mode, for example, when there is excess patient motion, or if a cortical or trabecular boundary cannot be reliably determined by the software. In such cases a dialog box pops up that:

- Informs the user that a processing exception has been detected
- Identifies the processing exception
- Advises the user regarding what corrective action to take

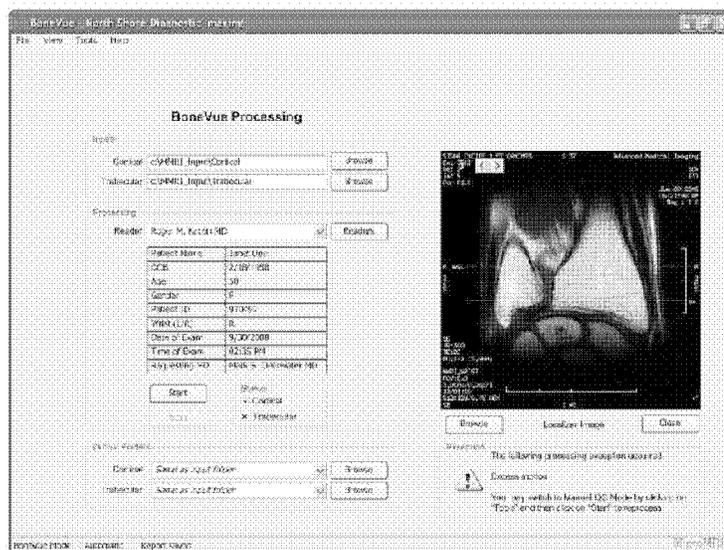
For example, if excess patient motion is detected, a message will be displayed similar to the example below.



In this case, the user is advised to either print/save a partial report that would contain only cortical measurements, or to attempt re-processing in Manual QC Mode. In this mode, the user may visually inspect the quality of the motion correction and decide whether or not to process the trabecular data, or if it is necessary to repeat the MRI acquisition.



If the user decides to switch to Manual QC Mode and reprocess, the start processing screen will be displayed with a message to remind the user that an exception has occurred. In this example, the processing status display indicates that the cortical series was processed, but a problem occurred in the trabecular processing (red highlight).



Low SNR

An alert is automatically displayed if the SNR (signal-to-noise ratio) in the trabecular or cortical series is below the recommended level. A low SNR can adversely impact the accuracy of bone measurements.

Indeterminate Cortical Boundary

If there is inadequate contrast in the MR images, BoneVue may not be able to automatically determine the inner or outer cortical boundary. In this case the user should switch to Manual QC Mode and visually inspect and set the ROI on each slice.

Indeterminate Trabecular Boundary

If there is inadequate contrast in the MR images, BoneVue may not be able to automatically determine the trabecular/marrow boundary in the trabecular image series. In this case the user should switch to Manual QC Mode and visually inspect and set the ROI on each slice.

Reprocessing Scan Data

BoneVue™ permits the user to re-process data that has already been processed. The user will be alerted if the re-processing will modify the final results and the user may choose whether to proceed or cancel the re-processing.



APPENDIX

Uninstall

The **BoneVue™** software can be uninstalled by using the Windows Add/Remove dialog in the Control Panel:

1. Select Control Panel
2. Click Add/Remove Programs
3. Select MicroMRI BoneVue™
4. Click "Remove". Select "Yes" to uninstall **BoneVue™** software.

Troubleshooting

BoneVue™ employs extensive logging capabilities that aid in troubleshooting potential problems with the software.

You can view log files by clicking **Tools** → **Master Log**. You can also send the log file as email attachments to your MicroMRI Application Specialist. To export the log file:

- Go to your BoneVue™ Installation Directory (by default, this is at C:/Program Files/MicroMRI.
- Copy or send the file "MasterLog.txt" to your Application Specialist.

Support Resources

MicroMRI offers technical support for help in installing, configuring, or troubleshooting MicroMRI software. For prompt response, contact MicroMRI at:

Service and Support offices

North America

MicroMRI
580 Middletown Blvd
Suite D-150
Langhorne, PA 19047
267-212-1100
info@micromri.com

ATTACHMENT 2
Substantial Equivalence Chart

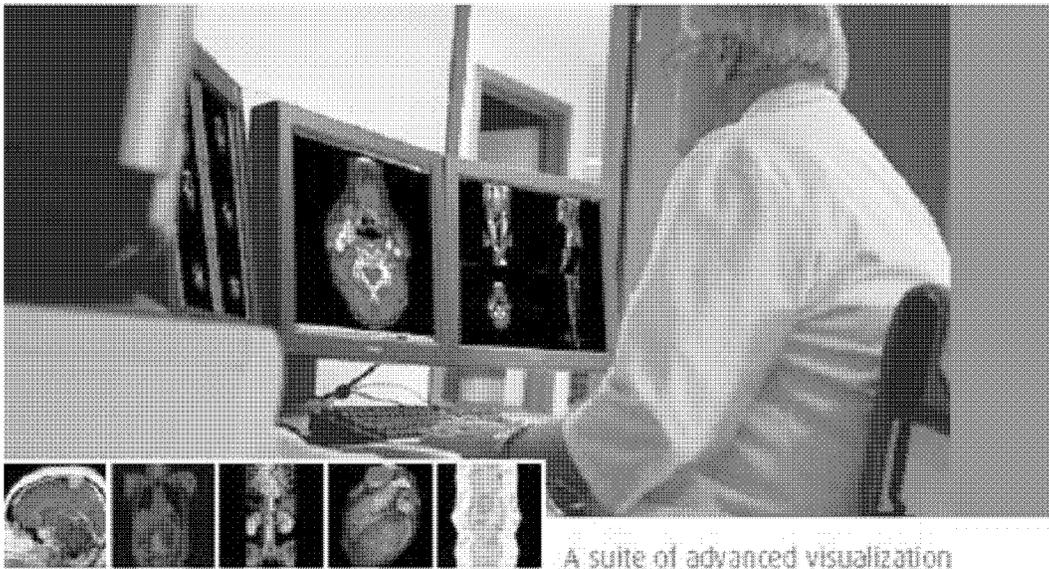
Company	MicroMRI, Inc.	Barco View MIS	TeraRecon, Inc.	Emageon Inc.	Vital Images, Inc.
Product Name	BoneVue	Voxar 3D™	Aquarius™	EVMS™	Vitreva®
510(k) Number	N/A	K070831	K011142	K053281	K071331
Intended Use	BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI datasets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI datasets of bone.	The Voxar 3D™ product family is a suite of products that is intended to provide tools for reading and review of a DICOM compliant series of medical images which can be interpreted as representing a volume of data. These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.	To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported.	The Enterprise Visual Medical System™ is classified as a picture archive and communications systems. It is a software only solution developed by Emageon Inc., combined with other 3 rd party off-the-shelf software, standard computer workstations and standard storage devices that allow authorized physicians and authorized health care professionals to manage access, visualize and store digital medical images, visualization tools, clinical content management and clinical work flow through a graphical user interface.	Vitreva® is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.
Product Characteristics	Software to be run on Windows PC	Software to be run on Windows PC	Software to be run on Windows PC	Software to be run on Windows PC	Software to be run on Windows PC
Main Functionality	3D visualization of images, particularly of trabecular bone micro-	3D visualization of data volumes	3D and 4D visualization of images, teleradiology, image	3D visualization, including surface and volume rendering and	3D visualization, post-processing analysis tools which include a

Company	MicroMRI, Inc.	Barco View MIS	TeraRecon, Inc.	Emageon Inc.	Vital Images, Inc.
Product Name	BoneVue	Voxar 3D™	Aquarius™	EVMS™	Vitreá®
510(k) Number	N/A	K070831	K011142	K053281	K071331
Input	architecture		archiving, image manipulation	real-time Multi-Planar Reformatting (MPR)	number of quantitative measurements
Tissue Segmentation	MRI Datasets	MRI and CT Datasets	MRI and CT Datasets	CT and PET Datasets	MRI and CT Datasets
Possibility of Manual Measurements	Yes	Yes	Yes	Yes	Yes, including auto bone segmentation
Examples	<ul style="list-style-type: none"> Cortical Thickness Trabecular Separation 	<ul style="list-style-type: none"> Vessel Diameter Vessel Length 	<ul style="list-style-type: none"> Curved Planar Reformats Distance Angle Volume Area 	<ul style="list-style-type: none"> Boundary Contours Volume Thickness 	<ul style="list-style-type: none"> Boundary Contours Volume Thickness
Possibility of Automated Measurements	Yes	Yes	Yes	Yes	Yes
Examples	<ul style="list-style-type: none"> Cortical Thickness Trabecular Separation Bone Volume Fraction (Fraction of Total Volume) 	<ul style="list-style-type: none"> Vessel Diameter Vessel Length Tissue Area Tissue Thickness Contours 	<ul style="list-style-type: none"> Vessel Diameter Tissue Thickness Tissue Volume Percent Tissue Volume (Fat) 	<ul style="list-style-type: none"> Vessel Diameter Vessel Length Tissue Volume Contour Detection 	<ul style="list-style-type: none"> Vessel Diameter Vessel Length Tissue Volume Contour Detection
Report Output	Yes	Yes	Yes	Yes	Yes
3D Visualization	Yes	Yes	Yes	Yes	Yes
Quantitative Parameter Reporting	Yes	Yes	Yes	Yes	Yes
Examples	<ul style="list-style-type: none"> Bone Volume Fraction Trabecular Thickness Trabecular Number Trabecular Separation 	<ul style="list-style-type: none"> Cardiac Application <ul style="list-style-type: none"> Coronary Vessel Size Coronary Artery Occlusions Calcium Scoring Ejection Fraction 	<ul style="list-style-type: none"> Vessel Analysis Tool Tissue Diameter Plaque Characterization Calcium Scoring Percent Fat in Region 	<ul style="list-style-type: none"> Volume Rendering Maximum Intensity Projection (MIP) Vessel Diameter Vessel Length Tissue Volume 	<ul style="list-style-type: none"> Vessel Diameter Vessel Length Tissue Volume VScore™ (quantify calcium deposits in the coronary arteries)

Company	MicroMRI, Inc.	Barco View MIS	TeraRecon, Inc.	Emageon Inc.	Vital Images, Inc.
Product Name	BoneVue	Voxar 3D™	Aquarius™	EVMS™	Vitreá®
510(k) Number	N/A	K070831	K011142	K053281	K071331
	<ul style="list-style-type: none"> • Cortical Diameter • Cortical Thickness 	<ul style="list-style-type: none"> ○ Wall thickness ○ Stroke volume • Colon Application ○ 3D visualization of colon interior surface ○ Distance measurement 	of Interest		<ul style="list-style-type: none"> • Cardiac Functional Analysis CFA (automatically calculates end diastolic and end systolic volumes to compute ejection fraction)
Safety:	<ul style="list-style-type: none"> • Clinician review of data is integral to use of the software. 	<ul style="list-style-type: none"> • Clinician review of data is integral to use of the software. 	<ul style="list-style-type: none"> • Clinician review of data is integral to use of the software. 	<ul style="list-style-type: none"> • Clinician review of data is integral to use of the software. 	<ul style="list-style-type: none"> • Clinician review of data is integral to use of the software.

ATTACHMENT 3
Predicate Device Promotional Literature
Barco's Voxar 3D

Voxar 3D™



A suite of advanced visualization
and analysis software tools



The power to drive productivity

To effectively manage the rapid growth of large volumetric image studies and the impact that has on your productivity and image quality, you need more than a few 60 workstation. You need advanced visualization and analysis tools anywhere you are working.

Whether you host PACS or are planning to if you work this capacity, integrated into your system and available on every PACS workstation throughout the enterprise.

VueX 3D™ is your solution

VueX 3D™ offers a full suite of advanced visualization and analysis tools optimized to deliver productivity and high-quality multi-media reports. With VueX 3D™ you can read large volumetric datasets more efficiently, in any plane, at any thickness without compromising on image quality, speed and ease-of-use.

Designed to provide rapid, multi-user access to your volumetric image studies throughout the enterprise, VueX 3D™ can be seamlessly integrated into your radiology workflow, directly into an existing PACS, or as an economical interim solution.

Flexible licensing options

Depending on your individual imaging requirements, VueX 3D™ allows you to separately license the advanced visualization and analysis tools you need on a routine basis.

• VueX 3D™ Core

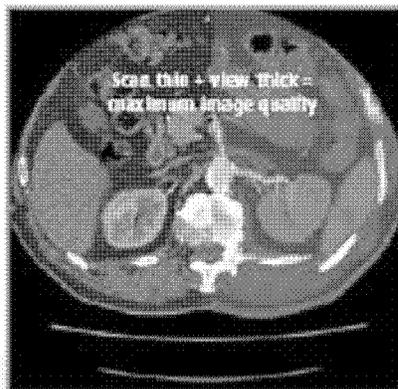
Provides quick and easy access to industry-leading MIP and MPR tools, including auto, display and different intensity projections.

• VueX 3D™ Advanced

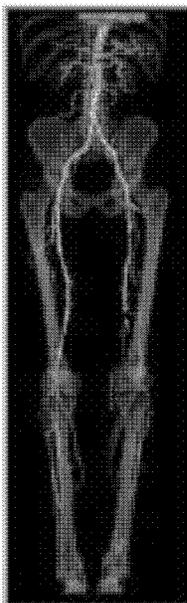
Extends the functionality of VueX 3D™ Core with additional tools such as longest review, fly-through and polygonal segmentation and bone removal tools.

• VueX 3D™ Clinical applications

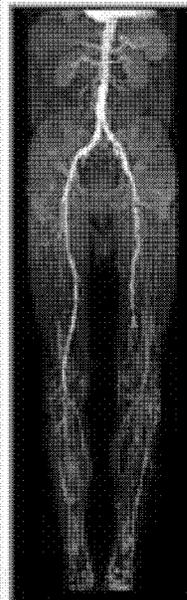
An optional suite of clinical applications allows you to get through your most common clinical studies with speed and ease.



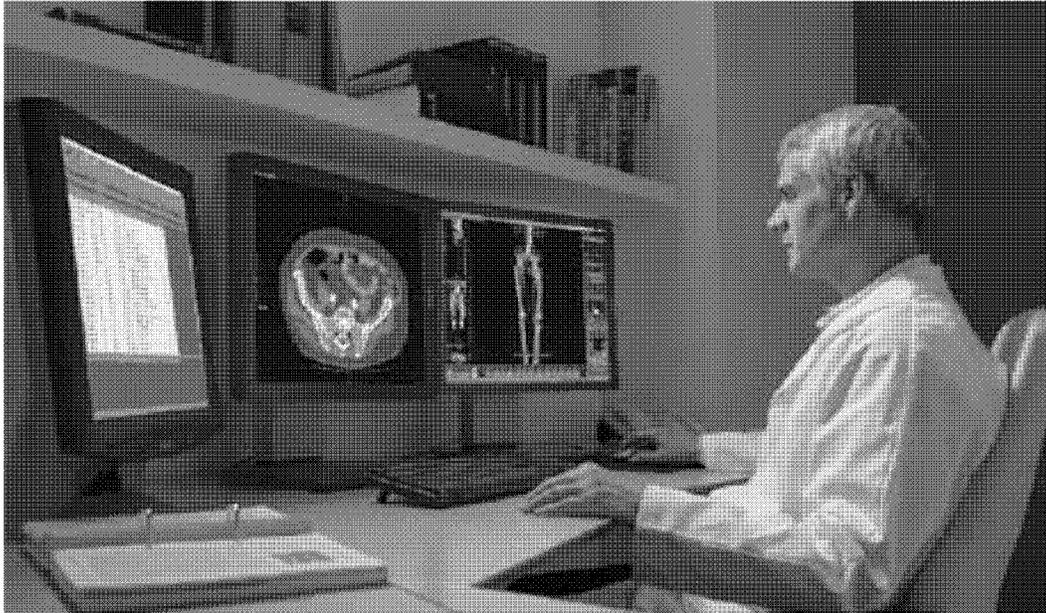
300 Axial 200 MPR create



300 3D color volume review



300 General Anatomic MIP



Designed, configured and priced to be an advanced visualization and analysis tool for everyday reading

Vue 3D provides you with rapid access to the advanced visualization and analysis tools you need every day when reading CT, MRI and PET. It brings major benefits such as:

- rapid data loading and high-performance visualization
- intuitive user interface and task-based workflows
- easy-to-use, GUI-based MIP analysis tools
- powerful, multi-task segmentation and bone removal
- comprehensive suite of display applications
- intuitive, user-interactive comment marking options
- integration with over 30 PACS vendor workstations

"We chose Vue 3D to give us full CT and MRI 3D workstation functionality on every one of our PACS workstations. The ability to view the images in multiple planes is essential when reporting routine studies. For example, when excluding bony metastases, it is much faster to view the images in a sagittal MIP rather than scrolling through 1000+ axial images. Vue 3D also provides excellent 3D volume rendering and bone removal tools valuable for studies such as CTA and MRA."

*Richard H. III, Consultant Radiologist,
City of Sacramento Hospital, CA*

The freedom to work anywhere

Live interaction with clinical colleagues

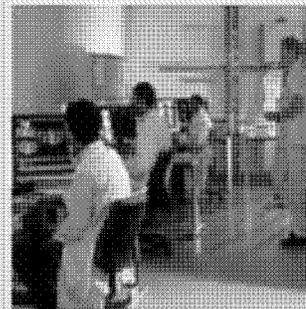
With View 3D, you can easily save complex image reconstructions. Clinical colleagues can restore your work on any View 3D enabled workstation and create any additional views they need. This allows you to modify and easily communicate key images that are essential for surgical planning, treatment and follow-up.

3D acceleration with off-the-shelf graphics cards

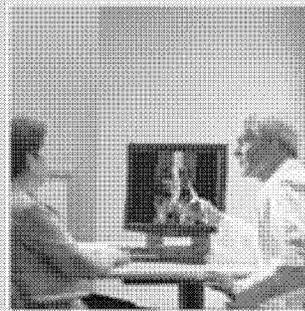
View 3D takes advantage of powerful off-the-shelf graphics cards, which dramatically increase performance and image quality. Complex image reconstructions can be viewed at more than 20 frames per second, delivering real-time, on-the-fly interaction.

Easy communication with multi-vendor modalities

View 3D strictly adheres to the DICOM standard for effortless communication with multi-vendor modalities and techniques.



»»» Enabling remote viewing



»»» Facile communication



xxx Physician's office

One-click, seamless PACS integration

View 3D integrates seamlessly into your enterprise PACS, providing a single, streamlined diagnostic radiology workflow. One mouse click on your PACS workstation gives you instant access to advanced visualization tools.



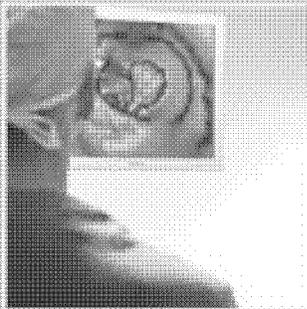
xxx Clinical case conferences

Multi-user access throughout the enterprise

The View 3D container license program gives multiple users access to "floating" View 3D licenses anywhere View 3D is installed - without restriction - on any PACS workstation or PC.

Cost-effective access to the tools you need

View 3D's advanced visualization and analysis tools can be licensed separately. You can independently license View 3D's gold-standard NRR analysis tools and from there concurrently license View 3D's advanced 3D visualization tools. Clinical applications can also be licensed separately in addition to View 3D Access.



xxx Surgical team

3D everywhere

Diagnostic tools that transform your studies into real clinical decisions

— optimized for fast, easy access

Voxar 3D™ Core

- * Live image captures
- * Orthogonal, oblique, double-oblique MPR rendering
- * Curved and cross-curved MPR rendering
- * MIP, AvellP, MiniP and color volume slabs
- * 2D review and compare

Voxar 3D™ Advanced

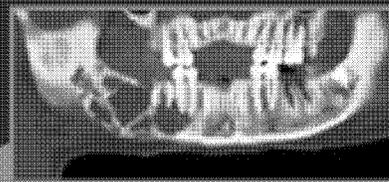
- * Voxar 3D™ Core, plus...
- * Color volume rendering
- * MIP volume rendering
- * Grayscale volume rendering
- * Shaded surface display
- * Fly-through navigation
- * Targeted color volume review
- * 3D segmentation and volume measurement
- * Sculpting and automatic 3D bone removal
- * MPR shape selection

Voxar 3D™ clinical applications

- * Vessel analysis with VasoMux
- * Cardiac analysis with CardioMux
 - + Vessel analysis
 - + Calcium scoring
 - + 4D cardiac viewer
 - + Cardiac (LV) analysis
- * CT colonography with Voxar 3D ColonMux
- * PET/CT Fusion

Multiplanar reformats

Real-time multiplanar reformating of images into any user-defined linear or curved planes.



Mandible volume: curved reformats

Living renal donor access mass: double oblique reformats



Coronal endocervix: curved reformats



Striplip a cerebral aneurysm: color volume slab reformats

3D reconstruction

Powerful easy-to-use segmentation and bone removal tools make complex reconstructions quick and easy.

*Craniocervical junction
3D angiographic volume*

*Peripheral lower
limbs: 3D boneless MRI*

*Cervical vertebrae
3D color volume*

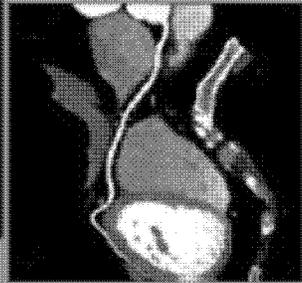
*Origin of renal arteries and
aortic arch: 3D fly-through*

*Femoral artery
occlusion: 3D MIP*

VOXAR 3D™

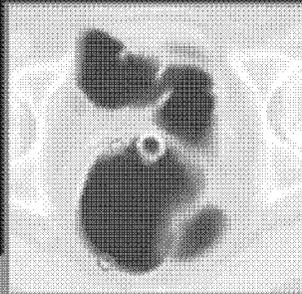
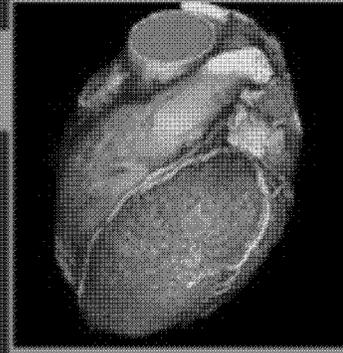
Clinical applications

An integrated suite of clinical applications for the studies you read on a routine basis.

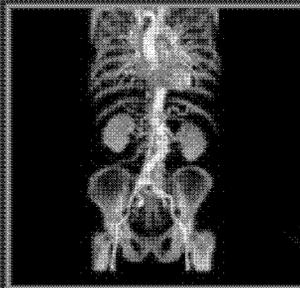


Right coronary artery assessment-
curved reformatted

Coronary artery
stenosis- 2D color
reformatted

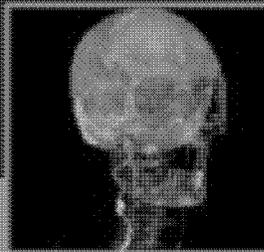
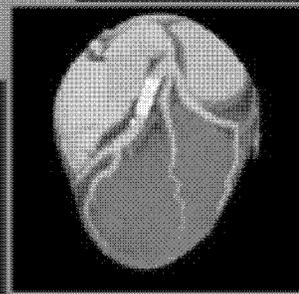


Renal artery- 2D color
reformatted

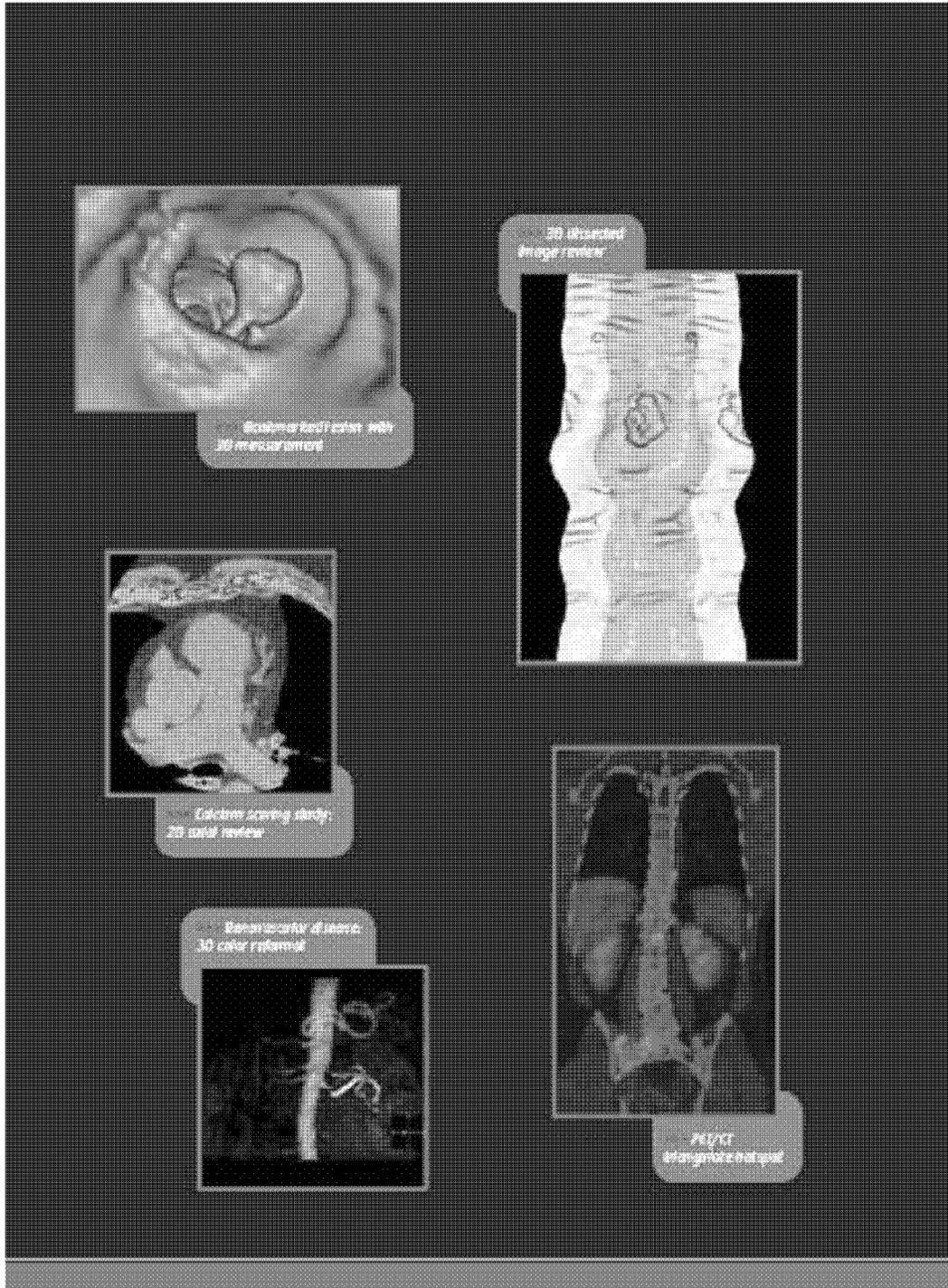


Thoracic aorta
stenosis- 2D color
reformatted

RAO view
dissecting aortic
aneurysm-
3D MIP



Right carotid
stenosis- 3D color
reformatted

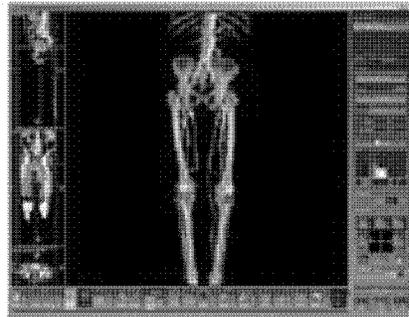
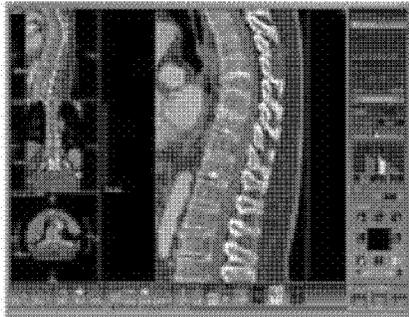




The technology to improve results

Vue 3D Core provides the industry-leading standard in 3D and 2D analysis tools. The easy-to-use solution allows you to access the power of Vue 3D's 3D and 2D tools, including: slices, oblique and different viewing projections.

Vue 3D Advance offers an advanced set of visualization modes including targeted review and fly-through. Powerful segmentation and bone removal tools allow you to create beautiful 3D in seconds.



VOXAR 3D VESSELMETRIX

Delivers all the tools you need for quantitative vascular analysis and start-graph planning of CTA and MRA studies on one easy screen.



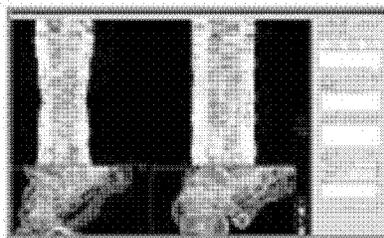
VOXAR 3D CARDIOMETRIX

Analyzes multi-phase cardiac CT studies and provides 2D, 3D and 4D visualization for quantitative evaluation of cardiac anatomy and function.



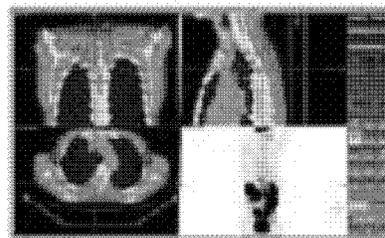
VOXAR 3D COLONMETRIX

Optimized to visualize native and prone image studies simultaneously in 2D and 3D. CACAD reports are automatically generated on-the-fly as you diagnose.



VOXAR 3D PET/CT FUSION

Supports the effective interpretation of whole body FDG oncology studies and provides real-time interaction with PET/CT images.



TeraRecon's Aquarius Workstation

Aquarius
PREMIER 3D/2D/4D IMAGING WORKSTATION

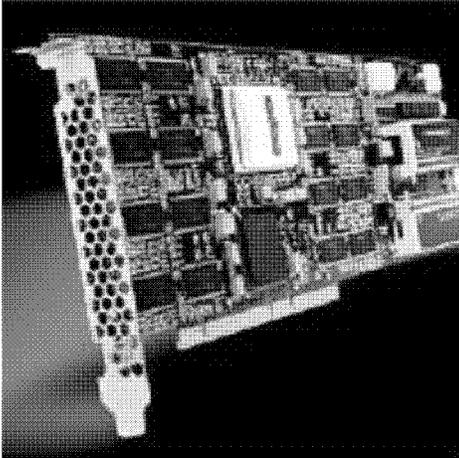
Discover the Power of Real-time Imaging with
TeraRecon's Patented Image Processing Technology

Aquarius brings award-winning real-time
3D visualization technology to diagnostic
imaging. It offers a comprehensive suite
of clinical applications, and unsurpassed
image quality at incredible speed.

TERARECON, INC.

Designed For Modern Multi-Slice CT & MR Scanners

Aquarius enables real-time diagnostic review of 2D, 3D and 4D images from almost all modalities, and incorporates workflow-enhancing tools with an intuitive user interface. Aquarius is designed to manage the most demanding volumetric datasets acquired from modern multi-slice CT and MR scanners. It offers a comprehensive suite of clinical application modules and has been carefully designed for streamlined workflow and ease-of-use.

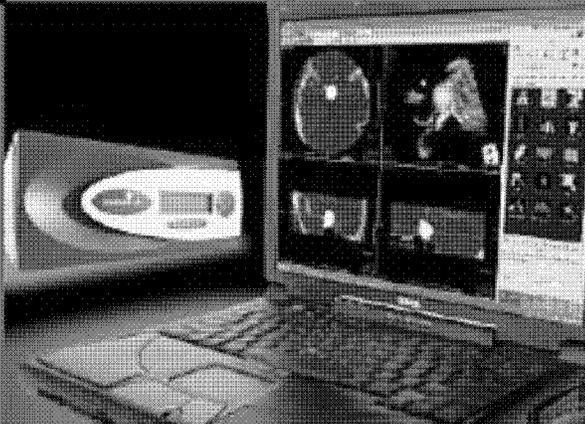


Real-time VolumePro™ Volume Rendering Technology for the Most Demanding Data

Aquarius offers uncompromised performance, image quality, and clinical functionality. Thanks to its patented VolumePro rendering technology, Aquarius delivers real-time interactive 3D, even on cardiac or run-off studies with 2000 or 5000 slices. Studies can be rapidly loaded with segmentation, editing, analysis, and region-growing tools to distinguish pathologies, blood vessels, and bones.

Aquarius Grows with your Enterprise

Aquarius is designed to work seamlessly with AquariusNET Servers and the Personal Digital Light Box, extending the reach of your available infrastructure and your imaging investment. Clinical findings can be illustrated on Aquarius, then sent to AquariusNET Server for interactive image distribution across the clinical enterprise to thin client PCs anywhere.



Diagnostic Radiology

Vascular Analysis—
Endovascular analysis & interventional planning.

Neurology—Interventional planning for aneurysms & tumors including time-density analysis.

Orthopedic—Trauma evaluation & surgical planning.

Vascular—Evaluation of occlusive and aneurysm disease, intra-abdominal abnormalities, embolization, dissection, thrombosis, and malignancy.

Cardiac

Coronary stent planning, plaque evaluation, and stenosis of coronary branches.

Volume Analysis—CT / MR evaluations of ventricular function and myocardial dynamics.

4D Time Resolved MRA—view multiple 3D datasets for better diagnosis & faster workflow.

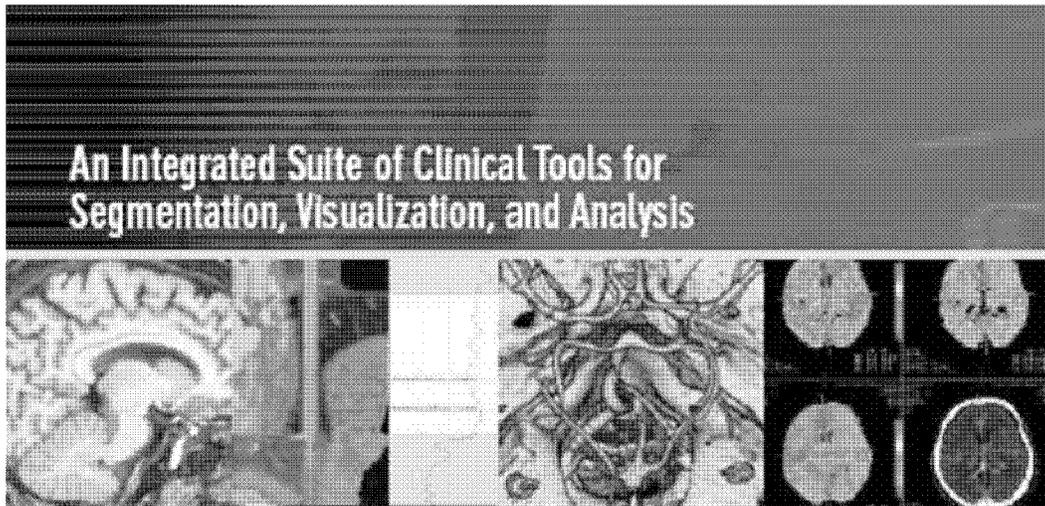
Calcium Scoring—
Automated workflow and reporting.

Oncology

Oncology—Tumor characterization with volume measurements and detailed evaluation of vascular supply.

Lung—Solitary pulmonary nodule assessment with auto segmentation and volume measurements.

Colonography—Integrated 2D/3D and side-by-side review. Rapid auto-navigation with endoluminal analysis.



Clinical Analysis Tools

SAE: Segmentation-Analysis Tracking for analyzing and tracking volumes.
(e.g. soft-tissue masses or solitary pulmonary nodules.)

TDA: Time-Density Analysis for studying time-dependence of contrast enhancement.
(e.g. Enhancement of brain tissue due to perfusion with contrast enhanced blood.)

TVA: Time-Volume Analysis for analyzing changes in volume over time.
(e.g. change in volume of left ventricle during the cardiac cycle.)

VAT: Vascular Analysis Tool for analyzing thrombus, calcifications, and endoleaks.

Calcium Scoring Analysis to detect and quantify atherosclerotic plaque burden in the coronary and other arteries.

Advanced Segmentation, Measuring, and Editing Tools.

Automated Templates load cases directly to the clinically appropriate 3D and/or reformatted views.

Quick Cubic Viewing is a quick examination tool to visualize volume regions of interest from the inside and outside.

Advanced 3D measurement tools allow for angle and distance measurements relative to fiducial markers.

Region growing includes erosion, dilation, and masking.

Colon, Vascular, and Pulmonary Flythroughs

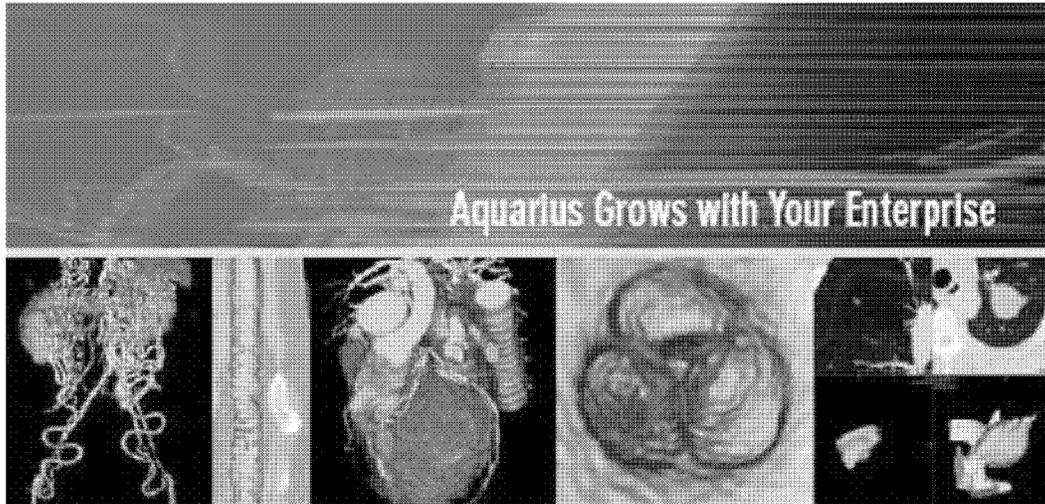
Fly-Through 3D with fast loading allows for interactive navigation of colon, vasculature, and bronchial airways.

Flythrough movies may be created and distributed to referring physicians.

Suspect lesion markers facilitate later correlation between 3D and 2D source images.

Cameras may be stopped and reoriented on the fly.

Unfold the colon and visualize in wrap-around endoluminal 3D to reveal and assess the entire structure rapidly.

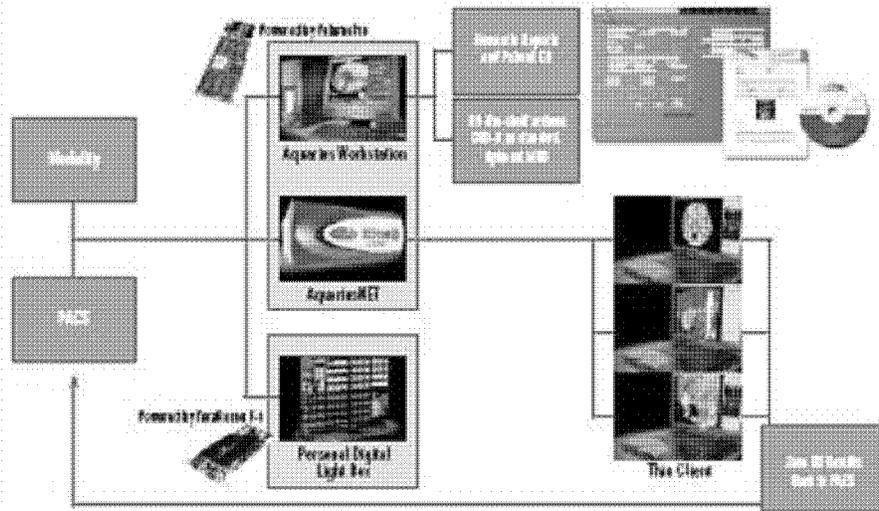


Integrated 3D Your Diagnostic Environment

Aquarius Workstations, AquariusNET Servers, and Personal Digital Light Boxes are real-time interactive imaging solutions designed to be easily incorporated into everyday clinical workflow.

When combined with AquariusNET imaging server, the Aquarius family of products deliver distributed, real-time interactive 2D, 3D, and 4D clinical solutions anywhere in the networked enterprise.

When combined with the Personal Digital Light Box, softcopy review can be extended on high resolution, large format displays, delivering real-time interaction for 2D, 3D, and 4D imaging to radiology reading rooms, physicians offices and surgical settings.



"I've reviewed many vendor's iterations of Radiology Workstations. The Terarecon WS is already an excellent product, but what truly differentiates Terarecon's software is the addition of their real-time volume rendering graphics card which dramatically improves its speed, which of course improves our efficiency."

Ted S. Wen, M.D.
Medical Director, Radiology
Presbyterian Hospital of Plano, TX



Solutions Along the Entire Medical Imaging Pathway

Terarecon offers advanced imaging solutions, including enterprise image distribution servers, advanced 3D workstations coupled with workflow-enhancing clinical applications, real-time volume rendering engines, the Personal Digital Light Box, and other innovative image processing solutions.

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San Mateo, CA 94403 USA
Tel: +1 650.572.1100
Fax: +1 650.572.1101

Concord, MA Branch

300 Baker Avenue, Suite 301
Concord, MA 01742
Tel: +1 978.369.6500
Fax: +1 978.369.7724

Japan Branch

Daiyuu Building 2nd Floor,
2-9-10 Shiba, Minato-ku
105-0014 Tokyo, Japan
Tel: +81 3 5730 6240
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Vital Images Vitrea

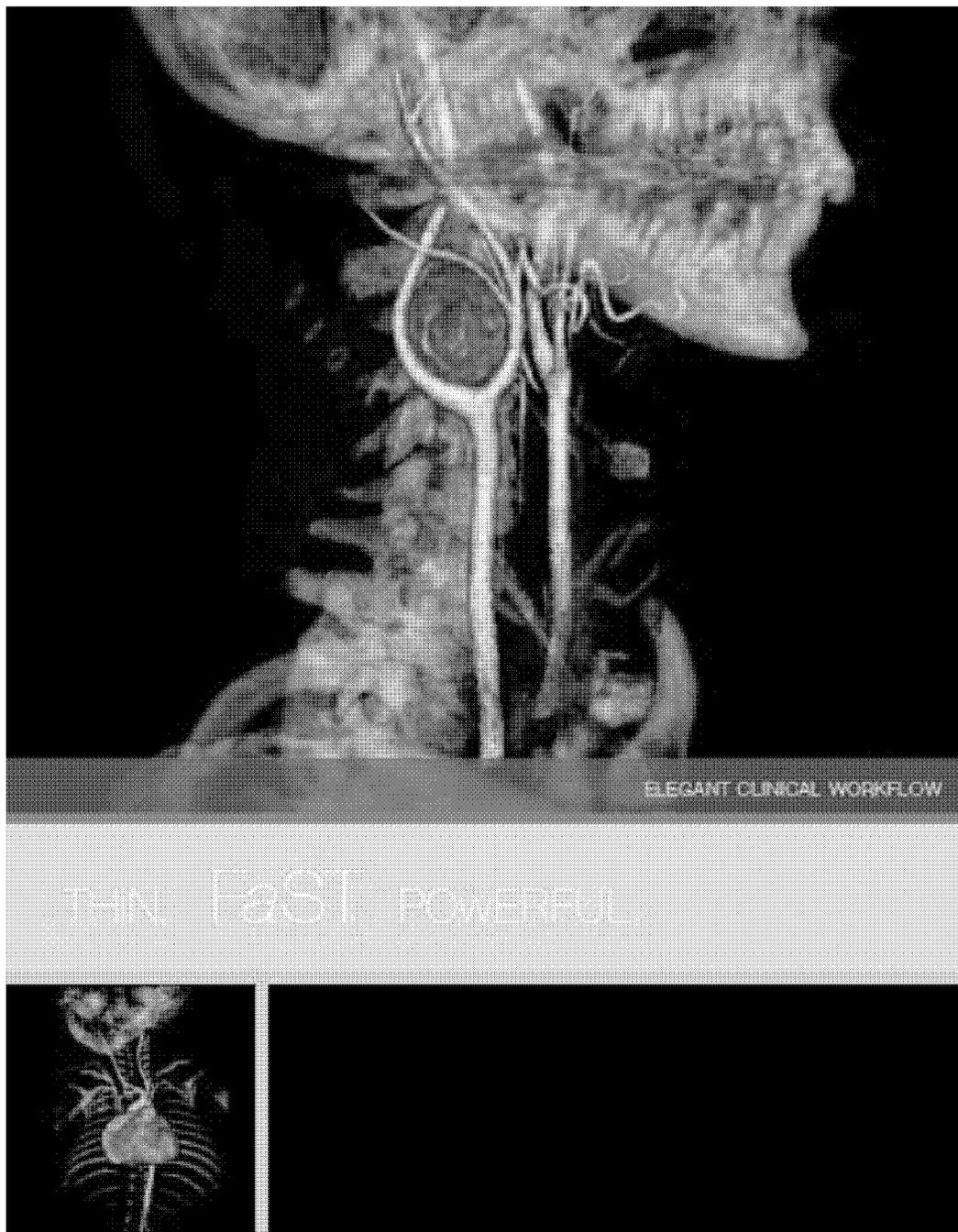
neuro
cardiac
vascular
colon
thoracic
lung

Advanced visualization software for the life of your enterprise.

VITREA®

VITAL

The advertisement features a large 3D brain scan of a human head in profile, showing internal structures. To the right of the head is a vertical list of medical categories: neuro, cardiac, vascular, colon, thoracic, and lung. Below the main image is a horizontal band with the text "Advanced visualization software for the life of your enterprise." Below this band is another horizontal band containing the "VITREA®" logo on the left and the "VITAL" logo (an eye icon) on the right. At the bottom of the advertisement is a row of four small square images: a heart, a colon, a thoracic scan, and a lung scan.





THEY. FAST. POWERFUL.

Vitreax®, Vital Images' signature software, is a 3D, fast and powerful advanced visualization and analysis solution that creates 3D, 3D and 4D images of human anatomy from CT (computed tomography) and MR (magnetic resonance) image data. With Vitreax, physicians can easily navigate image data to better understand disease conditions. Vitreax addresses specialists' needs through various options for cardiac, chest, torso and other applications, and contributes an easy-to-use, elegant clinical solution with automatic outputs to improve speed and help simplify complex data.

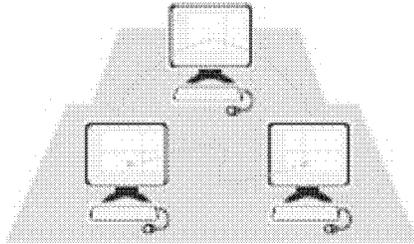
The VITAL Community

In addition to its many features and benefits, Vitreax software is backed by the VITAL Community, which includes our maintenance and service program, VITALPerformance™, our exceptional education center, VITALit, and our relationships with customers and key strategic partners that share our vision of developing an integrated solution for the life of your enterprise. These strategic partnerships include PACS (Picture Archiving and Communications Systems) and CAD (Computer-Aided Detection) providers, as well as other technical and clinical alliances.

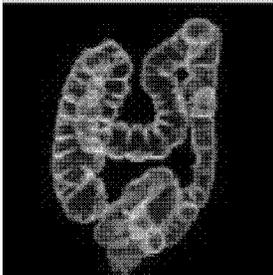


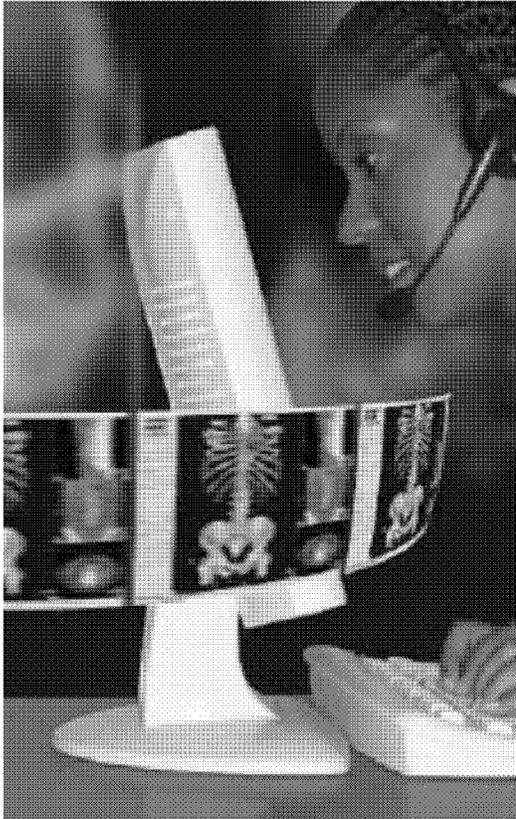
Access through V2V (Virtual to Virtual)

Virtual to Virtual (V2V) streamlines workflows by enabling workstations to transfer data from one Virex to another. With V2V, a physician can work on a study, within the workflow and receive the same case from another Virex-enabled workstation or PACS. V2V also provides physicians and technologists with the ability to restore a study from a PACS and prepare a case for review on a test bench.

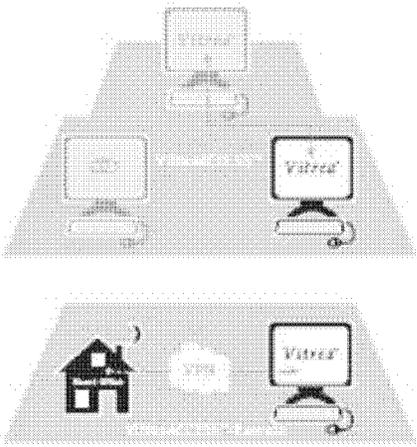


V2V



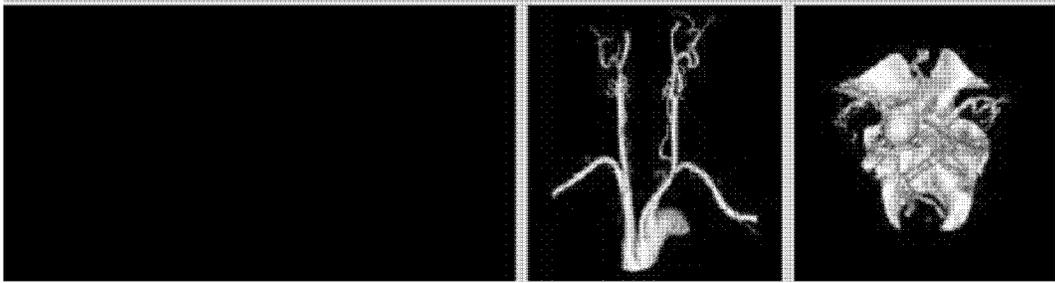


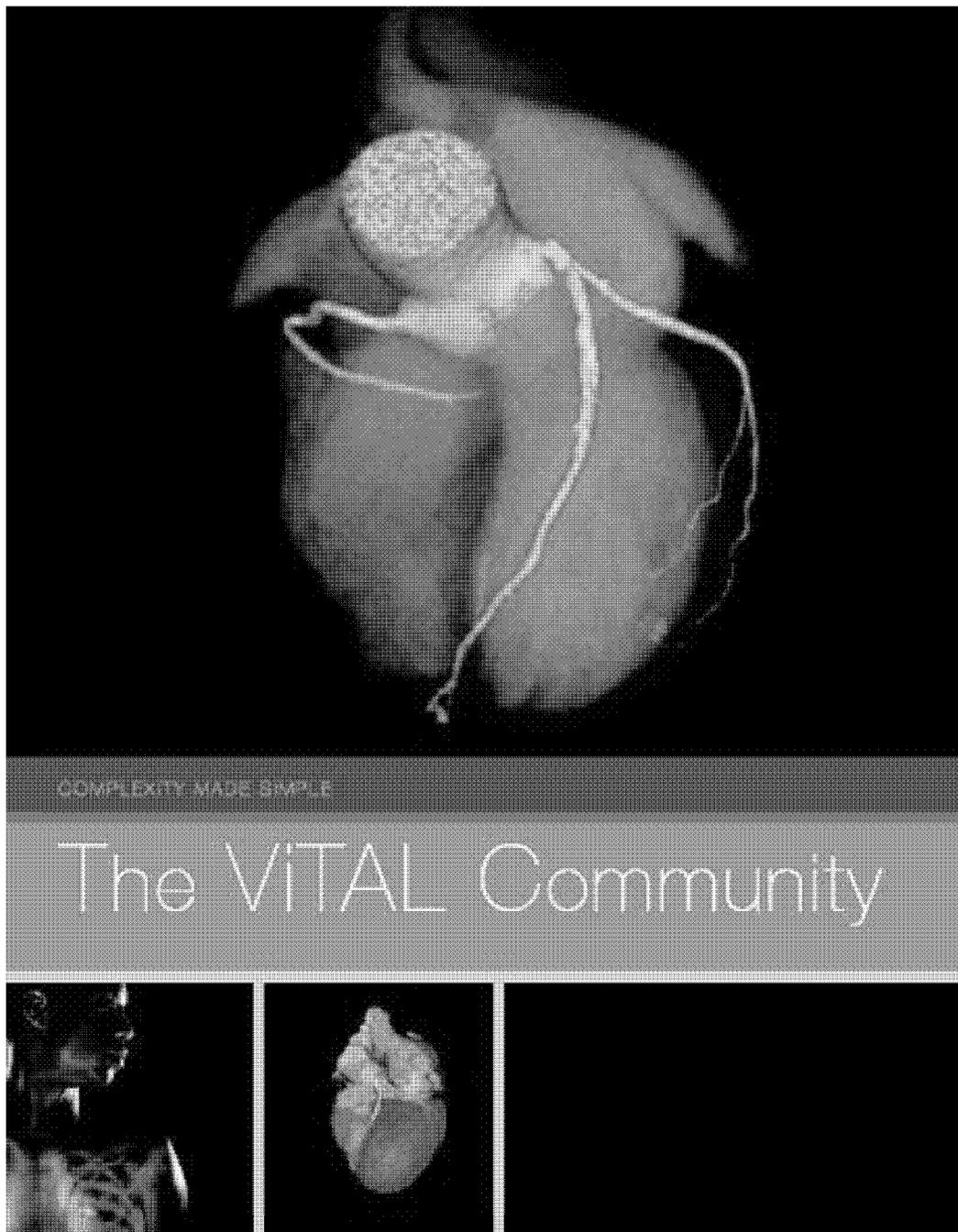
VitreACCESS™ provides the ability to "host" business and options to multiple workstations at access points across a Local Area Network (LAN). With VitreaACCESS™ users have the ability to connect to Vitrea's application business centrally, utilizing your facility's current VPE (Virtual Private Network) technology. Combining the advantages of both options shows you not only to stay within the walls of technology, but also allows our clients to address the demand for these late night critical, remote advanced visualization review needs.



ENHANCED COMMUNICATION

VitreACCESS™





THIN.

Enhanced Communication

Web-based and remote access tools
streamline workflow

- V-ViewAGE 3D™
- V-ViewAGE 3D™ Remote
- VITAL Connect™

FAST.

Elegant Clinical Workflow

- Automated Vessel
Reconstruction (AVM)
- CAD capabilities
- Cardiac Functional Analysis (CFA)
- CT Correlate
- CT Brain Correlate
- CT Osteography
- CT Lung Analysis
- Filtered™
- Viscera™
- Vessel Probe
- PACS Integration
- DataPivot™

POWERFUL.

Complexity Made Simple

- MR and MRI views
- Oblique and curved reformats
- AutoBone and vessel segmentation
- Batch view display
- HD review
- Customizable automated clinical protocols



The VITAL Community

VITAL IMAGES, INC. fosters relationships and delivers advanced visualization and analysis software with fish, fast and powerful products... VITAP®, VITALConnect®, and VITALCardis™ software—that help simplify complex data and provide enterprises with communication through accessibility tools and Web-based access. Combined with our VITALPerformance™ maintenance and services program and our VITAL U education center, Vital Images offers a comprehensive enterprise-wide solution.

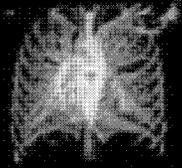
Join the VITAL Community today and experience benefits VITAL to the life of your enterprise.

Advanced visualization software for the life of your enterprise.

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952-487-9510

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Muzenstraat Bp. 1511 WB Den Haag, The Netherlands
[fax] +31 (0) 704 262 111
+31 (0) 704 262 181

M-00004



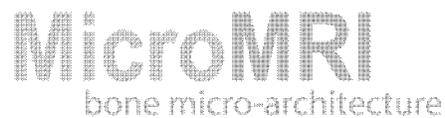
ATTACHMENT 4

BONEVUE HAZARD ANALYSIS Release Version: 1.0

Author: Allon Shahar

October 29, 2008

Internal Document
EN-002-F01.02



REVISION HISTORY

Version	Release Date	Responsible Party	Major Changes
1.0	10/20/2008	Allon Shahar	Initial Release
1.1	10/29/2008	Allon Shahar	Updated in accordance with review meeting decisions (10/22/08).

TABLE OF CONTENTS

1 Introduction 106

1.1 Definitions/Acronyms/Abbreviations 107

1.2 References..... 108

1.3 Purpose..... 108

1.4 Scope..... 108

2 Key to columns in Hazard Analysis Table 109

3 Hazard Analysis Table 111

4 Signatures 121

1. Introduction

1.1. Definitions/Acronyms/Abbreviations

Detectability - If, when and how would the occurrence of the failure be detected?

Hazard - The inherent characteristic of a material, condition, or activity that has the potential to cause harm to people, property, or the environment.

Hazard Analysis - The identification of material properties, system elements or events that lead to harm or loss. The term hazard analysis may also include evaluation of consequences from an event or incident.

Major Hazard - The operation of the device directly affects the patient and/or operator so that failures or latent flaws could result in death or serious injury to the patient and/or operator, or if it indirectly affects the patient and/or operator (e.g., through the action of care provider) such that incorrect or delayed information could result in death or serious injury of the patient and/or operator.

Minor Hazard - The operation of the device causes failures or latent design flaws which are not expected to result in any injury to the patient and/or operator.

Moderate Hazard - The operation of the device directly affects the patient and/or operator so that failures or latent design flaws could result in non-serious injury to the patient and/or operator, or if it indirectly affects the patient and/or operator (e.g., through the action of a care provider) where incorrect or delayed information could result in non-serious injury of the patient and/or operator.

Potential Hazard Index (PHI) - A relative scale that allows comparison between events with regard to their likeliness of occurring, consequence, and detectability.

Probability- How likely is the hazard event going to occur?

Risk- The combination of the likelihood and the consequence of a specified hazard being realized. It is a measure of harm or loss associated with an activity.

Risk Analysis - The study of risk in order to understand and quantify risk so it can be managed.

Risk Level - An estimate of the severity of the injury that a device could permit or inflict (directly or indirectly) on a patient or operator as a result of latent failures, design flaws, or using the medical device.

Severity - What are the consequences of the failure?

1.2. References

1. BoneVue, System Requirements Specification
2. Bone Processing Software (BPS), Software Requirements Specification
3. OP-008, SOP on Signature Meanings of Regulatory Documents

1.3. Purpose

The purpose of this document is to perform hazard analysis on the BoneVue system, Version 1.0.

1.4. Scope

The scope of this document extends to BoneVue v1.0 and all its components, including Bone Processing Software v1.0. It addresses the system's configuration and deployment as defined in [1-2].

2. Key to columns in Hazard Analysis Table

Failure:

Insert in this column a description of the failure that may occur.

Cause of Failure:

Insert in this column the reasons that the failure may occur.

Hazard Event:

Give one or more of the failures an overall description for the hazard event.

P (Probability):

Insert the number into the column, which corresponds to the probability of the failure occurring:

- 5 = Frequent (Greater than 10%).
- 4 = Moderate (Between 1 and 10%).
- 3 = Occasional (Between 0.1 and 1%).
- 2 = Unlikely (Between 0.01 and 0.1%).
- 1 = Remote (Between 0.001 and 0.01%).
- 0.1 = Virtually Impossible (Less than 0.001%).

S (Severity):

Insert the number into the column, which corresponds to the severity as a result of the failure:

- 4 = Major injury to patient or user, or regulatory compliance compromised.
- 3 = Potential long-term effects, or unsubstantiated or undelivered claims.
- 2 = Minor physical harm to patient or user.
- 1 = Procedural interruptions or inconveniences, or inconvenience to users

D (Detectability)

Insert the number into the column, which corresponds to how detectable the failure will be:

- 4 = Not detectable.
- 3 = Fault will be detected only after user involvement.
- 2 = Likely to be detected during normal operations.
- 1 = Likely to be detected in prototype stage through normal validation testing.

PHI (Potential Hazard Index)

Multiply $P * S * D$ and insert the value into this column.

Control Measure:

Insert in this column a description of how the failure will be mitigated.

Outcome:

Insert in this column a description of what will occur as a result of the failure.

E (Mitigation Effectiveness)

Insert the number into the column, which corresponds to how effective the control measure will be in mitigating the outcome of the failure:

- 0 = Fully effective, the mitigation is implemented and validated at the design stage.
- 0.2 = Mitigation relies on online alerts and messages.
- 0.3 = Mitigation relies on labeling claims, instructions, and user training.
- 0.5 = Mitigation relies on the quality system maintenance.
- 1 = No effective mitigation can be assured.

RHI (Residual Hazard Index)

Multiply PHI * E and insert the value into this column.

- RHI ≥ 18: Not acceptable
- RHI ≥ 12: Alternate designs/process strongly recommended
- RHI ≥ 8: Perpetual monitoring through GMP controls required
- RHI ≥ 2: Monitoring through complaint files required
- RHI < 2: Acceptable

Risk Level:

Insert in this column the risk level according to the definitions listed below:

- Minor: RHI value of 0-2
- Moderate: RHI value of 2.1-18
- Major: RHI value of 18-100

3. Hazard Analysis Table

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
1.	(b)(4)											
2.												
										.3	.6	Minor



BoneVue 1.0 Hazard Analysis
Document Version: 1.1
Internal Document

10/29/2008

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
3.									(b)(4)	.3	1.2	Minor
4.										.2	.8	Minor
5.										.2	1.6	Minor

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10/29/2008

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
6.									(b)(4)	1	4	Moderate
7.										0	0	Minor
8.										.3	8.1	Moderate
9.										0	0	Minor
10.										0	0	Minor

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#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
11.									(b)(4)	.3	5.4	Moderate

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Page 114 of 218

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
12.									(b)(4)	.3	5.4	Moderate
13.										.2	3.6	Moderate
14.										.2	.4	Minor

² This may happen either unknowingly or accidentally, with the latter being the simpler case to mitigate.

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#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
15.									(b)(4)	.3	5.4	Moderate
16.										.3	8.1	Moderate

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#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
									(b)(4)	.3	8.1	Moderate

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Page 117 of 218



BoneVue 1.0 Hazard Analysis
Document Version: 1.1
Internal Document

10/29/2008

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
17.									(b)(4)	.3	8.1	Moderate
18.										0	0	Minor

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10/29/2008

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
19.									(b)(4)	.3	5.4	Moderate

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Document Version: 1.1
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10/29/2008

#	Failure	Cause of Failure	Hazard Event	P	S	D	PHI	Control Measure	Outcome	E	RHI	Risk Level
20.									(b)(4)	.3	8.1	Moderate
21.										.2	2.4	Moderate

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Signatures

Signatory meanings are described in SOP OP-008 [3].

Originator:

Signature: _____ Name: _____ Date: _____
Sr. Software Engineer

Required Review By:

Signature: _____ Name: _____ Date: _____
Software Engineer

Independent Review By:

Signature: _____ Name: _____ Date: _____
Manager of Quality Assurance and Regulatory Affairs

Authorized By:

Signature: _____ Name: _____ Date: _____
CTO

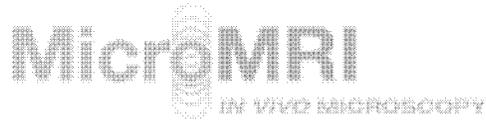
ATTACHMENT 5

BONEVUE SYSTEM REQUIREMENTS SPECIFICATION Release Version: 1.0

November 7, 2008

Internal Document
OP-001.F03.01

	<i>BoneVue System Requirements Specification</i> <i>Document Version: 1.2</i> <i>Internal Document</i>	11/7/2008
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REVISION HISTORY

Version	Release Date	Responsible Party	Major Changes
1.0	10/14/2008	Allon Shahar	Initial Release
1.1	11/05/2008	Allon Shahar	Updates based on SRS review meetings of 10/22/2008 and UI requirements review of 10/28/2008. Also, use cases were added as an appendix.
1.2	11/07/2008	Allon Shahar	Updated based on the review comments of 11/6/2008.

Table of Contents

1.	Introduction	126
1.1	Overview.....	126
1.2	Purpose.....	129
1.3	Scope	129
2.	Definitions, Acronyms, Notations	129
2.1	Acronyms.....	129
2.2	Definitions	129
2.3	Nomenclature	130
2.4	Ranking.....	130
3.	References	130
4.	User Application Features	131
4.1	File Management.....	131
4.2	Bone Processing.....	132
4.2.1	Process Control.....	132
4.2.2	132
4.2.3	Processing Alerts	132
4.2.4	Reprocessing.....	133
4.3	Manual QC of Bone Processing.....	134
4.3.1	General Requirements.....	134
4.3.2	Preprocessing and SNR QC.....	135
4.3.3	Trabecular Bone Processing	135
4.3.4	Cortical Bone Processing.....	135
4.4	Image and Result Viewers	136
4.4.1	General Requirements.....	136
4.4.2	ROI Selection Tool	136
4.4.3	Results Viewer.....	137
4.5	Report Generator.....	138
4.5.1	Report Operations and Format.....	138
4.5.2	Report Contents	139
4.6	System Services.....	139
4.6.1	System Configuration	139
4.6.2	System Information (About pop-up).....	140
4.6.3	Audit Trail	140
4.6.4	User Support	140
5.	Nonfunctional Requirements	141
5.1	Hardware Requirements.....	141
5.2	Operating System Requirements.....	141

5.3 *Performance Requirements* 141

5.4 *Application Installation Requirements* 141

6. Appendix – Use Cases 143

6.1 *Introduction* 143

6.2 *Use Cases* 144

UC-1 *Input Handling*..... 144

UC-2 *User-Initiated Automatic Processing* 145

UC-3 *User-Initiated Manual Processing* 149

UC-4 *ROI Manipulation*..... 156

UC-5 *Report Generation*..... 158

7. Signatures 160

1. Introduction

1.1. Overview

BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MR datasets of bone, facilitating 3D visualization of bone micro-architecture and the measurement of descriptive parameters of cortical and trabecular bone morphology. While *BoneVue* can process data from a variety of commercially available pulse sequences, it will typically be used to process datasets acquired with two pulse sequences: one for volumetric imaging of cortical bone and another for volumetric imaging of trabecular bone. *BoneVue* will allow the user to load the image data (DICOM[®] format [2]) from the cortical scan and the raw (k-space) data (or image data in DICOM format) from the trabecular scan, and will process it using its core subsystem, the Bone Processing Software (BPS) application. In addition to visualizing the bone, *BoneVue* will produce a report that includes the measured parameters and representative images. This report may be printed or stored for later review.

A schematic diagram of the system's architecture is given in **Error! Reference source not found.**; the *BoneVue* typical data and processing flow, including a high-level breakdown of the BPS pipeline, is illustrated in Figure 4. *BoneVue* can operate in either fully automated or manual mode, the latter allowing the user to interactively adjust parameters that affect the processing flow.

[®] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

(b)(4)



Figure 3: Architecture of the BoneVue System

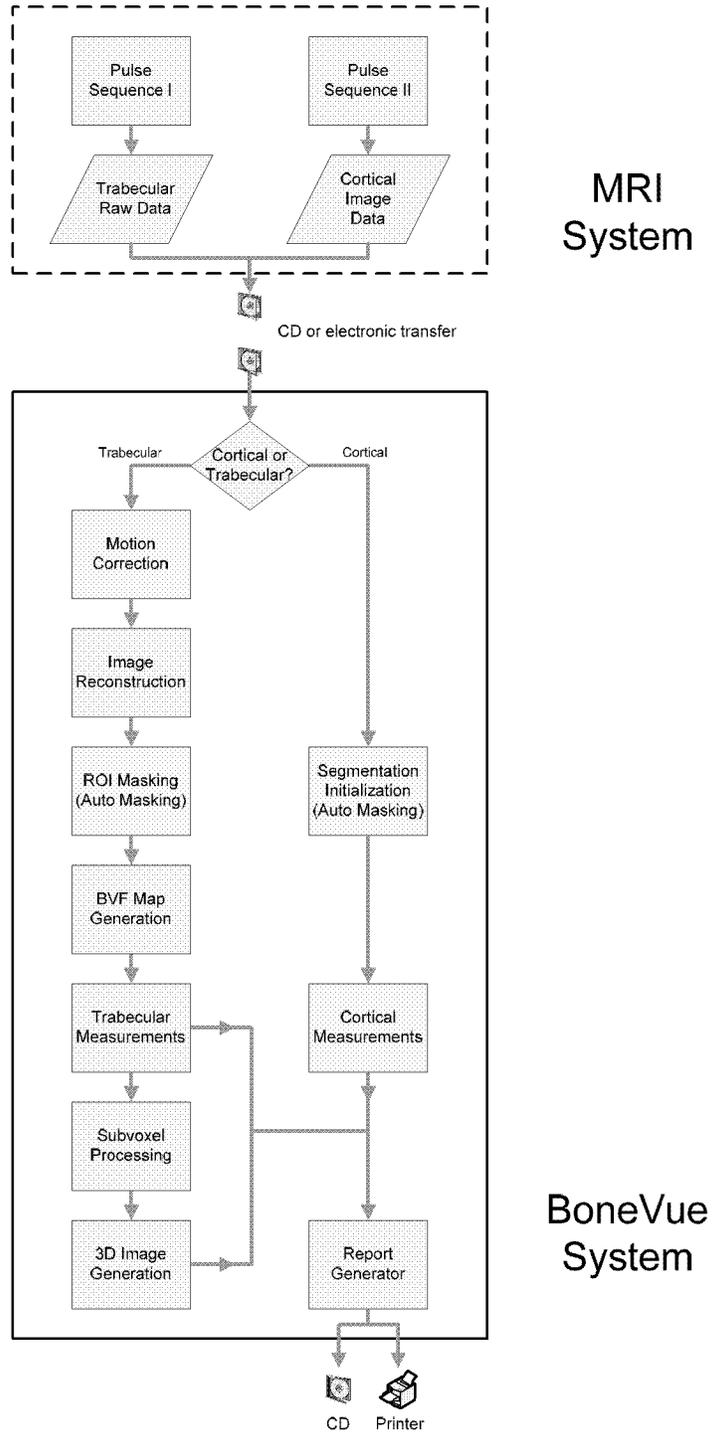


Figure 4: A typical BoneVue/BPS processing flow; QC steps are colored green.

1.2. Purpose

The present document lists the system and software requirements for the *BoneVue* v1.0 product, which reflect the expected use cases of the system (see the Appendix).

1.3. Scope

The present document captures the system-level and user application requirements for the BoneVue system, including the user application's interface to BPS. The detailed requirements of BPS itself are given in a dedicated document [1]. The requirements for deploying and operating BoneVue will be provided in the user manual and associated documentation.

2. Definitions, Acronyms, Notations

2.1. Acronyms

BPS— Bone Processing Software
CBP— Cortical Bone Processing
DICOM— Digital Imaging and Communications in Medicine
FLASE— Fast 3D Large-angle Spin-echo Imaging
GUI— Graphical User Interface
MR— Magnetic Resonance
QC— Quality Control
ROI— Region of Interest
SRS— Software Requirements Specifications
TBP— Trabecular Bone Processing
2D/3D— Two/Three Dimensional

2.2. Definitions

Bone Processing: Either trabecular bone processing or cortical bone processing applied by BPS to MR data.

Fully Automated Processing Mode: Following input selection BoneVue processes the data automatically until completion.

Manual QC Processing Mode: BoneVue requests the user to view/edit the results of the QC steps before processing is resumed.

QC steps: Bone processing steps that have intermediary results, which may be displayed to the user for editing, review or approval.

Processed Series: A series that has been either partially or fully processed

Partially Processed Series: When the applied bone processing was interrupted and, as a consequence, only a part of the results is available.

Bone Processed Series: When bone processing has been completed on a series at least once.

NOTE: The requirements below refer to an unprocessed MR series unless otherwise indicated by using the terms processed or partially processed series.

2.3.Nomenclature

Shall: indicates requirements strictly to be followed and in which no deviation is permitted. Equivalent expressions include is to, is required to, has to, it is necessary. (Must is not used as an alternative to shall).

Shall not: converse of shall.

Should: indicates that among several possibilities one is the recommended as particularly suitable, without mentioning or excluding others.

Should not: converse of should.

May: indicates a course of action that is permissible. Equivalent expressions include: is permitted, is allowed.

Need not: indicates that a course of action is not required.

Can: indicates statement of possibility and capability, whether material, physical or causal. Equivalent expressions include: be able to, it is possible to.

Cannot: converse of can.

2.4.Ranking

Each requirement will be ranked according to the following table. This scale may be used in prioritizing design and implementation efforts, assessing validation results, and deciding on release strategies.

Rank	Description of rank
1	This is an essential feature of this application.
2	This is a moderate feature of this application. This feature is desirable but not critical.
3	This is a minor feature of this application. This feature is beneficial but incidental.

3. References

1. "Bone Processing Software Rev 1.0 Software Requirement Specification", rev. 1.1.

2. Digital Imaging and Communications in Medicine (DICOM), ACR-NEMA PS 3-2008, <ftp://medical.nema.org/medical/dicom/2008/>.
3. SOP OP-008, Management Role and Delegation of Responsibilities

4. User Application Features

Each of the following subsections refers to a set of application features that are grouped together as they pertain to a certain key functionality of the system.

4.1. File Management

Req. Index	Req. No	Rank	Description
1.	RGUI-1	1	(b)(4)
2.	RGUI-2	1	
3.	RGUI-3	1	
4.	RGUI-4	1	
5.	RGUI-5	1	
6.	RGUI-6	2	
7.	RGUI-7	2	
8.	RGUI-8	3	
9.	RGUI-9	1	

Reported Series Information

Req. Index	Field	Format	Comments/Example
a.	Patient Name	Name	
b.	Patient ID	Alphanumeric	
c.	Date of Birth (DOB)	DD-MM-YYYY	18-Feb-1958
d.	Age	Years	
e.	Gender	M/F	Male/Female
f.	Wrist	R/L	Right/Left
g.	Date of Exam	DD-MM-YYYY	19-Mar-2008
h.	Time of Exam	HH:MM AM/PM	11:35 AM
i.	Requesting MD	Name	

Table 1: Series information to be extracted from the dataset header and displayed/reported by the application.

4.2. Bone Processing

1. Process Control

Req. Index	Req. No	Rank	Description
10.	RGUI-10	1	(b)(4)
11.	RGUI-11	1	
12.	RFUN-1	1	
13.	RGUI-12	1	
14.	RGUI-13	1	
15.	RGUI-14	1	
16.	RFUN-2	2	
17.	RFUN-3	1	

2. Processing Alerts

Req. Index	Req. No	Rank	Description
18.	RGUI-15	1	(b)(4)
19.	RGUI-16	1	
20.	RGUI-17	1	
21.	RGUI-18	1	
22.	RGUI-19	1	
23.	RGUI-20	1	
24.	RGUI-21	1	

3. Reprocessing

Req. Index	Req. No	Rank	Description
25.	RFUN-4	1	(b)(4)
26.	RFUN-5	1	

³ The requirement applies only to input in raw file format, as data in DICOM format will not undergo motion detection.

⁴ The requirement allows, for example, the integrative reporting of pre-existing trabecular results along with new cortical results.

27.	RFUN-6	1
28.	RGUI-22	1
29.	RFUN-7	1
30.	RFUN-8	1

(b)(4)

4.3. Manual QC of Bone Processing

The following requirements apply to the Manual QC mode of operation.

4. General Requirements

Req. Index	Req. No	Rank	Description
31.	RGUI-23	1	(b)(4)
32.	RGUI-24	1	
33.	RGUI-25	1	
34.	RFUN-9	1	
35.	RFUN-10	1	
36.	RGUI-26	1	
37.	RGUI-27	1	

38. RFUN-11 1

(b)(4)

5. Preprocessing and SNR QC

Req. Index	Req. No	Rank	Description
39.	RGUI-28	1	(b)(4)
40.	RGUI-29	1	

6. Trabecular Bone Processing

Req. Index	Req. No	Rank	Description
41.	RGUI-30	1	(b)(4)
42.	RGUI-31	1	
43.	RGUI-32	1	
44.	RGUI-33	1	

7. Cortical Bone Processing

Req. Index	Req. No	Rank	Description
------------	---------	------	-------------

45. RGUI-34 1

46. RGUI-35 1

(b)(4)

4.4. Image and Result Viewers

The application shall provide image visualization areas to display relevant image information (2D/3D), as well as to obtain various user inputs.

8. General Requirements

Req. Index	Req. No	Rank	Description
47.	RGUI-36	1	(b)(4)
48.	RGUI-37	2	
49.	RGUI-38	2	
50.	RGUI-39	1	
51.	RGUI-40	1	
52.	RGUI-41	1	

9. ROI Selection Tool

Req. Index	Req. No	Rank	Description
53.	RGUI-42	1	(b)(4)
54.	RGUI-43	1	

55.	RGUI-44	2
56.	RGUI-45	1
57.	RGUI-46	1
58.	RGUI-47	1
59.	RGUI-48	1
60.	RGUI-49	1
61.	RGUI-50	1
62.	RGUI-51	1
63.	RGUI-52	2
64.	RGUI-53	2

(b)(4)

10. Results Viewer

Req. Index	Req. No	Rank	Description
65.	RGUI-54	1	(b)(4)
66.	RGUI-55	1	
67.	RGUI-56	1	
68.	RGUI-57	1	
69.	RGUI-58	1	

70.	RGUI-59	2
71.	RGUI-60	2
72.	RGUI-61	1
73.	RGUI-62	2
74.	RGUI-63	1
75.	RGUI-64	1
76.	RGUI-65	2

(b)(4)

4.5. Report Generator

11. Report Operations and Format

Req. Index	Req. No	Rank	Description
77.	RFUN-12	1	(b)(4)
78.	RFUN-13	1	
79.	RFUN-14	1	
80.	RFUN-15	1	
81.	RGUI-66	2	
82.	RGUI-67	1	
83.	RFUN-16	1	
84.	RFUN-17	2	

85. RFUN-18 1

86. RGUI-68 1

(b)(4)

12. Report Contents

Req. Index	Req. No	Rank	Description
87.	RFUN-19	1	(b)(4)
88.	RFUN-20	1	
89.	RGUI-69	1	
90.	RFUN-21	1	
91.	RFUN-22	1	
92.	RFUN-23	1	
93.	RFUN-24	1	
94.	RFUN-25	1	

4.6. System Services

13. System Configuration

Req. Index	Req. No	Rank	Description
95.	RGUI-70	1	(b)(4)
96.	RGUI-71	1	
97.	RGUI-72	1	
98.	RGUI-73	3	

99. RGUI-74 1

(b)(4)

14. System Information (About pop-up)

Req. Index	Req. No	Rank	Description
100.	RGUI-75	1	(b)(4)
101.	RGUI-76	1	
102.	RGUI-77	1	
103.	RGUI-78	3	

15. Audit Trail

Req. Index	Req. No	Rank	Description
104.	RFUN-26	2	(b)(4)
105.	RFUN-27	2	
106.	RGUI-79	2	

16. User Support

Req. Index	Req. No	Rank	Description
107.	RGUI-80	1	(b)(4)

5. Nonfunctional Requirements

5.1. Hardware Requirements

Req. Index	Req. No	Rank	Description
108.	RHW-1.	2	(b)(4)
109.	RHW-2.	2	(b)(4)
110.	RHW-3.	3	(b)(4)

5.2. Operating System Requirements

Req. Index	Req. No	Rank	Description
111.	ROS-1	1	(b)(4)

5.3. Performance Requirements

Req. Index	Req. No	Rank	Description
112.	RPER-1	2	(b)(4)

5.4. Application Installation Requirements

Req. Index	Req. No	Rank	Description
113.	RINS-1	1	(b)(4)
114.	RINS-2	1	(b)(4)
115.	RINS-3	1	(b)(4)
116.	RINS-4	1	(b)(4)

⁵ The exact OS version is TBD based on the typical configuration offered with new computers at the time of the application's validation

117.	RINS-5	2
118.	RINS-6	2
119.	RINS-7	2
120.	RINS-8	1
121.	RINS-9	1
122.	RINS-10	1

(b)(4)

Req. Index	Field	Comments
a.	Facility Name	
b.	Facility Street Address	May be divided into two fields
c.	City	
d.	State	
e.	Zip Code	
f.	Telephone Number	
g.	Fax Number	
h.	Email Address	
i.	Logo	A path to an image file

Table 2: Facility information to be configured by the user during installation.

6. Appendix – Use Cases

6.1. Introduction

This appendix captures the foreseen, chief use cases for the *BoneVue* application, as it will be utilized in a clinical setting. While the use cases were used to drive the BoneVue system requirements, which are presented in the main document, they **are not** in themselves requirements, but rather general term guidelines to the structuring of the application, provided in a flow-oriented format. It is therefore expected that the fine details of the use cases may change during the system's design, though in concept they remain valid. The ultimate usage of the application will be captured in the BoneVue User Manual.

The use cases given here include the system-level interactions between the User and the BoneVue User Application (referred to simply as BoneVue in the use cases), as well as the internal communication between the application and its underlying components, primarily, the Bone Processing Software (BPS). The details of the processing flow within BPS are outside the scope of this document aside from the flow's impact on the manual QC procedures. Note also that use cases for the technical user relating to system configuration and maintenance were not developed at this time.

6.2. Use Cases

UC-4 Input Handling

4.1 Prerequisites

4.1.1 A dataset is available on one of the file system's drives.

4.2 Trigger

4.2.1 The user wishes to load a dataset for processing.

4.3 Main flow (success-oriented)

4.3.1 The user opens an input selection screen.

4.3.2 BoneVue opens a file browser.

4.3.3 The user browses through the file system to the input dataset's location.

4.3.4 The user selects the input dataset.

4.3.5 BoneVue displays and stores the path to the input dataset.

4.3.6 BoneVue displays key information, such as patient name/ID, age, scan date/time, and referring physician, which is extracted from the dataset's header.

4.4 Comments

4.4.1 The user may copy the dataset from an optical drive, received from the scanner, to any folder on the local system.

4.4.2 The selection GUI will allow folder selection for cortical bone processing input and file or folder selection for trabecular bone processing input.

4.5 Success conditions

4.5.1 The requested dataset is available for processing.

4.6 Failure conditions⁶

4.6.1 None

4.7 Alternative flows

4.7.1 None

⁶ Structural failures, such as a optical media corruption, are ignored throughout this document.

UC-5 User-Initiated Automatic Processing

5.1 Prerequisites

- 5.1.1 A dataset is available in the local file system.
- 5.1.2 The system is not set to *Manual QC* mode (i.e., without user interaction).

5.2 Trigger

- 5.2.1 The user wishes to process a dataset.

5.3 Main flow (success-oriented)

- 5.3.1 The user selects the series (single or pair) for which processing is needed (see UC-1).
- 5.3.2 BoneVue passes the dataset's path to BPS.
- 5.3.3 BoneVue launches a progress bar (or similar mechanism) to indicate which dataset is being processed and the status of processing.
- 5.3.4 BPS generates the required outputs.
- 5.3.5 BPS generates a *processing successfully completed* event.
- 5.3.6 BoneVue marks the dataset as *processed*.
- 5.3.7 BoneVue indicates to the user that the dataset was successfully processed.
- 5.3.8 BoneVue launches the results viewer.

5.4 Comments

- 5.4.1 Currently available processing flows include Trabecular Bone Processing (TBP) and Cortical Bone Processing (CBP), each requiring dedicated data acquisition.
- 5.4.2 In the typical case where a study includes both a TBP and CBP series, BoneVue will display in step 2.3.8 the results of both flows in a combined view, so as to facilitate an integrated report.

5.5 Success conditions

- 5.5.1 The required results are stored.
- 5.5.2 The dataset is labeled as *processed*.

5.6 Failure conditions

- 5.6.1 The user selects two series, each pertaining to a different study (step 2.3.1)

- 5.6.1.1 BoneVue alerts the user to the mismatch and suggests processing each series separately.
- 5.6.1.2 BoneVue terminates the flow.
- 5.6.2 The user selects an input folder with more than one valid series (step 2.3.1)
 - 5.6.2.1 BoneVue alerts the user to the multiplicity and suggests copying the dataset to a new location.
 - 5.6.2.2 BoneVue terminates the flow.
- 5.6.3 BPS is unable to process the dataset, for example, due to an unsupported file format or type, or excessive motion (step 2.3.4)
 - 5.6.3.1 BPS generates a *failure* event for the relevant processing step.
 - 5.6.3.2 BoneVue indicates processing failure in the processing progress view.
 - 5.6.3.3 BoneVue marks the dataset as *processing failed* and logs the reason for failure.
 - 5.6.3.4 If the other series (TBP/CBP) can be successfully processed, BPS will do so. On step 2.3.8, BoneVue will utilize the available results.
- 5.6.4 The user aborts processing (step 2.3.4).
 - 5.6.4.1 BoneVue marks the dataset as *partial processing* and logs the reason for failure.

5.7 Alternative flows

- 5.7.1 Both series selected by the user had already been processed in the automated mode (step 2.3.1)
 - 5.7.1.1 BoneVue displays the results viewer.
- 5.7.2 One of two series selected by the user had already been processed in the automated mode (step 2.3.1)
 - 5.7.2.1 BoneVue passes to BPS only the dataset ID for the not-yet-processed series.
 - 5.7.2.2 The procedure follows the main flow given above from step 2.3.3.
 - 5.7.2.3 If a combined display is required on step 2.3.8, BoneVue will utilize the pre-existing results for the relevant processing flow.
- 5.7.3 Restart processing - the user selects a series, which is marked *partial processing* (step 2.3.1)
 - 5.7.3.1 The procedure follows the main flow.
 - 5.7.3.2 On step 2.3.8, BPS will utilize all available outputs and resume processing from the relevant stage.
- 5.7.4 A series selected by the user had already been processed in the manual QC mode (step 2.3.1)

- 5.7.4.1 BoneVue alerts the user that all the output files for this exam will be deleted, including the final report.
- 5.7.4.2 If the user approves, BoneVue requests BPS to clear the output folder of all files and deletes the report file.
- 5.7.4.3 BoneVue performs the main flow.

5.8 Use case diagram

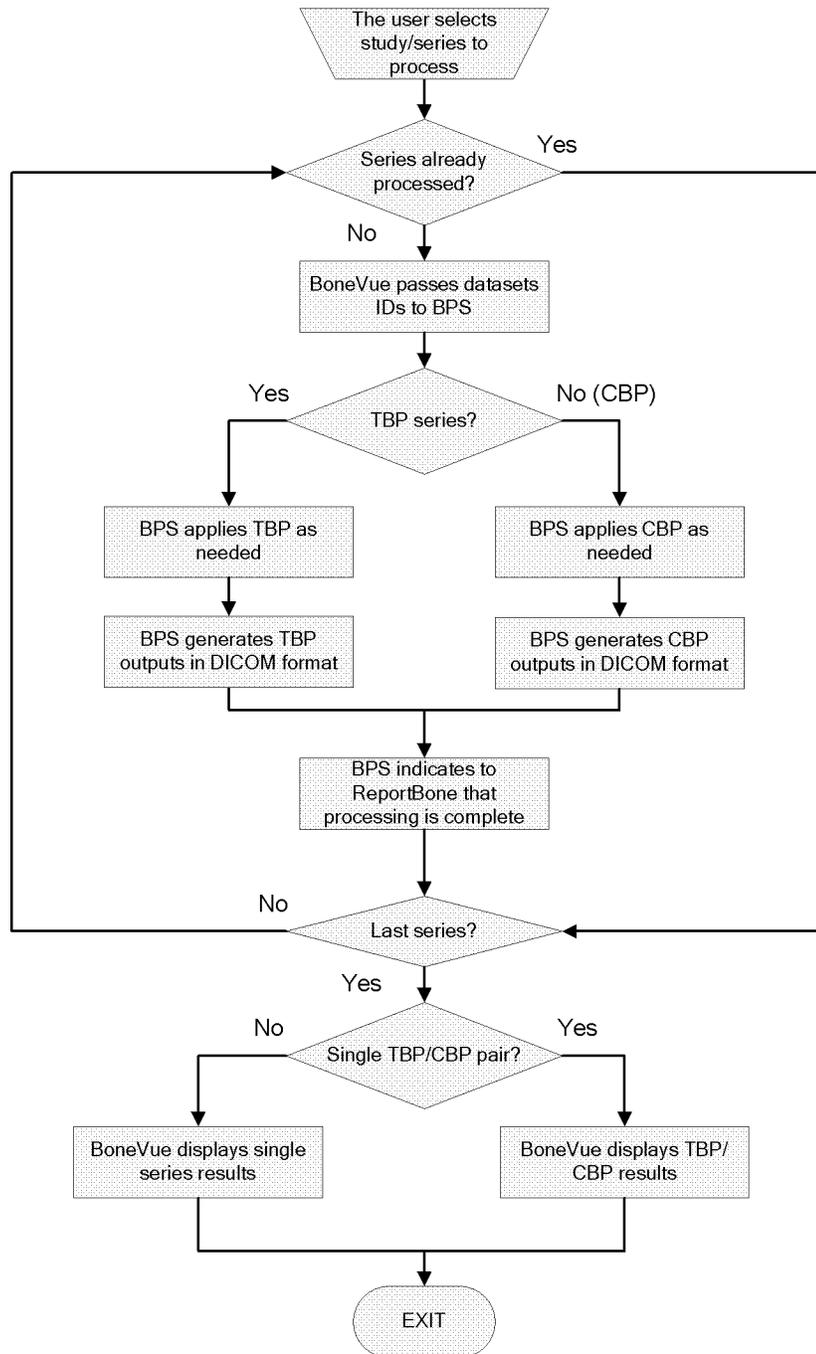


Figure 5: User-initiated automatic processing of a single study. The diagram covers the main flow as well as the alternative flows pertaining to previously processed data (in the current mode) and single series processing.

UC-6 User-Initiated Manual Processing

6.1 Prerequisites

- 6.1.1 A dataset is available in the local file system.
- 6.1.2 The system is set to *QC* mode.

6.2 Trigger

- 6.2.1 The user wishes to process a study, verifying the results at key intermediary steps (and editing the results as needed).

6.3 Main flow (success-oriented)

- 6.3.1 The user selects the series (single or pair) for which processing is needed (see UC-1).
- 6.3.2 BoneVue passes the dataset ID to BPS, requesting a controlled process.
- 6.3.3 BPS reads the CBP series and generates the 3D mask, which initializes the endosteal boundary for cortical segmentation.
- 6.3.4 BPS indicates to BoneVue that CBP has been initialized.
- 6.3.5 BoneVue displays to the user the automatically-generated 3D mask in a stack view, where each slice of the mask is represented by a contour overlaid on the corresponding image slice.
- 6.3.6 The user approves the mask.
- 6.3.7 BoneVue orders BPS to resume processing.
- 6.3.8 BPS performs cortical segmentation.
- 6.3.9 BPS indicates to BoneVue that cortical segmentation is done.
- 6.3.10 BPS displays to the user the automatically-generated cortical boundaries in a stack view, where the corresponding boundaries are represented as overlaid colored contours on each image slice.
- 6.3.11 The user approves the detected boundaries.
- 6.3.12 BoneVue orders BPS to resume processing.
- 6.3.13 BPS completes CBP, storing the required outputs.
- 6.3.14 BPS indicates to BoneVue the completion of CBP.
- 6.3.15 BoneVue marks the series as *processed*.
- 6.3.16 BPS reads the TBP series and performs motion correction.
- 6.3.17 BPS indicates to BoneVue that motion correction is done.

- 6.3.18 BoneVue displays the motion-corrected image and/or motion graphs to the user.
- 6.3.19 The user approves that the image is fit to be processed.
- 6.3.20 BoneVue orders BPS to resume processing.
- 6.3.21 BPS generates the ROI mask.
- 6.3.22 BPS indicates to BoneVue that the automatic ROI generation is done for TBP.
- 6.3.23 BoneVue displays to the user the automatically-generated 3D mask (ROI) in a stack view, where each slice of the mask is represented by a contour overlaid on the corresponding image slice.
- 6.3.24 The user approves the ROI.
- 6.3.25 BoneVue orders BPS to resume processing.
- 6.3.26 BPS processes the dataset, generating a *successful completion* event at the end of each processing step.
- 6.3.27 BoneVue updates the processing status in the processing progress view.
- 6.3.28 BPS generates the required outputs.
- 6.3.29 BPS indicates to BoneVue the completion of TBP.
- 6.3.30 BoneVue marks the series as *processed*.
- 6.3.31 BoneVue indicates to the user that the study was successfully processed.
- 6.3.32 BoneVue launches the results viewer, displaying the results of both flows.

6.4 Comments

6.4.1 None.

6.5 Success conditions

6.5.1 The required results are in the database.

6.5.2 The dataset(s) is labeled as *processed*.

6.6 Failure conditions

6.6.1 The user rejects CBP initialization (step 3.3.6) or the cortical boundaries (step 3.3.11)

6.6.1.1 The user enters or selects a rejection reason.

6.6.1.2 BoneVue terminates CBP (it may continue to TBP if the relevant input is available).

6.6.1.3 BoneVue marks the CBP series as *rejected by user* and logs the reason.

6.6.2 BPS is unable to process a CBP series, for example, due to an unsupported file format or type (steps 3.3.3, 3.3.8, 3.3.13)

6.6.2.1 BPS generates a *failure* event for the relevant processing step.

6.6.2.2 BoneVue indicates processing failure in the processing progress view.

6.6.2.3 BoneVue marks the CBP series as *processing failed* and logs the reason.

6.6.2.4 The procedure continues from step 3.3.16 (TBP).

6.6.2.5 Only TBP results will be shown on step 3.3.32.

6.6.3 The user rejects the motion correction results (step 3.3.19) or the ROI mask (step 3.3.24)

6.6.3.1 The user enters or selects a rejection reason.

6.6.3.2 BoneVue marks the TBP series as *rejected by user* and logs the reason.

6.6.3.3 Only CBP results will be shown on step 3.3.32.

6.6.4 BPS is unable to process a TBP series, for example, due to an unsupported file format or type (steps 3.3.16, 3.3.21, 3.3.26)

6.6.4.1 BPS generates a *failure* event for the relevant processing step.

6.6.4.2 BoneVue indicates processing failure in the processing progress view.

6.6.4.3 BoneVue marks the TBP series as *processing failed* and logs the reason.

6.6.4.4 Only CBP results will be shown on step 3.3.32.

- 6.6.5 The user aborts the process midway or selects to cancel processing at any of the QC steps (steps 3.3.6, 3.3.11, 3.3.19, 3.3.24)
 - 6.6.5.1 BoneVue/BPS stores all the output available at this point.
 - 6.6.5.2 BoneVue ensures the appropriate dataset is marked *partial processing*.
 - 6.6.5.3 BoneVue terminates the procedure.
- 6.6.6 The user selects an input folder with more than one valid series (step 3.3.1)
 - 6.6.6.1 BoneVue alerts the user to the multiplicity and suggests copying the dataset to a new location.
 - 6.6.6.2 BoneVue terminates the flow.
- 6.6.7 BPS detects that the SNR is lower than the recommended threshold.
 - 6.6.7.1 BPS generates a *failure* event for the relevant processing step.
 - 6.6.7.2 BoneVue indicates a low SNR instance.
 - 6.6.7.3 The user may approve processing nevertheless – the main flow is resumed; the user may choose to reject the dataset – see 3.6.3; the user may choose to cancel processing altogether – see 3.6.5.

6.7 Alternative flows

- 6.7.1 The user selects to process a single dataset (step 3.3.1)
 - 6.7.1.1 Main flow steps 3.3.3-3.3.15 or 3.3.16-3.3.30 are skipped, depending on the dataset's type.
 - 6.7.1.2 On step 3.3.32, BoneVue will display single series results.
- 6.7.2 Restart processing - the user selects a series, which is marked *partial processing* (step 3.3.1)
 - 6.7.2.1 The procedure is handled as reprocessing with partial data (see 3.7.4).
- 6.7.3 The user wishes to edit the automatically generated results (steps 3.3.6, 3.3.11, or 3.3.24) – see UC-7.
 - 6.7.3.1 The procedure continues with the edited mask.
- 6.7.4 A series selected by the user had already been processed (step 3.3.1)
 - 6.7.4.1 The flow will go from one QC step to the other until the user decides to change the existing data on steps 3.3.6, 3.3.11, or 3.3.24 (or the required data does not exist in the case of a partially processed dataset as input).
 - 6.7.4.2 Once the user changes the existing data, BoneVue alerts the user that all the output files for this and subsequent processing steps, including the final report, will be deleted.

- 6.7.4.3 If the user approves, BoneVue requests BPS to clear the output folder of all relevant files and deletes the report file.
- 6.7.4.4 BoneVue will resume the main flow from the appropriate step until the results are displayed.

6.8 Use case diagram

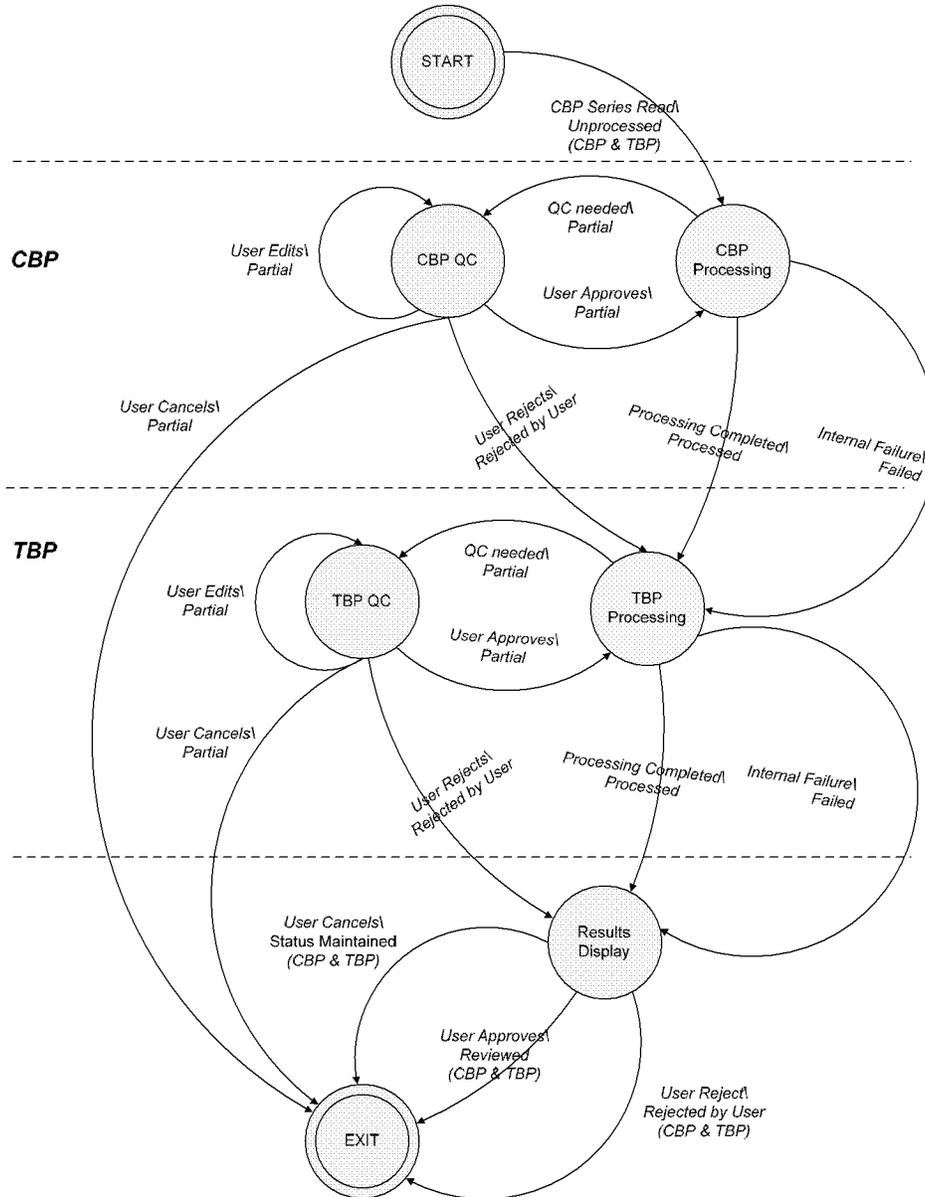


Figure 6: State diagram for the user-initiated manual processing of a study, including results review. The states in this case are the main steps along the use case, merging the various QC steps along the flow into one for more concise representation. Each arrow between states is labeled according to the following convention: <Action>\<Status of dataset following action>. Unless otherwise notes, the status pertains to the dataset currently processed whether by CBP or TBP. **Note:** The Results Display stage may be skipped if both processing flows failed or if they were rejected by the user. Failure/rejection of only one flow will result in a single dataset display, and also

	<i>BoneVue System Requirements Specification</i> <i>Document Version: 1.2</i> <i>Internal Document</i>	<i>11/7/2008</i>
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a possible deviation from the status labels given here on the arrows between Results Display and Exit.

UC-7 ROI Manipulation

7.1 Prerequisites

- 7.1.1 A ROI mask is associated with a certain dataset in the database.
- 7.1.2 BoneVue displayed to the user an image with an overlaid ROI mask.

7.2 Trigger

- 7.2.1 The user wishes to edit an existing ROI mask.⁷

7.3 Main flow (success-oriented)

- 7.3.1 The user adds polygonal, rectangular or elliptical regions to the existing mask or removes such regions from it.
- 7.3.2 The user moves to the next/previous slice.
- 7.3.3 The user repeats steps 7.3.1-7.3.2.
- 7.3.4 When editing is done, the user commits the new mask.
- 7.3.5 BoneVue confirms that the mask changed.
- 7.3.6 BoneVue stores the new mask.

7.4 Comments

- 7.4.1 The use case is written assuming the ROI mask will be represented as a contour on the image.
- 7.4.2 The last mask editing action (step 7.3.1) may be undone.
- 7.4.3 The user may replicate a mask from the previous slice to the currently-displayed one.
- 7.4.4 Options for adjusting the view are not included here.

⁷ This use case is typically reached through a QC step, as part of one of the main processing flows.

7.5 Success conditions

7.5.1 The edited mask is stored.

7.6 Failure conditions

7.6.1 The user cancels the mask editing (steps 7.3.1-7.3.2)

7.6.1.1 BoneVue aborts the process (no mask will be saved).

7.6.2 The user attempts to store an empty mask (step 7.3.4)

7.6.2.1 BoneVue alerts the user.

7.6.2.2 BoneVue does not exit the ROI editing mode - the user can either resume editing or cancel.

7.7 Alternative flows

7.7.1 Creating a new mask (step 7.3.1)

7.7.1.1 The user selects the Create New (or Clear ROI) option.

7.7.1.2 BoneVue removes the overlay from all slices.

7.7.1.3 The process follows main flow steps 7.3.1-7.3.4.

7.7.2 Resetting the mask (step 7.3.4)

7.7.2.1 The user selects to revert to the initial mask.

7.7.2.2 BoneVue replaces the currently displayed ROI with the initial one.

7.7.2.3 The process follows main flow steps 7.3.1-7.3.4.

7.7.3 The edited mask is the same as the original one (step 7.3.5).

7.7.3.1 If the user did in fact edit the mask, BoneVue alerts the user.

7.7.3.2 If the user approves, BoneVue exits the editing mode without creating a new mask; otherwise, BoneVue returns to edit mode.

UC-8 Report Generation

8.1 Prerequisites

8.1.1 The user is reviewing processing results of a dataset that was processed to completion.

8.2 Trigger

8.2.1 The user wishes to generate a report based on the viewed results.

8.3 Main flow (success-oriented)

8.3.1 The user selects to generate a report that will combine the viewed results.

8.3.2 BoneVue displays a preview of the report in the default format that is applicable to the type of reviewed results (see comment below).

8.3.3 BoneVue launches the printing dialog box.

8.3.4 The user approves to proceed with printing (possibly selecting a specific printer).

8.3.5 BoneVue stores the report in PDF or DICOM format.

8.3.6 BoneVue closes the report mode and returns to the results viewer.

8.4 Comments

8.4.1 The use case should apply, in general terms, to any of the results viewer's modes of operation, namely, single flow (TBP or CBP) or combined TBP/CBP. Each of the modes may have a default report format associated with it.

8.4.2 Report generation is not available for partially processed datasets.

8.5 Success conditions

8.5.1 The report has been successfully stored and printed.

8.6 Failure conditions

8.6.1 The printer is unavailable (step 8.3.4)

8.6.1.1 BoneVue alerts the user.

8.7 Alternative flows

8.7.1 A report already exists in the database for the dataset (step 8.3.5)

8.7.1.1 BoneVue alerts the user that a report already exists.

8.7.1.2 The user may cancel the operation or store a new report, overwriting the existing one.

7. Signatures

Signatory meanings are described in SOP OP-008 [3].

Originator:

Signature: _____ Name: _____ Date: _____
Sr. Software Engineer

Required Review By:

Signature: _____ Name: _____ Date: _____
Software Engineer

Signature: _____ Name: _____ Date: _____
Director, Project Management/Data Analysis

Independent Review By:

Signature: _____ Name: _____ Date: _____
Manager of Quality Assurance and Regulatory Affairs

Authorized By:

Signature: _____ Name: _____ Date: _____
CTO

	Traceability Matrix for BoneVue v1 BV-DHF-TRM-001.000.01 Internal Document	12/11/08 Page 161 of 218
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ATTACHMENT 6

TRACEABILITY MATRIX

Project: BoneVue™ Software v1

Internal Document

REVISION HISTORY

Version	Release Date	Responsible Party	Major Changes
000		Allon Shahar	Initial Creation

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
1	RFUN-01	DBPS-1	TP_FUN_1	TC#9	
2	RFUN-01	DBPS-4	TP_FUN_1	TC#9	
3	RFUN-02	DMEN-4	TP_FUN_1	TC#12	
4	RFUN-02	DMEN-4	TP_FUN_2	TC#12	
5	RFUN-02	DMEN-4	TP_FUN_2	TC#18	
6	RFUN-02	DMEN-4	TP_FUN_2	TC#20	
7	RFUN-02	DMEN-4	TP_FUN_3	TC#11	
8	RFUN-02	DMEN-4	TP_FUN_5	TC#4	
9	RFUN-02	DMEN-4	TP_FUN_7	TC#8	
10	RFUN-03	DMAI-21	TP_FUN_1	TC#1	
11	RFUN-03	DMAI-21	TP_FUN_2	TC#1	
12	RFUN-04	DBPS-15	TP_FUN_4	TC#1	
13	RFUN-05	DBPS-16	TP_EXC_1	TC#10	
14	RFUN-05	DMAI-22	TP_EXC_1	TC#10	
15	RFUN-06	DBPS-17	TP_QCP_2	TC#1	
16	RFUN-06	DBPS-18	TP_QCP_2	TC#1	
17	RFUN-06	DQCP-5	TP_QCP_2	TC#1	
18	RFUN-06	DQCP-6	TP_QCP_2	TC#1	
19	RFUN-06	DQCP-7	TP_QCP_2	TC#1	
20	RFUN-06	DQCP-8	TP_QCP_2	TC#1	
21	RFUN-07	DBPS-19	TP_QCP_1	TC#1	
22	RFUN-08	DMAI-23	TP_FUN_4	TC#1	
23	RFUN-08	DBPS-20	TP_FUN_4	TC#1	
24	RFUN-09	DBPS-21	TP_FUN_2	TC#14	
25	RFUN-10	DBPS-22	TP_FUN_3	TC#23	
26	RFUN-10	DBPS-22	TP_FUN_3	TC#25	
27	RFUN-10	DBPS-22	TP_FUN_3	TC#26	
28	RFUN-10	DBPS-22	TP_FUN_3	TC#27	
29	RFUN-10	DBPS-23	TP_FUN_3	TC#23	
30	RFUN-10	DBPS-23	TP_FUN_3	TC#25	
31	RFUN-10	DBPS-23	TP_FUN_3	TC#26	
32	RFUN-10	DBPS-23	TP_FUN_3	TC#27	
33	RFUN-10	DBPS-24	TP_FUN_3	TC#23	
34	RFUN-10	DBPS-24	TP_FUN_3	TC#25	
35	RFUN-10	DBPS-24	TP_FUN_3	TC#26	
36	RFUN-10	DBPS-24	TP_FUN_3	TC#27	
37	RFUN-10	DBPS-25	TP_FUN_3	TC#23	
38	RFUN-10	DBPS-25	TP_FUN_3	TC#25	
39	RFUN-10	DBPS-25	TP_FUN_3	TC#26	
40	RFUN-10	DBPS-25	TP_FUN_3	TC#27	
41	RFUN-11	DQCP-4	TP_FUN_2	TC#18	
42	RFUN-11	DQCP-4	TP_FUN_4	TC#9	
43	RFUN-11	DQCP-4	TP_FUN_5	TC#4	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
44	RFUN-11	DQCP-4	TP_FUN_7	TC#8	
45	RFUN-12	DREP-01	TP_FUN_5	TC#1	
46	RFUN-13	DRES-13	TP_FUN_4	TC#9	
47	RFUN-14	DREP-15	TP_FUN_5	TC#3	
48	RFUN-15	DREP-16	TP_FUN_5	TC#2	
49	RFUN-16	DREP-02	TP_FUN_5	TC#2	
50	RFUN-16	DREP-02	TP_FUN_5	TC#3	
51	RFUN-17	DREP-09	TP_FUN_5	TC#3	
52	RFUN-17	DREP-13	TP_FUN_5	TC#2	
53	RFUN-18	DREP-14	TP_FUN_5	TC#2	
54	RFUN-19	DREP-01	TP_FUN_5	TC#2	
55	RFUN-20	DREP-03	TP_FUN_5	TC#2	
56	RFUN-20	DREP-03	TP_FUN_5	TC#2	
57	RFUN-21	DREP-04	TP_FUN_5	TC#2	
58	RFUN-22	DREP-05	TP_FUN_5	TC#2	
59	RFUN-23	DREP-06	TP_FUN_5	TC#2	
60	RFUN-24	DREP-07	TP_FUN_5	TC#2	
61	RFUN-25	DREP-08	TP_FUN_5	TC#2	
62	RFUN-26	DMSG-01	TP_FUN_6	TC#4	
63	RFUN-26	DMSG-02	TP_FUN_6	TC#4	
64	RFUN-26	DMSG-03	TP_FUN_6	TC#4	
65	RFUN-26	DMSG-04	TP_FUN_6	TC#4	
66	RFUN-26	DMSG-05	TP_FUN_6	TC#4	
67	RFUN-26	DMSG-06	TP_FUN_6	TC#4	
68	RFUN-26	DMSG-07	TP_FUN_6	TC#4	
69	RFUN-26	DMSG-08	TP_FUN_6	TC#4	
70	RFUN-26	DMSG-09	TP_FUN_6	TC#4	
71	RFUN-26	DMSG-10	TP_FUN_6	TC#4	
72	RFUN-27	DMSG-01	TP_FUN_6	TC#3	
73	RFUN-27	DMSG-02	TP_FUN_6	TC#3	
74	RFUN-27	DMSG-03	TP_FUN_6	TC#3	
75	RFUN-27	DMSG-04	TP_FUN_6	TC#3	
76	RFUN-27	DMSG-05	TP_FUN_6	TC#3	
77	RFUN-27	DMSG-06	TP_FUN_6	TC#3	
78	RFUN-27	DMSG-07	TP_FUN_6	TC#3	
79	RFUN-27	DMSG-08	TP_FUN_6	TC#3	
80	RFUN-27	DMSG-09	TP_FUN_6	TC#3	
81	RFUN-27	DMSG-10	TP_FUN_6	TC#3	
82	RGUI-01	DMAI-1	TP_FUN_1	TC#3	
83	RGUI-01	DMAI-1	TP_FUN_2	TC#3	
84	RGUI-01	DMAI-2	TP_FUN_1	TC#3	
85	RGUI-01	DMAI-2	TP_FUN_2	TC#3	
86	RGUI-01	DMAI-3	TP_FUN_1	TC#3	
87	RGUI-01	DMAI-3	TP_FUN_2	TC#3	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
88	RGUI-02	DMAI-4	TP_FUN_1	TC#5	
89	RGUI-02	DMAI-4	TP_FUN_2	TC#5	
90	RGUI-02	DMAI-5	TP_FUN_1	TC#5	
91	RGUI-02	DMAI-5	TP_FUN_2	TC#5	
92	RGUI-02	DMAI-6	TP_FUN_1	TC#5	
93	RGUI-02	DMAI-6	TP_FUN_2	TC#5	
94	RGUI-03	DMAI-7	TP_FUN_1	TC#5	
95	RGUI-03	DMAI-7	TP_FUN_2	TC#5	HAZ-001(4,5)
96	RGUI-04	DEXC-1	TP_FUN_1	TC#2	
97	RGUI-04	DEXC-1	TP_FUN_1	TC#4	HAZ-001(9)
98	RGUI-04	DEXC-1	TP_FUN_2	TC#2	
99	RGUI-04	DEXC-1	TP_FUN_2	TC#4	
100	RGUI-04	DEXC-1	TP_FUN_7	TC#2	
101	RGUI-04	DEXC-1	TP_FUN_7	TC#4	
102	RGUI-05	DMAI-8	TP_FUN_1	TC#2	HAZ-001(10)
103	RGUI-05	DMAI-8	TP_FUN_1	TC#4	
104	RGUI-05	DMAI-8	TP_FUN_2	TC#2	
105	RGUI-05	DMAI-8	TP_FUN_2	TC#4	
106	RGUI-05	DMAI-8	TP_FUN_7	TC#2	
107	RGUI-05	DMAI-8	TP_FUN_7	TC#4	
108	RGUI-05	DBPS-3	TP_FUN_1	TC#2	HAZ-001(10)
109	RGUI-05	DBPS-3	TP_FUN_1	TC#4	
110	RGUI-05	DBPS-3	TP_FUN_2	TC#2	
111	RGUI-05	DBPS-3	TP_FUN_2	TC#4	
112	RGUI-05	DBPS-3	TP_FUN_7	TC#2	
113	RGUI-05	DBPS-3	TP_FUN_7	TC#4	
114	RGUI-06	DMAI-9	TP_FUN_1	TC#2	
115	RGUI-06	DMAI-9	TP_FUN_1	TC#4	
116	RGUI-06	DMAI-9	TP_FUN_2	TC#2	
117	RGUI-06	DMAI-9	TP_FUN_2	TC#4	
118	RGUI-06	DMAI-9	TP_FUN_7	TC#2	
119	RGUI-06	DMAI-9	TP_FUN_7	TC#4	
120	RGUI-06	DMAI-10	TP_FUN_1	TC#2	
121	RGUI-06	DMAI-10	TP_FUN_1	TC#4	
122	RGUI-06	DMAI-10	TP_FUN_2	TC#2	
123	RGUI-06	DMAI-10	TP_FUN_2	TC#4	
124	RGUI-06	DMAI-10	TP_FUN_7	TC#2	
125	RGUI-06	DMAI-10	TP_FUN_7	TC#4	
126	RGUI-07	DMAI-11	TP_FUN_1	TC#3	
127	RGUI-07	DMAI-11	TP_FUN_1	TC#5	
128	RGUI-07	DMAI-11	TP_FUN_2	TC#3	
129	RGUI-07	DMAI-11	TP_FUN_2	TC#5	
130	RGUI-07	DMAI-11	TP_FUN_7	TC#3	
131	RGUI-07	DMAI-11	TP_FUN_7	TC#5	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
132	RGUI-07	DMAI-12	TP_FUN_1	TC#3	
133	RGUI-07	DMAI-12	TP_FUN_1	TC#5	
134	RGUI-07	DMAI-12	TP_FUN_2	TC#3	
135	RGUI-07	DMAI-12	TP_FUN_2	TC#5	
136	RGUI-07	DMAI-12	TP_FUN_7	TC#3	
137	RGUI-07	DMAI-12	TP_FUN_7	TC#5	
138	RGUI-08	DEXC-2	TP_FUN_1	TC#3	
139	RGUI-08	DEXC-2	TP_FUN_1	TC#5	
140	RGUI-08	DEXC-2	TP_FUN_2	TC#3	
141	RGUI-08	DEXC-2	TP_FUN_2	TC#5	
142	RGUI-08	DEXC-2	TP_FUN_7	TC#3	
143	RGUI-08	DEXC-2	TP_FUN_7	TC#5	
144	RGUI-09	DMAI-13	TP_FUN_2	TC#12	
145	RGUI-09	DMAI-13	TP_FUN_3	TC#2	
146	RGUI-09	DMAI-13	TP_FUN_7	TC#3	
147	RGUI-09	DBPS-1	TP_FUN_2	TC#12	
148	RGUI-09	DBPS-1	TP_FUN_3	TC#2	
149	RGUI-09	DBPS-1	TP_FUN_7	TC#3	
150	RGUI-09	DBPS-2	TP_FUN_2	TC#12	
151	RGUI-09	DBPS-2	TP_FUN_3	TC#2	
152	RGUI-09	DBPS-2	TP_FUN_7	TC#3	
153	RGUI-09	DBPS-3	TP_FUN_2	TC#12	
154	RGUI-09	DBPS-3	TP_FUN_3	TC#2	
155	RGUI-09	DBPS-3	TP_FUN_7	TC#3	
156	RGUI-10	DMAI-14	TP_FUN_1	TC#7	
157	RGUI-10	DMAI-14	TP_FUN_2	TC#8	
158	RGUI-10	DMAI-15	TP_FUN_1	TC#7	
159	RGUI-10	DMAI-15	TP_FUN_2	TC#8	
160	RGUI-10	DREA-1	TP_FUN_1	TC#7	
161	RGUI-10	DREA-1	TP_FUN_2	TC#8	
162	RGUI-11	DMAI-16	TP_FUN_2	TC#8	
163	RGUI-11	DREA-2	TP_FUN_2	TC#8	
164	RGUI-12	DMAI-17	TP_FUN_1	TC#1	
165	RGUI-12	DMAI-17	TP_FUN_1	TC#12	
166	RGUI-12	DMAI-17	TP_FUN_2	TC#1	
167	RGUI-12	DMAI-17	TP_FUN_2	TC#12	
168	RGUI-12	DMAI-17	TP_FUN_2	TC#19	
169	RGUI-12	DMAI-17	TP_FUN_2	TC#20	
170	RGUI-12	DMAI-17	TP_FUN_2	TC#21	
171	RGUI-12	DMAI-17	TP_FUN_2	TC#22	
172	RGUI-12	DMAI-17	TP_FUN_2	TC#23	
173	RGUI-12	DMAI-17	TP_FUN_2	TC#25	
174	RGUI-12	DMAI-17	TP_FUN_2	TC#26	
175	RGUI-12	DMAI-17	TP_FUN_7	TC#1	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
176	RGUI-12	DMAI-17	TP_FUN_7	TC#6	
177	RGUI-12	DMAI-17	TP_FUN_7	TC#8	
178	RGUI-13	DMAI-18	TP_FUN_1	TC#1	
179	RGUI-13	DMAI-18	TP_FUN_1	TC#12	
180	RGUI-13	DMAI-18	TP_FUN_2	TC#1	
181	RGUI-13	DMAI-18	TP_FUN_2	TC#12	
182	RGUI-13	DMAI-18	TP_FUN_2	TC#23	
183	RGUI-13	DMAI-18	TP_FUN_2	TC#25	
184	RGUI-13	DMAI-18	TP_FUN_2	TC#26	
185	RGUI-13	DMAI-18	TP_FUN_7	TC#1	
186	RGUI-13	DMAI-18	TP_FUN_7	TC#6	
187	RGUI-13	DMAI-19	TP_FUN_1	TC#1	
188	RGUI-13	DMAI-19	TP_FUN_1	TC#12	
189	RGUI-13	DMAI-19	TP_FUN_2	TC#1	
190	RGUI-13	DMAI-19	TP_FUN_2	TC#12	
191	RGUI-13	DMAI-19	TP_FUN_2	TC#23	
192	RGUI-13	DMAI-19	TP_FUN_2	TC#25	
193	RGUI-13	DMAI-19	TP_FUN_2	TC#26	
194	RGUI-13	DMAI-19	TP_FUN_7	TC#1	
195	RGUI-13	DMAI-19	TP_FUN_7	TC#6	
196	RGUI-13	DBPS-5	TP_FUN_1	TC#1	
197	RGUI-13	DBPS-5	TP_FUN_1	TC#12	
198	RGUI-13	DBPS-5	TP_FUN_2	TC#1	
199	RGUI-13	DBPS-5	TP_FUN_2	TC#12	
200	RGUI-13	DBPS-5	TP_FUN_2	TC#23	
201	RGUI-13	DBPS-5	TP_FUN_2	TC#25	
202	RGUI-13	DBPS-5	TP_FUN_2	TC#26	
203	RGUI-13	DBPS-5	TP_FUN_7	TC#1	
204	RGUI-13	DBPS-5	TP_FUN_7	TC#6	
205	RGUI-13	DBPS-6	TP_FUN_1	TC#1	
206	RGUI-13	DBPS-6	TP_FUN_1	TC#12	
207	RGUI-13	DBPS-6	TP_FUN_2	TC#1	
208	RGUI-13	DBPS-6	TP_FUN_2	TC#12	
209	RGUI-13	DBPS-6	TP_FUN_2	TC#23	
210	RGUI-13	DBPS-6	TP_FUN_2	TC#25	
211	RGUI-13	DBPS-6	TP_FUN_2	TC#26	
212	RGUI-13	DBPS-6	TP_FUN_7	TC#1	
213	RGUI-13	DBPS-6	TP_FUN_7	TC#6	
214	RGUI-14	DMAI-20	TP_FUN_7	TC#8	
215	RGUI-14	DBPS-7	TP_FUN_7	TC#8	
216	RGUI-15	DEXC-3	TP_EXC_1	TC#1	
217	RGUI-15	DBPS-8	TP_EXC_1	TC#1	
218	RGUI-16	DEXC-4	TP_EXC_1	TC#2	HAZ-001(11)

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
219	RGUI-16	DBPS-9	TP_EXC_1	TC#2	
220	RGUI-17	DEXC-5	TP_EXC_1	TC#3	HAZ-001(7)
221	RGUI-17	DBPS-10	TP_EXC_1	TC#3	
222	RGUI-18	DEXC-6	TP_EXC_1	TC#4	
223	RGUI-18	DBPS-11	TP_EXC_1	TC#4	
224	RGUI-19	DEXC-7	TP_FUN_7	TC#8	HAZ-001(15)
225	RGUI-19	DBPS-12	TP_FUN_7	TC#8	
226	RGUI-20	DEXC-8	TP_EXC_1	TC#5	
227	RGUI-20	DBPS-13	TP_EXC_1	TC#5	
228	RGUI-20	DEXC-8	TP_FUN_8	TC#1	
229	RGUI-20	DBPS-13	TP_FUN_8	TC#1	
230	RGUI-21	DEXC-9	TP_EXC_1	TC#6	HAZ-001(16)
231	RGUI-21	DBPS-14	TP_EXC_1	TC#6	
232	RGUI-22	DQCP-9	TP_QCP_2	TC#1	
233	RGUI-23	DQCP-1	TP_FUN_1	TC#3	
234	RGUI-23	DQCP-1	TP_FUN_7	TC#3	
235	RGUI-24	DQCP-2	TP_FUN_7	TC#6	HAZ-001(6)
236	RGUI-24	DQCP-2	TP_FUN_1	TC#12	
237	RGUI-24	DQCP-2	TP_FUN_1	TC#23	
238	RGUI-25	DQCP-3	TP_FUN_2	TC#12	HAZ-001(16)
239	RGUI-25	DQCP-9	TP_FUN_2	TC#12	
240	RGUI-25	DQCP-10	TP_FUN_2	TC#12	
241	RGUI-25	DQCP-11	TP_FUN_2	TC#12	
242	RGUI-25	DQCP-3	TP_QCP_1	TC#1	
243	RGUI-25	DQCP-9	TP_QCP_1	TC#1	
244	RGUI-25	DQCP-10	TP_QCP_1	TC#1	
245	RGUI-25	DQCP-11	TP_QCP_1	TC#1	
246	RGUI-26	DQCP-12	TP_FUN_2	TC#20	HAZ-001(14)
247	RGUI-26	DQCP-12	TP_FUN_2	TC#21	
248	RGUI-26	DQCP-12	TP_QCP_1	TC#2	
249	RGUI-26	DQCP-12	TP_QCP_1	TC#2	
250	RGUI-27	DQCP-13	TP_FUN_2	TC#20	
251	RGUI-27	DQCP-13	TP_FUN_2	TC#21	
252	RGUI-27	DQCP-13	TP_FUN_7	TC#8	
253	RGUI-27	DBPS-26	TP_FUN_2	TC#20	
254	RGUI-27	DBPS-26	TP_FUN_2	TC#21	
255	RGUI-27	DBPS-26	TP_FUN_7	TC#8	
256	RGUI-28	DMAI-24	TP_FUN_4	TC#2	HAZ-001(11)
257	RGUI-28	DMAI-24	TP_FUN_4	TC#3	
258	RGUI-28	DMAI-24	TP_FUN_4	TC#4	
259	RGUI-28	DMAI-24	TP_FUN_5	TC#2	
260	RGUI-29	DQCP-14	TP_FUN_8	TC#8	HAZ-001(21)
261	RGUI-29	DBPS-27	TP_FUN_8	TC#8	
262	RGUI-29	DQCP-14	TP_EXC_1	TC#5	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
263	RGUI-29	DBPS-27	TP_EXC_1	TC#5	
264	RGUI-30	DQCP-15	TP_FUN_2	TC#25	HAZ-001(21)
265	RGUI-30	DBPS-27	TP_FUN_2	TC#25	
266	RGUI-30	DBPS-28	TP_FUN_2	TC#25	
267	RGUI-30	DBPS-29	TP_FUN_2	TC#25	
268	RGUI-31	DQCP-16	TP_FUN_7	TC#8	HAZ-001(13)
269	RGUI-31	DBPS-30	TP_FUN_7	TC#8	
270	RGUI-32	DQCP-17	TP_FUN_2	TC#12	
271	RGUI-32	DQCP-17	TP_FUN_2	TC#13	
272	RGUI-32	DQCP-17	TP_FUN_2	TC#14	
273	RGUI-32	DQCP-17	TP_FUN_2	TC#25	
274	RGUI-32	DBPS-31	TP_FUN_2	TC#12	
275	RGUI-32	DBPS-31	TP_FUN_2	TC#13	
276	RGUI-32	DBPS-31	TP_FUN_2	TC#14	
277	RGUI-32	DBPS-31	TP_FUN_2	TC#25	
278	RGUI-33	DQCP-17	TP_FUN_2	TC#26	HAZ-001(16)
279	RGUI-33	DROI-1	TP_FUN_2	TC#26	
280	RGUI-33	DBPS-32	TP_FUN_2	TC#26	
281	RGUI-33	DBPS-33	TP_FUN_2	TC#26	
282	RGUI-34	DBPS-34	TP_FUN_3	TC#5	
283	RGUI-34	DBPS-34	TP_FUN_3	TC#6	
284	RGUI-34	DBPS-34	TP_FUN_3	TC#7	
285	RGUI-34	DBPS-34	TP_FUN_3	TC#9	HAZ-001(16)
286	RGUI-34	DBPS-35	TP_FUN_3	TC#5	
287	RGUI-34	DBPS-35	TP_FUN_3	TC#6	
288	RGUI-34	DBPS-35	TP_FUN_3	TC#7	
289	RGUI-34	DBPS-35	TP_FUN_3	TC#9	HAZ-001(16)
290	RGUI-34	DBPS-36	TP_FUN_3	TC#5	
291	RGUI-34	DBPS-36	TP_FUN_3	TC#6	
292	RGUI-34	DBPS-36	TP_FUN_3	TC#7	
293	RGUI-34	DBPS-36	TP_FUN_3	TC#9	HAZ-001(16)
294	RGUI-34	DROI-2	TP_FUN_3	TC#5	
295	RGUI-34	DROI-2	TP_FUN_3	TC#6	
296	RGUI-34	DROI-2	TP_FUN_3	TC#7	
297	RGUI-34	DROI-2	TP_FUN_3	TC#9	HAZ-001(16)
298	RGUI-34	DQCP-18	TP_FUN_3	TC#5	
299	RGUI-34	DQCP-18	TP_FUN_3	TC#6	
300	RGUI-34	DQCP-18	TP_FUN_3	TC#7	
301	RGUI-34	DQCP-18	TP_FUN_3	TC#9	HAZ-001(16)
302	RGUI-35	DBPS-37	TP_FUN_3	TC#5	
303	RGUI-35	DBPS-37	TP_FUN_3	TC#6	
304	RGUI-35	DBPS-37	TP_FUN_3	TC#7	
305	RGUI-35	DBPS-37	TP_FUN_3	TC#9	
306	RGUI-35	DROI-3	TP_FUN_3	TC#5	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
307	RGUI-35	DROI-3	TP_FUN_3	TC#6	
308	RGUI-35	DROI-3	TP_FUN_3	TC#7	
309	RGUI-35	DROI-3	TP_FUN_3	TC#9	
310	RGUI-35	DQCP-19	TP_FUN_3	TC#5	
311	RGUI-35	DQCP-19	TP_FUN_3	TC#6	
312	RGUI-35	DQCP-19	TP_FUN_3	TC#7	
313	RGUI-35	DQCP-19	TP_FUN_3	TC#9	
314	RGUI-36	DVIS-1	TP_FUN_4	TC#6	
315	RGUI-37	DVIS-2	TP_FUN_4	TC#3	
316	RGUI-38	DVIS-3	TP_FUN_4	TC#7	
317	RGUI-39	DVIS-4	TP_FUN_4	TC#4	
318	RGUI-40	DVIS-5	TP_FUN_2	TC#12	
319	RGUI-40	DVIS-5	TP_FUN_2	TC#14	
320	RGUI-40	DVIS-5	TP_FUN_2	TC#25	
321	RGUI-40	DVIS-6	TP_FUN_4	TC#1	
322	RGUI-40	DVIS-6	TP_FUN_4	TC#2	
323	RGUI-40	DVIS-6	TP_FUN_4	TC#3	
324	RGUI-40	DVIS-6	TP_FUN_4	TC#4	
325	RGUI-41	DVIS-7	TP_FUN_2	TC#12	
326	RGUI-41	DVIS-7	TP_FUN_2	TC#14	
327	RGUI-41	DVIS-7	TP_FUN_2	TC#25	
328	RGUI-41	DVIS-8	TP_FUN_4	TC#1	
329	RGUI-41	DVIS-8	TP_FUN_4	TC#2	
330	RGUI-41	DVIS-8	TP_FUN_4	TC#3	
331	RGUI-41	DVIS-8	TP_FUN_4	TC#4	
332	RGUI-42	DROI-4	TP_FUN_2	TC#15	
333	RGUI-42	DROI-4	TP_FUN_3	TC#10	
334	RGUI-42	DROI-4	TP_FUN_3	TC#5	
335	RGUI-42	DROI-4	TP_FUN_3	TC#6	
336	RGUI-42	DROI-4	TP_FUN_3	TC#7	
337	RGUI-42	DROI-4	TP_FUN_3	TC#8	
338	RGUI-42	DROI-4	TP_FUN_3	TC#9	
339	RGUI-43	DROI-5	TP_FUN_3	TC#10	
340	RGUI-43	DROI-5	TP_FUN_3	TC#5	
341	RGUI-43	DROI-5	TP_FUN_3	TC#6	
342	RGUI-43	DROI-5	TP_FUN_3	TC#7	
343	RGUI-43	DROI-5	TP_FUN_3	TC#8	
344	RGUI-43	DROI-5	TP_FUN_3	TC#9	
345	RGUI-43	DROI-6	TP_FUN_3	TC#10	
346	RGUI-43	DROI-6	TP_FUN_3	TC#5	
347	RGUI-43	DROI-6	TP_FUN_3	TC#6	
348	RGUI-43	DROI-6	TP_FUN_3	TC#7	
349	RGUI-43	DROI-6	TP_FUN_3	TC#8	
350	RGUI-43	DROI-6	TP_FUN_3	TC#9	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
351	RGUI-44	DROI-7	TP_FUN_3	TC#7	
352	RGUI-44	DROI-8	TP_FUN_3	TC#7	
353	RGUI-45	DROI-9	TP_FUN_3	TC#8	HAZ-001(18)
354	RGUI-45	DROI-10	TP_FUN_3	TC#8	HAZ-001(18)
355	RGUI-46	DROI-11	TP_FUN_3	TC#5	
356	RGUI-46	DROI-12	TP_FUN_3	TC#6	
357	RGUI-46	DROI-13	TP_FUN_3	TC#7	
358	RGUI-47	DROI-14	TP_FUN_3	TC#7	
359	RGUI-47	DROI-14	TP_FUN_3	TC#9	
360	RGUI-48	DROI-15	TP_FUN_3	TC#4	
361	RGUI-48	DROI-15	TP_FUN_3	TC#5	
362	RGUI-48	DROI-15	TP_FUN_3	TC#6	
363	RGUI-48	DROI-15	TP_FUN_3	TC#7	
364	RGUI-48	DROI-15	TP_FUN_3	TC#9	
365	RGUI-49	DROI-16	TP_EXC_1	TC#8	HAZ-001(18)
366	RGUI-50	DROI-17	TP_FUN_3	TC#10	
367	RGUI-51	DROI-18	TP_FUN_3	TC#11	
368	RGUI-51	DROI-19	TP_FUN_3	TC#11	
369	RGUI-52	DROI-20	TP_FUN_3	TC#10	
370	RGUI-53	DROI-21	TP_FUN_3	TC#5	
371	RGUI-54	DRES-1	TP_FUN_4	TC#1	
372	RGUI-54	DBPS-38	TP_FUN_4	TC#1	
373	RGUI-55	DRES-2	TP_FUN_4	TC#1	
374	RGUI-56	DRES-3	TP_FUN_4	TC#1	
375	RGUI-56	DRES-3	TP_FUN_4	TC#3	
376	RGUI-56	DBPS-39	TP_FUN_4	TC#1	
377	RGUI-56	DBPS-39	TP_FUN_4	TC#3	
378	RGUI-57	DRES-4	TP_FUN_4	TC#4	
379	RGUI-57	DRES-4	TP_FUN_4	TC#5	
380	RGUI-57	DRES-4	TP_FUN_4	TC#6	
381	RGUI-57	DBPS-40	TP_FUN_4	TC#4	
382	RGUI-57	DBPS-40	TP_FUN_4	TC#5	
383	RGUI-57	DBPS-40	TP_FUN_4	TC#6	
384	RGUI-58	DRES-5	TP_FUN_4	TC#5	
385	RGUI-59	DRES-6	TP_FUN_4	TC#1	
386	RGUI-60	DRES-7	TP_FUN_5	TC#7	
387	RGUI-60	DRES-7	TP_FUN_5	TC#8	
388	RGUI-61	DRES-8	TP_FUN_2	TC#12	
389	RGUI-62	DRES-9	TP_FUN_2	TC#17	
390	RGUI-63	DRES-10	TP_FUN_2	TC#25	
391	RGUI-64	DRES-11	TP_FUN_2	TC#27	
392	RGUI-64	DBPS-41	TP_FUN_2	TC#27	
393	RGUI-65	DRES-12	TP_FUN_4	TC#8	
394	RGUI-65	DBPS-42	TP_FUN_4	TC#8	

No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
395	RGUI-66	DREP-10	TP_FUN_5	TC#3	
396	RGUI-67	DREP-11	TP_FUN_5	TC#3	
397	RGUI-68	DREP-12	TP_FUN_5	TC#1	
398	RGUI-68	DREP-12	TP_FUN_5	TC#2	
399	RGUI-69	DSET-1	TP_FUN_5	TC#2	
400	RGUI-70	DSET-2	TP_FUN_2	TC#1	
401	RGUI-70	DSET-2	TP_FUN_7	TC#1	
402	RGUI-71	DSET-3	TP_FUN_1	TC#1	
403	RGUI-71	DSET-3	TP_FUN_2	TC#1	
404	RGUI-72	DSET-4	TP_FUN_5	TC#2	
405	RGUI-72	DSET-4	TP_FUN_6	TC#2	
406	RGUI-72	DSET-5	TP_FUN_5	TC#2	
407	RGUI-72	DSET-5	TP_FUN_6	TC#2	
408	RGUI-72	DSET-6	TP_FUN_5	TC#2	
409	RGUI-72	DSET-6	TP_FUN_6	TC#2	
410	RGUI-72	DSET-7	TP_FUN_5	TC#2	
411	RGUI-72	DSET-7	TP_FUN_6	TC#2	
412	RGUI-73	DSET-8	TP_FUN_5	TC#2	
413	RGUI-73	DSET-8	TP_FUN_6	TC#2	
414	RGUI-74	DREA-3	TP_FUN_1	TC#7	
415	RGUI-74	DREA-4	TP_FUN_2	TC#8	
416	RGUI-75	DHLP-1	TP_FUN_6	TC#6	
417	RGUI-76	DHLP-2	TP_FUN_6	TC#6	
418	RGUI-77	DHLP-3	TP_FUN_6	TC#6	
419	RGUI-78	DHLP-4	TP_FUN_6	TC#6	
420	RGUI-79	DSYS-1	TP_FUN_6	TC#3	
421	RGUI-79	DSYS-2	TP_FUN_6	TC#4	
422	RGUI-80	DHLP-6	TP_FUN_6	TC#5	
423	RHW-02	DBLD-2	TP_Build_1	TC#1	
424	RHW-02	DBLD-3	TP_Build_1	TC#1	
425	RHW-1	DBLD-4	TP_Build_1	TC#1	
426	RHW-1	DBLD-5	TP_Build_1	TC#1	
427	RHW-3	DBLD-1	TP_Build_1	TC#1	
428	RINS-01	DINS-04	TP_INS_1	TC#1	
429	RINS-01	DINS-08	TP_INS_1	TC#1	
430	RINS-02	DINS-10	TP_INS_1	TC#1	
431	RINS-03	DINS-09	TP_INS_1	TC#1	
432	RINS-04	DINS-01	TP_INS_1	TC#1	
433	RINS-05	DINS-05	TP_INS_1	TC#1	
434	RINS-06	DINS-07	TP_INS_1	TC#1	
435	RINS-07	DINS-11	TP_INS_1	TC#1	
436	RINS-08	DINS-05	TP_INS_1	TC#1	HAZ-001(3)
437	RINS-09	DINS-03	TP_INS_2	TC#1	
438	RINS-09	DINS-06	TP_INS_1	TC#1	

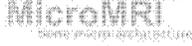
No.	Requirement Number	Design Number	Test Procedure	Test Case	Hazard Analysis
439	RINS-09	DINS-06	TP_INS_2	TC#1	
440	RINS-10	DINS-12	TP_INS_2	TC#1	
441	ROS-1	DBLD-6	TP_Build_1	TC#1	
442	ROS-1	DBLD-7	TP_Build_1	TC#1	
443	RPER-01	DSYS-1	TP_PER_1	TC#1	
444	RPER-01	DSYS-1	TP_PER_1	TC#2	
445	RPER-01	DSYS-1	TP_PER_1	TC#3	
446	RPER-01	DSYS-2	TP_PER_1	TC#1	
447	RPER-01	DSYS-2	TP_PER_1	TC#2	
448	RPER-01	DSYS-2	TP_PER_1	TC#3	
449	RPER-01	DSYS-3	TP_PER_1	TC#1	
450	RPER-01	DSYS-3	TP_PER_1	TC#2	
451	RPER-01	DSYS-3	TP_PER_1	TC#3	

*SIGNATURE	NAME	DATE
Director of Software Engineering		
Director of QA/MRA		

* Signatory meaning is described in SOP OP-008 Management Role and Delegation of Responsibilities

December 11, 2008

ATTACHMENT 7

	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 1 of 35
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TEST PROCEDURES
Test Type: Functional Tests (System-Level)

System Name: BoneVue
Version Number: 1.0

December 3, 2008

Internal Document
EN-001-F03.01

MicroMRI
bone micro-architecture

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 2 of 35</p>
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REVISION HISTORY

Version	Release Date	Responsible Party	Major Changes
000.01	12/01/2008	Bob Sohval	Initial release of test cases.
000.02	12/02/2008	Fiona Sng	Converted to current template and added common procedure steps.
000.03	12/03/2008	Allon Shahar	Added introductory text, plan and traceability sections. Also expanded test procedures.

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 <small>bone micro-architecture</small>	<p align="center">BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p align="right">12/03/2008 Page 3 of 35</p>
---	---	--

TABLE OF CONTENTS

1	Introduction.....	4
1.1	Definitions/Acronyms/ Abbreviations.....	4
1.2	References.....	4
1.3	Purpose.....	4
1.4	Scope.....	5
2	Test Scripts and Data.....	5
3	Traceability Matrix.....	5
4	Test Procedures.....	8
	BoneVue.sav: TP_FUN_1.....	10
	BoneVue.sav: TP_FUN_2.....	13
	BoneVue.sav: TP_FUN_3.....	19
	BoneVue.sav: TP_FUN_5.....	25
	BoneVue.sav: TP_FUN_6.....	28
	BoneVue.sav: TP_FUN_7.....	30
	BoneVue.sav: TP_FUN_8.....	33
5	Signatures.....	35

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 4 of 35
---	--	----------------------------

1 Introduction

BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MR datasets of bone, facilitating 3D visualization of bone micro-architecture and the measurement of descriptive parameters of cortical and trabecular bone morphology. While *BoneVue* can process data from a variety of commercially available pulse sequences, it will typically be used to process datasets acquired with two pulse sequences: one for volumetric imaging of cortical bone and another for volumetric imaging of trabecular bone. *BoneVue* will allow the user to load the image data (DICOM[®] format [1.4]) from the cortical scan and the raw (k-space) data (or image data in DICOM format) from the trabecular scan, and will process it using its core subsystem, the Bone Processing Software (BPS) application. In addition to visualizing the bone, *BoneVue* will produce a report that includes the measured parameters and representative images. This report may be printed or stored for later review.

1.1 Definitions/Acronyms/ Abbreviations

SRS — Software Requirements Specifications
SDS — Software Design Specifications
TC — Test Case
TP — Test Plan

1.2 References

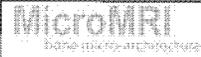
1. BV-SDS-001.000, "BoneVue v1.0 Software Design Specifications for the User Application"
2. BV-SRS-001.000, "BoneVue v1.0 System Requirements Specification"
3. BP-VVP-001.000, "BPS v1.0 Verification and Validation Plan"
4. QSP-002, "Management Role and Delegation of Responsibilities"
5. Digital Imaging and Communications in Medicine (DICOM), ACR-NEMA PS 3-2008, <http://medical.nema.org/medical/dicom/2008/>.

1.3 Purpose

The purpose of this document is to formally record the functional testing effort. It lists the requirement specifications that are being tested, and provides test procedures in the format of forms. The template for the forms allows the tester to capture the results of the tests, defects discovered, and the defect number generated from the defect tracking software, if applicable.

[®] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

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 bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 5 of 35
--	---	--

1.4 Scope

The current document covers the functionality BoneVue 1.0 User Application (*BoneVue.sav* IDL executable), including all its screens and menus as well as the report generator (see [1]). All sub-systems, components, modules and third party tools (if applicable) were tested as part of the unit-level verification and integration testing. Furthermore, non-functional requirements of the User Application, including the installer, are tested separately.

2 Test Scripts and Data

The testing in question is done at the system level. The actual user application, provided as an IDL executable file (*BoneVue.sav*), will be operated explicitly by the tester and therefore there is no need for external test scripts. For its operation the application requires the IDL Virtual Machine (version 7.0), which will be installed on the test platform. The test platform will also be loaded with all the BoneVue configuration files, templates, and sub-system C executables that are required for the application's operation (see [1]).

Typical test data, including cortical DICOM series and trabecular raw data (see also [2]), are used as input to the tests. In addition, outlier data is also used to test the exception handling of the user application (see the appropriate test procedure below).

3 Traceability Matrix

The Test Procedures that are covered by the current document and their correspondence to system and software requirement specifications (see also [2]) are listed in the table below.

SRS #	TP #
RGUI-01	TP_FUN_1: TC#3; TP_FUN_2: TC#3
RGUI-02	TP_FUN_1: TC#5; TP_FUN_2: TC#5
RGUI-03	TP_FUN_1: TC#5; TP_FUN_2: TC#5
RGUI-04	TP_FUN_1: TC#2, TC#4; TP_FUN_2: TC#2, TC#4; , TP_FUN_7: TC#2, TC#4
RGUI-05	TP_FUN_1: TC#2, TC#4; TP_FUN_2: TC#2, TC#4; , TP_FUN_7: TC#2, TC#4
RGUI-06	TP_FUN_1: TC#2, TC#4; TP_FUN_2: TC#2, TC#4; , TP_FUN_7: TC#2, TC#4
RGUI-07	TP_FUN_1: TC#3, TC#5; TP_FUN_2: TC#3, TC#5; TP_FUN_7: TC#3, TC#5
RGUI-08	TP_FUN_1: TC#3, TC#5; TP_FUN_2: TC#3, TC#5; TP_FUN_7: TC#3, TC#5
RGUI-09	TP_FUN_2: TC#12; TP_FUN_3: TC#2; TP_FUN_7: TC#3
RGUI-10	TP_FUN_1: TC#7; TP_FUN_2: TC#8

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	<p align="center">BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p align="right">12/03/2008 Page 6 of 35</p>
---	---	--

RGUI-11	TP_FUN_2: TC#8
RGUI-12	TP_FUN_1: TC#1 & TC#12 TP_FUN_2: TC#1 & TC#12, TC#19, TC#20, TC#21, TC#22, TC#23, TC#25, TC#26; TP_FUN_7: TC#1, TC#6, TC#8
RGUI-13	TP_FUN_1: TC#1, TC#12; TP_FUN_2: TC#1, TC#12, TC#23, TC#25, TC#26 TP_FUN_7: TC#1, TC#6
RGUI-14	TP_FUN_7: TC#8
RGUI-15	TP_EXE_1: TC#1
RGUI-16	TP_EXE_1: TC#2
RGUI-17	TP_EXE_1: TC#3
RGUI-18	TP_EXE_1: TC#4
RGUI-19	TP_FUN_7: TC#8
RGUI-20	TP_EXE_1: TC#5
RGUI-21	TP_EXE_1: TC#6
RGUI-22	TP_EXE_1: TC#7
RGUI-23	TP_FUN_1: TC#3; TP_FUN_7: TC#3
RGUI-24	TP_FUN_1: TC#12; TC#23,; TP_FUN_7 TC#6
RGUI-25	TP_FUN_2: TC#12
RGUI-26	TP_FUN_2: TC#20
RGUI-27	TP_FUN_7: TC#8; TP_FUN_2: TC#20, TC#21
RGUI-28	TP_FUN_4: TC#2, TC#3, TC#4; TP_FUN_5: TC#2
RGUI-29	TP_FUN_4: TC#8
RGUI-30	TP_FUN_2: TC#25
RGUI-31	TP_FUN_7: TC#8
RGUI-32	TP_FUN_2: TC#12, TC#13, TC#14, TC#25
RGUI-33	TP_FUN_2: TC#26
RGUI-34	TP_FUN_3: TC#5, TC#6, TC#7, TC#9
RGUI-35	TP_FUN_3: TC#5, TC#6, TC#7, TC#9
RGUI-36	TP_FUN_4: TC#6
RGUI-37	TP_FUN_4: TC#3
RGUI-38	TP_FUN_4: TC#7
RGUI-39	TP_FUN_4: TC#4
RGUI-40	TP_FUN_4: TC#1, TC#2, TC#3, TC#4 TP_FUN_2: TC#12, TC#14, TC#25
RGUI-41	TP_FUN_4: TC#1, TC#2, TC#3, TC#4; TP_FUN_2: TC#12, TC#14, TC#25
RGUI-42	TP_FUN_2: TC#15; TP_FUN_3: TC#5, TC#6, TC#7, TC#8, TC#9, TC#10.

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 bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 7 of 35
--	---	--

RGUI-43	TP_FUN_3: TC#5, TC#6, TC#7, TC#8, TC#9, TC#10
RGUI-44	TP_FUN_3: TC#7
RGUI-45	TP_FUN_3: TC#8
RGUI-46	TP_FUN_3: TC#5, TC#7, TC#6
RGUI-47	TP_FUN_3: TC#7, TC#9
RGUI-48	TP_FUN_3: TC#4, TC#5, TC#6, TC#7, TC#9
RGUI-49	TP_EXE_1: TC#8
RGUI-50	TP_FUN_3: TC#10
RGUI-51	TP_FUN_3: TC#11
RGUI-52	TP_FUN_3: TC#10
RGUI-53	TP_FUN_3: TC#5
RGUI-54	TP_FUN_4: TC#1
RGUI-55	TP_FUN_4: TC#1
RGUI-56	TP_FUN_4: TC#1, TC#3
RGUI-57	TP_FUN_4: TC#2, TC#4, TC#6
RGUI-58	TP_FUN_4: TC#5
RGUI-59	TP_FUN_4: TC#1
RGUI-60	TP_FUN_5: TC#7, TC#8
RGUI-61	TP_FUN_2: TC#12
RGUI-62	TP_FUN_2: TC#17
RGUI-63	TP_FUN_2: TC#25
RGUI-64	TP_FUN_2: TC#27
RGUI-65	TP_FUN_4: TC#8
RGUI-66	TP_FUN_5: TC#3
RGUI-67	TP_FUN_5: TC#3
RGUI-68	TP_FUN_5: TC#1, TC#2
RGUI-69	TP_FUN_5: TC#2
RGUI-70	TP_FUN_7: TC#1; TP_FUN_2: TC#1
RGUI-71	TP_FUN_1: TC#1; TP_FUN_2: TC#1
RGUI-72	TP_FUN_6: TC#2; TP_FUN_5: TC#2
RGUI-73	TP_FUN_6: TC#2; TP_FUN_5: TC#2
RGUI-74	TP_FUN_1: TC#1; TP_FUN_2: TC#8
RGUI-75	TP_FUN_6: TC#6
RGUI-76	TP_FUN_6: TC#6
RGUI-77	TP_FUN_6: TC#6
RGUI-78	TP_FUN_6: TC#6
RGUI-79	TP_FUN_6: TC#3, TC#4
RGUI-80	TP_FUN_6: TC#5
RFUN-01	TP_EXE_1: TC#9
RFUN-02	TP_FUN_2: TC#12, TC#18, TC#20; TP_FUN_1: TC#12, TP_FUN_3: TC#11; TP_FUN_7: TC#8; TP_FUN_5: TC#4

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 <small>Bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 8 of 35
---	--	----------------------------

RFUN-03	TP_FUN_1: TC#1; TP_FUN_2: TC#1
RFUN-04	TP_FUN_4: TC#1; TP_FUN_5: TC#1
RFUN-05	TP_EXE_1: TC#10
RFUN-06	TP_EXE_1: TC#11
RFUN-07	TP_EXE_1: TC#12
RFUN-08	TP_FUN_4: TC#1; TP_FUN_5: TC#1
RFUN-09	TP_FUN_2: TC#14
RFUN-10	TP_FUN_3: TC#23, TC# 25, TC#26, TC#27
RFUN-11	TP_FUN_4: TC#9; TP_FUN_5: TC#4; TP_FUN_7: TC#8; TP_FUN_2: TC#18
RFUN-12	TP_FUN_5: TC#1
RFUN-13	TP_FUN_4: TC#9
RFUN-14	TP_FUN_5: TC#3
RFUN-15	TP_FUN_5: TC#2
RFUN-16	TP_FUN_5: TC#2, TC#3
RFUN-17	TP_FUN_5: TC#2, TC#3
RFUN-18	TP_FUN_5: TC#2
RFUN-19	TP_FUN_5: TC#2
RFUN-20	TP_FUN_5: TC#2
RFUN-21	TP_FUN_5: TC#2
RFUN-22	TP_FUN_5: TC#2
RFUN-23	TP_FUN_5: TC#2
RFUN-24	TP_FUN_5: TC#2
RFUN-25	TP_FUN_5: TC#2
RFUN-26	TP_FUN_6: TC#4
RFUN-27	TP_FUN_6: TC#4

4 Test Procedures

Each test procedure and associated test cases are described in the forms below. The tester will fill out her/his name, test platform (labels given in [3]), date and time of execution, and the code's revision number (as given by the version control system or the responsible software engineer) in the appropriate fields on the form.

The Observed Outcome column for each line of the test case will be filled out, capturing what occurred as a result of processing the dataset and/or taking the action specified in the Input/Action column. If the observed outcome corresponds to the description in the Expected Outcome column, *Pass* will be written in the Pass/Fail column. Otherwise, *Fail* will be recorded there. At the end of executing the test procedure the tester will determine whether, overall, the test procedure *Passed* or *Failed* and check the appropriate box in the Overall Results section. If the current test procedure is not (or could not be) executed, but is part of a packet, which includes executed files, the *Not Executed* box will be checked.

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-YTP-003.000 Internal Document	12/03/2008 Page 9 of 35
---	---	--

In the Test Incident Log/Defect ID#'s/Comments text box the tester may write any information that pertains to what occurred while executing the test procedure. In a case of non-execution, the tester will utilize the text box to explain the relevant circumstances. If the tester has nothing to notate, a "No Comments" or "None" remark will be written in the text box. The tester will sign and date at the end of the test procedure. All attached screenshots and printouts (where applicable), carefully labeled to indicate to which test procedure they correspond and their pages numbered (Page X of Y), should be signed and dated by the tester as well.

Unless noted otherwise, all test data is in the following location on the company's file server: \\MMRIMail\Storage\SOFTWARE\TEST_DATA.

At the end of test execution, all the result folders, including any screenshots, log files, etc., should be copied to the following location:

\\MMRIMail\Storage\SOFTWARE\BoneVue\BV 1.0 Validation Results\UI.

Note that the project's Verification and Validation Plan [3] may specify different/additional locations.

The reviewer will verify that all the parts of the test procedure form are filled out appropriately and that the relevant evidence has been attached and stored as required. The reviewer will sign and date at the end of the test procedure.

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 bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 10 of 35
--	--	-----------------------------

BoneVue.sav: TP_FUN_1

Description: Test the automatic mode of BoneVue.
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: FIONA SNG	Test Location/Equipment: Test Platform <u>1</u> (see 3)
---	---

Procedure
<ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue.

Preconditions: None.

Date & Time of execution: 12/11/08 11:21am **Revision:** 185

Test Case	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail
1.	Execute procedure steps 1 through 9. When in BoneVue, click on 'Tools' then go to 'Automatic Mode'.	(b)(4)		
2.	In Input area, click the 'Browse' button, next to 'Cortical'.			

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 11 of 35</p>
---	---	-------------------------------------

3.	In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series".	(b)(4)
4.	In Input area, click the 'Browse' button, next to 'Trabecular'.	
5.	In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder.	
6.	In processing box, click on Reader button.	
7.	Click on New . In text box, type: "Mark Clemente MD". Click OK .	
8.	Close the window.	
9.	Under Localizer window, click on Browse .	
10.	In browser window, click on folder labeled "C:\MMRI_Input\Localizer". Select subfolder labeled "Localizer_test_series".	
11.	Click the spinner control in the Localizer window.	

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 12 of 35
---	--	-----------------------------

12.	Click Start.	(b)(4)
13.	Click File → Exit	

Overall Results:
 Passed Failed Not Executed (explain below)

Test Incident Log/Defect ID#'s/Comments:
None



 Test Engineer Signature

12/10/08

 Date

A. Shelton

 Reviewer Signature

12/11/2008

 Date

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 13 of 35
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BoneVue.sav: TP_FUN_2

Description: Test the manual mode of BoneVue
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: FIONA SNGI	Test Location/Equipment: Test Platform <i>CL</i> (see 3)
Procedure	
<ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 	

Preconditions: A list of readers are created in the "Readers" section of BoneVue, including one that is "Mark Clemente MD".

Date & Time of execution: *2/11/08 / p.m.* **Revision:** *1/5*

Test Case	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail
1.	Execute procedure steps 1 through 9. On menu bar, click on Tools→Manual QC Mode.	(b)(4)		
2.	In Input area, click Browse button next to Cortical.			

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 14 of 35
---	---	---

3.	In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series".	Browser popup closes. Following text string displayed in cortical area: "C:\MMRI_Input\Cortical\Cortical_test_series". Patient demographic data is displayed in table in processing area. Start button is enabled.	(b)(4)
4.	In Input area, click Browse button next to Trabecular .	Explorer-style browser window pops up with directory tree, with focus on C:\MMRI_Input folder.	
5.	In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder.	Browser popup closes. Following text string displayed in trabecular area: "C:\MMRI_Input\Trabecular\Trabecular_test_series\P18432.7"	
6.	In Input area, click Browse button next to Cortical	Explorer-style browser window pops up with directory tree, with focus on C:\MMRI_Input folder.	
7.	In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series".	Browser popup closes. Following text string displayed in cortical area: "C:\MMRI_Input\Cortical\Cortical_test_series"	
8.	In processing box, click on Reader combo box and select "Mark Clemente MD".	Drop down list displays list of readers. Upon selecting "Mark Clemente MD", that name appears in one-line combo box.	
9.	Under Localizer window, click on Browse .	Explorer-style browser window pops up with directory tree, with focus on C:\MMRI_Input folder.	
10.	In browser window, click on folder labeled "C:\MMRI_Input\Localizer". Select subfolder labeled "Localizer_test_series".	Localizer image is displayed in Localizer window.	
11.	Click the spinner control in the Localizer window.	Next Localizer image in file folder is displayed. After last image is displayed, the next click displays the first image.	

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 MicroMRI bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 15 of 35
--	---	-----------------------------

12.	Click Start .	The Cortical Segmentation screen is displayed. In the Processing Status box, the text "Cortical Segmentation" is highlighted. Below the Processing Status box, a table with patient demographic data is displayed. Below the table, the following command buttons are displayed: Accept, Reject, Cancel, ROI, Default, Add, Remove, Undo, Replicate, Revert . In addition, the following radio buttons are displayed: x1, x2, x4, Polygon, Ellipse, Box . On the right side of the screen, an axial slice is displayed with a spinner control and a pair of slider controls for window level and width. A white ROI contour is displayed just inside the trabecular/marrow boundary.	(b)(4)
13.	Click the spinner control several times.	The displayed image steps through the stack of images in the series. The slice number is displayed. On each slice, the ROI boundary is displayed.	
14.	Adjust the window slider controls.	The window level and width numerical values displayed above the sliders are updated and the image window level and width change, accordingly.	
15.	Click the Default button.	The contour boundary reverts to its original state and the window level and width also revert to their original state.	
16.	Click the x2, x4 and x1 radio buttons in the Zoom box.	The image is zoomed the corresponding amount. In the case of x2 and x4, horizontal and vertical scroll bars are displayed next to the image. Adjusting the scroll bars causes the image to pan horizontally and vertically.	
17.	Click the ROI button several times.	The white cortical boundary toggles on and off.	
18.	Click the Cancel button.	The Cortical Segmentation screen disappears and the original BoneVue Processing screen is displayed.	

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	<p align="center">BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p align="right">12/03/2008 Page 16 of 35</p>
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19.	Click the Start button.	After a short delay for processing, the Cortical Segmentation screen is again displayed.
20.	Click the Reject button.	Processing of the cortical data is suspended and processing of the trabecular data is begun. After a delay for processing, the Motion Correction screen is displayed.
21.	Click the Reject button.	System returns to the BoneVue Processing screen, still in Manual QC Mode.
22.	Click the Start button.	After a short delay for processing, the Cortical Segmentation screen is again displayed.
23.	Click the Accept button.	The Cortical Boundaries screen is displayed. In the Processing Status box, the text Cortical Boundaries is highlighted. A red contour is displayed along the inner cortical boundary. A green contour is displayed along the outer cortical boundary.
24.	Click the Add button. Click the Polygon radio button. Left click the mouse to draw a polygon around a small cluster of green points along the outer cortical boundary.	The cluster of green points is circumscribed by the polygon ROI. After a brief delay, the circumscribed green points are removed are no longer displayed.

(b)(4)

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 <small>Bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 17 of 35
---	---	---

25.	Click the Accept button.	After a processing delay, the Motion Correction screen is displayed. In the Processing Status box, the text "Motion Correction" is highlighted. The table with patient demographics is displayed. Two images of the trabecular bone are displayed side-by-side, with a spinner button and window level and width slider controls. The left image is labeled, "Before Motion Correction" and the right image is labeled, "After Motion Correction". A graph of motion during the scan is displayed in the upper-right quadrant. A table reporting motion parameters, including maximum displacement and root mean square displacement in the x and y directions is displayed in the upper left quadrant.	(b)(4)
26.	Click the Accept button.	The Trabecular ROI Masking screen is displayed. In the Processing Status box, the text, "Trabecular ROI Masking" is displayed. A trabecular image is displayed with a white contour defining the trabecular boundary.	
27.	Click the Accept button.	The Results screen is displayed.	
28.	Click File → Exit	<i>BoneVue</i> closes.	
Overall Results: <input checked="" type="checkbox"/> Passed <input type="checkbox"/> Failed <input type="checkbox"/> Not Executed <i>(explain below)</i>			

Test Incident Log/Defect ID#s/Comments:

None.



 Test Engineer Signature

12/11/08

 Date

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December 11, 2008

MicroMRI bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 18 of 35
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A. Shaheen
Reviewer Signature

12/11/2008
Date

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 19 of 35</p>
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BoneVue.sav: TP_FUN_3

<p>Description: Test the ROI Tools of BoneVue</p>
<p>Associated Requirements: Refer to Section 3 of this document.</p>
<p>Test Environment Needs: The IDE Virtual Machine should be installed on the test system.</p>

<p>Test Engineer Name:</p>	<p>Test Location/Equipment: Test Platform (see 3)</p>								
<p style="text-align: center;">Procedure</p> <ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 10. On menu bar, click on Tools→Manual QC Mode. 									
<p>Preconditions:</p>									
<p>Date & Time of execution:</p>									
<p>Revision:</p>									
<p>Test Case</p>	<table border="1"> <thead> <tr> <th data-bbox="451 1444 829 1589">Input/Action</th> <th data-bbox="829 1444 1096 1589">Expected Outcome</th> <th data-bbox="1096 1444 1279 1589">Observed Outcome</th> <th data-bbox="1279 1444 1351 1589">Pass/Fail</th> </tr> </thead> <tbody> <tr> <td data-bbox="451 1589 829 1589">1. Execute procedure steps 1 through 10. In Input area, click Browse button next to Cortical.</td> <td data-bbox="829 1589 1096 1589">(b)(4)</td> <td data-bbox="1096 1589 1279 1589"></td> <td data-bbox="1279 1589 1351 1589"></td> </tr> </tbody> </table>	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail	1. Execute procedure steps 1 through 10. In Input area, click Browse button next to Cortical .	(b)(4)		
Input/Action	Expected Outcome	Observed Outcome	Pass/Fail						
1. Execute procedure steps 1 through 10. In Input area, click Browse button next to Cortical .	(b)(4)								

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 20 of 35
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2.	In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series".	Browser popup closes. Following text string displayed in cortical area: "C:\MMRI_Input\Cortical\Cortical_test_series". Patient demographic data is displayed in table in processing area. Start button is enabled.
3.	Click Start .	The Cortical Segmentation screen is displayed.
4.	Click Accept .	The Cortical Boundaries screen is displayed.
5.	In the ROI Tools box, click the Ellipse radio button and then click Add . Place the mouse cursor over the image. Left-click the mouse and drag the cursor.	An elliptical ROI is displayed on the image with size and position determined by the mouse.
6.	In the ROI Tools box, click Undo and then click the Box radio button and then click Add . Place the mouse cursor over the image. Left-click the mouse and drag the cursor.	The elliptical ROI disappears. A square ROI is displayed on the image with size and position determined by the mouse.
7.	In the ROI Tools box, click Undo and then click the Polygon radio button and then click Add . Place the mouse cursor over the image, near the displayed contour. Make a series of left mouse clicks while dragging the cursor to new locations, circumscribing a section of the displayed contour line. Right click to close the contour.	The box-shaped ROI disappears. A polygon-shaped ROI is displayed circumscribing part of the original contour line. Upon right clicking the mouse, the polygon contour is closed and the segment of the original contour inside the polygonal ROI is replaced by the section of the polygonal ROI that lies outside the original contour.
8.	Click the Revert button.	The contour boundary reverts to its initial state.

(b)(4)

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 21 of 35
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9.	In the ROI Tools box, click the Polygon radio button and then click Remove . Place the mouse cursor over the image, near the displayed contour. Make a series of left mouse clicks while dragging the cursor to new locations, circumscribing a section of the displayed contour line. Right click to close the contour.	(b)(4)
10.	Click the Replicate button.	
11.	Click the Cancel button.	
12.	Click File → Exit	

Overall Results:
 Passed
 Failed
 Not Executed *(explain below)*

Test Incident Log/Defect ID#'s/Comments:

Name



 Test Engineer Signature

12/11/08

 Date

A. Shaker

 Reviewer Signature

12/11/2008

 Date

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 22 of 35
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BoneVue.sav: TP_FUN_4

Description: Test the results screen of BoneVue
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: <i>Fiona RUGT</i>	Test Location/Equipment: Test Platform <u>1</u> (see 3)			
<p style="text-align: center;">Procedure</p> <ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 10. In Input area, click the 'Browse' button, next to 'Cortical'. 11. In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series". 12. In Input area, click the 'Browse' button, next to 'Trabecular'. 13. In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder. 14. In browser window, click on folder labeled "C:\MMRI_Input\Localizer". Select subfolder labeled "Localizer_test_series". 15. On menu bar, click on Tools→Automatic Mode 16. Click Start in the processing window. 				
Preconditions: 1. Execute TP_FUN_1 2. Empty the reports folder.				
Date & Time of execution: <i>12/11/08 4 pm</i>				
Revision: <i>185</i>				
Test Case	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 23 of 35</p>
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1.	Execute procedure steps 1 through 16. Examine BoneVue Results Screen.	(b)(4)
2.	Left-click mouse on Localizer image. Manipulate the window level and width sliders. Click the spinner button.	
3.	Left-click mouse on 3D image. Manipulate the window level and width sliders. Manipulate the Tilt and Rotate sliders.	
4.	Left-click mouse on trabecular image. Manipulate the window level and width sliders. Click the spinner button.	
5.	Click the ROI button several times.	
6.	Click x2 and then x4 on the zoom box.	
7.	Click the Default button.	

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 24 of 35
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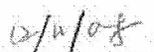
8.	On the menu bar, click View	The item "Quality Measures" is displayed in the list.	(b)(4)
9.	Click the Cancel button.	A dialog box pops up indicating that no report has been saved, and giving the user the option to create a report or close.	
10.	Click the Close button.	Application closes Results screen and returns to BoneVue Processing screen.	
11.	On the menu bar, click on Tools → Automatic Mode .	"BoneVue Mode: Automatic" is displayed on status bar.	
12.	Click the Start button.	After a processing delay, the Results screen closes.	
13.	Click File → Exit twice.	<i>BoneVue</i> closes.	

Overall Results:
 Passed
 Failed
 Not Executed (explain below)

Test Incident Log/Defect ID#’s/Comments:
 None



 Test Engineer Signature



 Date



 Reviewer Signature



 Date

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 25 of 35</p>
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BoneVue.sav: TP_FUN_5

<p>Description: Test the Report Generator of BoneVue</p>
<p>Associated Requirements: Refer to Section 3 of this document.</p>
<p>Test Environment Needs: The IDL Virtual Machine should be installed on the test system.</p>

<p>Test Engineer Name: <i>Fiona Sney</i></p>	<p>Test Location/Equipment: Test Platform <i>CI</i> (see 3)</p>			
<p style="text-align: center;">Procedure</p> <ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 10. In Input area, click the 'Browse' button, next to 'Cortical'. 11. In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series". 12. In Input area, click the 'Browse' button, next to 'Trabecular'. 13. In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder. 14. On menu bar, click on Tools→Automatic Mode 15. Click Start in the processing window. 				
<p>Preconditions: <i>None</i></p>				
<p>Date & Time of execution: <i>12/11/08 4:15pm</i></p>	<p>Revision: <i>185</i></p>			
<p>Test Case</p>	<p>Input/Action</p>	<p>Expected Outcome</p>	<p>Observed Outcome</p>	<p>Pass/Fail</p>

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	<p>BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document</p>	<p>12/03/2008 Page 26 of 35</p>
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1.	Execute procedure steps 1 through 15. Click the Report button.	(b)(4)
2.	Click the Print button.	
3.	Click on the Report button.	
4.	Click the Cancel button.	
5.	Click the Close button.	
6.	Click the Start button. Click File → Exit	
7.	Click File → Open Report .	
8.	Select the PDF file in the reports folder and click OK .	
9.	Click File → Print .	
10.	Click Cancel and then File → Close .	
11.	Click File → Exit .	
<p>Overall Results: <input checked="" type="checkbox"/> Passed <input type="checkbox"/> Failed <input type="checkbox"/> Not Executed <i>(explain below)</i></p>		

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December 11, 2008

	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 27 of 35
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Test Incident Log/Defect ID#s/Comments:

None



Test Engineer Signature

12/11/08

Date

A. Shalun

Reviewer Signature

12/11/2008

Date

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 28 of 35
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BoneVue.sav: TP_FUN_6

Description: Test the Menu Bar of BoneVue
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: FIONA SWEG	Test Location/Equipment: Test Platform <u>CI</u> (see 3)								
<p style="text-align: center;">Procedure</p> <ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\Normal\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 10. In Input area, click the 'Browse' button, next to 'Cortical'. 11. In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series". 12. In Input area, click the 'Browse' button, next to 'Trabecular' 13. In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series". 14. In browser window, click on folder labeled "C:\MMRI_Input\Localizer". Select subfolder labeled "Localizer_test_series". 									
Preconditions: None.									
Date & Time of execution: 12/11/08, 11:08 am									
Revision: 185									
Test Case	<table border="1"> <thead> <tr> <th data-bbox="451 1623 735 1648">Input/Action</th> <th data-bbox="735 1623 1101 1648">Expected Outcome</th> <th data-bbox="1101 1623 1263 1648">Observed Outcome</th> <th data-bbox="1263 1623 1347 1648">Pass/Fail</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail				
Input/Action	Expected Outcome	Observed Outcome	Pass/Fail						

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 29 of 35
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1.	Execute procedure steps 1 through 14. On the menu bar, click File .	(b)(4)
2.	On the menu bar, click Tools→Settings .	
3.	On the menu bar, click Tools→Log File→Session Log .	
4.	On the menu bar, click Tools→Log File→Master Log .	
5.	On the menu bar, click Help → User Manual .	
6.	On the menu bar, click Help → About .	
7.	Click File → Exit	

Overall Results:
 Passed
 Failed
 Not Executed *(explain below)*

Test Incident Log/Defect ID#’s/Comments:
 None



 Test Engineer Signature

12/14/08

 Date

A. Shukla

 Reviewer Signature

12/11/2008

 Date

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	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 30 of 35
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BoneVue.sav: TP_FUN_7

Description: Test the Exception Handling of BoneVue (Excessive Motion)
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: 1. The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: <i>PIONA SINGH</i>	Test Location/Equipment: Test Platform <u>CL</u> (see 3)			
Procedure				
<ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folders C:\MMRI_Input\Cortical\Cortical_test_series, C:\MMRI_Input\Trabecular\Trabecular_test_series and C:\MMRI_Input\Localizer\Localizer_test_series. 3. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\ExcessiveMotion\cortical to C:\MMRI_Input\Cortical\Cortical_test_series. 4. Copy the files from W:\SOFTWARE\TEST_DATA\BONEVUE\ExcessiveMotion\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 5. Copy the file from W:\SOFTWARE\TEST_DATA\BONEVUE\ExcessiveMotion\localizers to C:\MMRI_Input\Localizer\Localizer_test_series. 6. Click Start in Windows. 7. Select All Programs. 8. Select MicroMRI. 9. Select BoneVue. 				
Preconditions: <i>None -</i>				
Date & Time of execution: <i>12/11/08 12 pm.</i>		Revision: <i>1.5.</i>		
Test Case	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail
1.	Execute procedure steps 1 through 9. On menu bar, click on Tools → Automatic Mode .	(b)(4)		
2.	In Input area, click Browse button next to Trabecular .			

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 31 of 35
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3.	In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder.	(b)(4)
4.	In Input area, click Browse button next to Cortical	
5.	In browser window, click on folder labeled "C:\MMRI_Input\Cortical". Select subfolder labeled "Cortical_test_series".	
6.	In processing box, click on Reader combo box and select "Mark Clemente MD".	
7.	Under Localizer window, click on Browse .	
8.	In browser window, click on folder labeled "C:\MMRI_Input\Localizer". Select subfolder labeled "Localizer_test_series".	
9.	Click Start .	
10.	Click OK .	
11.	On Results Screen, click Cancel .	
12.	Click File → Exit	

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December 11, 2008

	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 32 of 35
---	--	-----------------------------

Overall Results:
 Passed Failed Not Executed (explain below)

Test Incident Log/Defect ID#'s/Comments:
None



Test Engineer Signature

12/11/08

Date

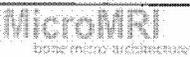
A. Shehar

Reviewer Signature

12/11/2008

Date

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 bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 33 of 35
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BoneVue.sav: TP_FUN_8

Description: Test the Exception Handling of BoneVue (Low SNR)
Associated Requirements: Refer to Section 3 of this document.
Test Environment Needs: 1. The IDL Virtual Machine should be installed on the test system.

Test Engineer Name: Fiona SNG	Test Location/Equipment: Test Platform (see 3)			
Procedure				
<ol style="list-style-type: none"> 1. Create the test folder C:\MMRI_Input. 2. Create the sub-folder C:\MMRI_Input\Trabecular\Trabecular_test_series. 3. Copy the file from W:\SOFTWARE\TEST_DATA\BONEVUE\LowSNR\trabecular to C:\MMRI_Input\Trabecular\Trabecular_test_series. 4. Click Start in Windows. 5. Select All Programs. 6. Select MicroMRI. 7. Select BoneVue. 				
Preconditions: None				
Date & Time of execution: 12/11/08 4:08 pm				
Revision: 185				
Test Case	Input/Action	Expected Outcome	Observed Outcome	Pass/Fail
1.	Execute procedure steps 1 through 7. On menu bar, click on Tools → Automatic Mode .	(b)(4)		
2.	In Input area, click Browse button next to Trabecular .			
3.	In browser window, click on folder labeled "C:\MMRI_Input\Trabecular". Select subfolder labeled "Trabecular_test_series" and the P-file in the folder.			

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 <small>bone micro-architecture</small>	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 34 of 35
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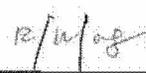
4.	Click Start.	(b)(4)
5.	Click OK.	
6.	On Results Screen, click Cancel.	
7.	Click File → Exit	

Overall Results:
 Passed Failed Not Executed *(explain below)*

Test Incident Log/Defect ID#’s/Comments:
 None.



 Test Engineer Signature



 Date



 Reviewer Signature

12/11/2008

 Date

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December 11, 2008

MicroMRI bone micro-architecture	BoneVue UI Functional Test Procedures BoneVue Version 1.0 BV-DHF-VTP-003.000 Internal Document	12/03/2008 Page 35 of 35
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5 Signatures

Signatory meanings are described in SOP OP-008 [4].

Originator:

Signature: A. Shaker Name: Allen Shaker Date: 12/5/2008
Sr. Software Engineer

Required Review By:

Signature: Haiyin Lu Name: Haiyin Lu Date: 12/10/2008
Software Engineer

Independent Review By:

Signature: R. Elrath Name: R. Elrath Date: 11 Dec 2008
Manager of Quality Assurance and Regulatory Affairs

Authorized By:

Signature: [Signature] Name: R. Schmal Date: 12/11/08
Chief Technology Officer

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COVER SHEET MEMORANDUM

From: Reviewer Name P. J. Hursey
Subject: 510(k) Number K083691
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ?			✓
(If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓	
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number	Class*	Product Code
902.100 2060	II <small>(*If unclassified, see 510(k) Staff)</small>	LLZ

Additional Product Codes: _____

Review: *[Signature]* (Branch Chief) RMB (Branch Code) 2/24/09 (Date)

Final Review: *[Signature]* (Division Director) 2/25/09 (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K083691

Date: February 18, 2009
To: The Record
From: Paul Hardy

Office: 310X
Division: RDB

510(k) Holder: MicroMRI
Applicant: MicroMRI
Device Name: BoneVue
Common Name: Image Processing Software
Contact: Richard Elrath
Manager of Quality Assurance and Regulatory Affairs
580 Middletown Blvd, Suite D-150
Langhorne, PA 19047
Phone: 267-212-1119
Fax: 267-212-1101
Email: relrath@micromri.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the BoneVue image processing software into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Pres		
Truthful and Accuracy Statement	Yes		
510(k) Summary or 510(k) Statement	Yes		
Standards Form	Yes		

III. Device Description

BoneVue evaluates high-resolution MRI data sets containing bone tissue and provides 3D visualization of trabecular structures as well as measurements of descriptive parameters regarding cortical and trabecular morphology.

The following cortical measurements are reported: average cortical inner diameter, average cortical outer diameter, and average cortical thickness.

The following trabecular measurements are reported: average measures of bone volume/total volume, trabecular thickness, trabecular number, and trabecular separation.

The 3D visualization module is used to display a high resolution 3D model of the trabecular bone and its micro-architecture. The 3D visualization helps a trained physician make a qualitative assessment of bone micro-architecture, which may be viewed from different angles. BoneVue allows standard surface rendering views as well as standard maximum intensity projection views.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?			N/A
Is the device reusable (not reprocessed single use)?			N/A
Are "cleaning" instructions included for the end user?			N/A

IV. Indications for Use

BoneVue is a software tool for 3D visualization of bone micro-architecture using MRI data sets with the possibility of manual or automated measurements of descriptive parameters regarding cortical and trabecular morphology. BoneVue is a workflow tool intended to assist a trained physician in the assessment of high-resolution MRI data sets of bone.

V. Predicate Device Comparison

The subject device has the same technological characteristics as the predicate devices. All of the devices are used to analyze the 3D nature of morphology contained in MRI and/or CT data sets in a variety of formats. The 3D visualization assists the physician in assessing the anatomical site of interest. Even though the anatomical sites are different (i.e. bone vs. cardiac regions) between the subject device and the predicates; the intended use of the devices are the same as they allow the physician to visualize areas of interest in 3D and allow for image manipulation and automated or manual measurements of the parameters.

Device(s) to which Equivalence is Claimed and Manufacturer:

Manufacturer	Trade Name	510(k) No.
TeraRecon	Aquarius	K011142
Emageon	EVMS	K053281
Vital Images	Vitrea	K071331
BarcoView MIS	Voxar 3D	K070831

Previous Submissions: None

Applicable Guidance:

VI. Labeling

Draft version of the product literature and instruction manual are attached with the submission package. The brochure's labeling language is consistent with the performance of the product.

VII. Sterilization/Shelf Life/Reuse

Not applicable

VIII. Biocompatibility

Not applicable.

IX. Software-

Version: N/A		
Level of Concern: Minor		
	Yes	No
Software description:	x	
Device Hazard Analysis:	x	
Software Requirements Specifications:	x	
Architecture Design Chart:		N/A
Design Specifications:		N/A
Traceability Analysis/Matrix:	x	
Development:		N/A
Verification & Validation Testing:	x	
Revision level history:	x	
Unresolved anomalies:		N/A
DICOM Conformance Statement		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

IEC 60601-1, IEC 60601-1-2

XI. Performance Testing – Bench

Not applicable

XII. Performance Testing – Animal

Not applicable

XIII. Performance Testing – Clinical

Not applicable

XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	Yes	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	Yes	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	Yes	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

XVI. Contact History

I wrote an e-mail to Mr. Elrath regarding the need to submit forms 3654 and 3674 as well as the DICOM conformance statement for his device. These items were sent via e-mail on 2/20/09.

Recommendation

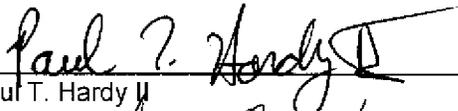
Regulation Number: 21 CFR 892.2050

Regulation Name: Picture Archiving and Communications System

Regulatory Class: Class II

Product Code: LLZ

I recommend that the subject device be found substantially equivalent to the predicate.



Paul T. Hardy II

2/23/09

Date



Dave Buckles

2/25/09

Date



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER MicroMRI Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES December 8, 2008
3. ADDRESS (Number, Street, State, and ZIP Code) 580 Middletown Boulevard D-150 Langhorne, PA 19047	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 267 212-1100 (Fax) 267 212-1101

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

BoneVue, Common Name: Image Processing Software,

Classification: System, Image Processing, Radiological

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
K083691

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY APPLICABLE CLINICAL TRIAL(S), UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)
NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.**

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Richard Elrath (Title) Manager Quality Assurance and Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 580 Middletown Boulevard D-150 Langhorne, PA 19047	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 267 212-1119 (Fax) 267 212-1101
15. DATE OF CERTIFICATION	

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Amundson Road
Beltsville, MD 20705-1268

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

FDA-3674 (1/08) (BACK)

Hardy, Paul T

From: Richard Elrath [relrath@micromri.com]
Sent: Wednesday, February 18, 2009 12:32 PM
To: Hardy, Paul T
Subject: RE: K083691
Attachments: FDA3674.pdf

Mr. Hardy,

Attached please find a completed copy of FDA-3674 as requested. I have a few questions about FDA-3654. We have claimed compliance with the following voluntary standards, DICOM, JPEG, and SMPTE. Do we need to complete FDA-3654 for each of these standards? If we complete a FDA-3654 for DICOM, do we also have to include a DICOM conformance statement?

Thank you,

Richard Elrath

Richard Elrath, CMQ/OE
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
267 212-1119
relrath@micromri.com

From: Hardy, Paul T [mailto:Paul.Hardy@fda.hhs.gov]
Sent: Wednesday, February 18, 2009 10:27 AM
To: relrath@micromri.com
Subject: K083691

Mr. Elrath,

My name is P.J. Hardy and I am currently reviewing your 510k for the BoneVue software. I noticed there are a couple of things missing from the submission. First, it does not appear that you have submitted Form 3654 or 3674 which are for the standards your device conforms to or the ClinicalTrials.gov form respectively. These forms need to be completely filled and sent to me. Second, it does not appear that you have submitted a DICOM conformance statement as well. This also needs to be completed and sent to me. These forms can be e-mailed or fax to me. If you have any questions, please let me know. My fax number is 240-276-3644

Thanks,
P.J. Hardy

The 3654 and 3674 forms can be found here... <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>
and

<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>

*P.J. Hardy, Biomedical Engineer
Collaborative Reviewer
CDRH/ODE/DRARD/OSB/DPS/PEB I
(240) 276-3661*

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at paul.hardy@fda.hhs.gov

Hardy, Paul T

From: Richard Elrath [relrath@micromri.com]
Sent: Friday, February 20, 2009 10:44 AM
To: Hardy, Paul T
Subject: RE: K083691
Attachments: 510(k) summary.pdf; DICOM3654.pdf; JPEG3654.pdf; DICOM Statement.pdf

Mr. P.J. Hardy,

Attached is the 510(k) Summary as requested, as well as a form FDA 3654 for the DICOM and JPEG Standards, and a DICOM Conformance Statement for BoneVue Software (K083691). If you need any additional information please let me know.

Regards,

Richard Elrath

Richard Elrath, CMQ/OE
Manager Quality Assurance and Regulatory Affairs
MicroMRI, Inc.
267 212-1119
relrath@micromri.com

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Digital Imaging and Communications in Medicine (DICOM)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 12-183

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Guidance for the Submission of Premarket Notifications for Medical Image Management Devices

¹ The formatting convention for the title is: {SDO} [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

⁶ The online search for CDH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE Digital Imaging and Communications in Medicine (DICOM)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER PS 3.1	SECTION TITLE Introduction and Overview	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER PS 3.2	SECTION TITLE Conformance	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER PS 3.3	SECTION TITLE Information Object Definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Digital Imaging and Communications in Medicine (DICOM)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.4	Service Class Specifications	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.5	Data Structure and Encoding	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.6	Data Dictionary	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Digital Imaging and Communications in Medicine (DICOM)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.7	Message Exchange	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Not relevant to this device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.8	Network Communication Support for Message Exchange	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Not relevant to this device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.10	Media Storage and File Format for Data Interchange	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE Digital Imaging and Communications in Medicine (DICOM)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER PS 3.11	SECTION TITLE Media Storage Application Profiles	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION Not relevant to this device.		
SECTION NUMBER PS 3.12	SECTION TITLE Storage Functions and Media formats for Data Interchange	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION Not relevant to this device.		
SECTION NUMBER PS 3.14	SECTION TITLE Grayscale Standard Display Function	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION Not relevant to this device.		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Digital Imaging and Communications in Medicine (DICOM)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.15	Security and System Management Profiles	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Not relevant to this device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.16	Content Mapping Resource	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Not relevant to this device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
PS 3.17	Explanatory Information	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Not relevant to this device.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

Digital Imaging and Communications in Medicine (DICOM)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

PS3.18

SECTION TITLE

Web Access to DICOM Persistent Objects

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

Not relevant to this device.

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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26 FEB 09

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

Joint Photographic Experts Group (JPEG)

Please answer the following questions

Yes No

Is this standard recognized by FDA²? Yes No

FDA Recognition number³ # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360c]. www.fda.gov/cdrh/stdsprog.html

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⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Joint Photographic Experts Group (JPEG2000)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER Part I	SECTION TITLE Core Coding System	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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BoneVue Rev 1.0 - DICOM® Conformance Summary

1. Introduction

This document is an abbreviated DICOM conformance statement for the *BoneVue* application, particularly its input file reading component. As described in the DICOM Standard PS 3.2 (Conformance), the purpose of this document is to outline the level of conformance to the DICOM v3.0 standard and to enumerate the supported DICOM Service Classes, Information Objects, and Communications Protocols supported by the implementation of *BoneVue*. Having said that, since the *BoneVue* application does not contain or support any of the DICOM services such as Storage, Query/Retrieve, Print, Verification, etc., there will be no conformance claims relating to these services and no mention of any Application Entities for these services. Communications Protocol profiles will also be absent from this document for the same reasons. The remainder of this document will describe how the *BoneVue* application handles the Information Objects it is capable of reading.

2. Reading of DICOM Part 10 files

BoneVue supports reading files that conform to the DICOM Standard PS 3.10 (Media Storage and File Format for Media Interchange). The DICOM file format provides a means to encapsulate in a file the Data Set representing a SOP (Service Object Pair) Instance related to a DICOM IOD (Information Object Definition). Files written to disk in this DICOM File Format will be referred to as DICOM Part 10 files for the remainder of this document. Note that the *BoneVue* application does NOT directly writes files in this DICOM File Format, only reads them.

3. Encapsulated SOP Classes and Transfer Syntaxes Supported

BoneVue supports reading DICOM Part 10 files whose contents encapsulate the data of the following SOP Classes. The SOP Class UID is in the file's DICOM Tag field (0008, 0016). The corresponding supported Transfer Syntaxes are also given. The Transfer Syntax UID is in the file's DICOM Tag field (0002, 0010).

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Explicit VR Little Endian	1.2.840.10008.1.2.1

⁵ DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

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	<p align="center"><i>BoneVue 1.0 - DICOM Conformance Statement</i> BV-DHF-GEN-001.000 <i>Internal Document</i></p>	<p align="right">2/19/2008 Page 2 of 2</p>
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All other Transfer Syntaxes that are detailed in the DICOM standard PS 3.5 (Data Structures and Encoding) are NOT supported. All other SOP Classes listed in the DICOM standard PS 3.4 (Service Class Specifications), such as CT Image Storage, Ultrasound Image Storage, etc., are not applicable, since *BoneVue* is intended for use with inputs of MR images only.

4. Exceptions

4.1 Handling of odd length data elements

The DICOM Standard PS 3.5 (Data Structures and Encoding) specifies that the data element values which make up a DICOM data stream must be padded to an even length. The library upon which *BoneVue*'s DICOM reading functionality is built strictly enforces this specification. If it encounters an incorrectly formed odd length data field while reading a DICOM Part 10 file, it will report an error relating to an unsupported file and stop the reading process.

4.2 Handling of undefined VRs

The VR (Value Representation) of a data element describes the data type and format of that data element's values. If an undefined VR is encountered while reading a DICOM Part 10 file, the data element's VR will be set to UN (unknown).

4.3 Handling of retired and private data elements

Certain data elements are no longer supported under the v3.0 of the DICOM standard and are denoted as retired. Also, some DICOM implementations may require the communication of information that cannot be contained in standard data elements, and thus create private data elements to contain such information. Retired and private data elements are silently ignored by *BoneVue*.