U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)

FOLDER: K103785 - 322 pages (FOI:11001512)

COMPANY: MIM SOFTWARE INC. (MIMSOFT)

PRODUCT: SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)

SUMMARY: Product: MOBILE MIM

DATE REQUESTED: Aug 26, 2011

DATE PRINTED: Oct 5, 2011

Note: Releasable Version

FEB - 4 2011

K103785

510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: Jan 26, 2011

Device Name

Trade Name: Mobile MIM
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Device

K062163	MIMviewer 1.0	MIM Software Inc. (formerly MIMvista Corp.)

Intended Use / Indications for Use

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device Description

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Device Comparison Table between new device and predicate:

ITEM	Mobile MIM	MIMviewer
Intended Use / Indications For Use	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI. Mobile MIM provides wireless and portable access	MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities. The MIMviewer software

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K103785

ITEM	Mobile MIM	MIMviewer
	to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	program is used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	Yes	Yes
Multi-Planar Reconstruction (MPR)	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Standardized Uptake Value (SUV)	Yes	Yes
Distance Measurements	Yes	Yes

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K103785

ITEM	Mobile MIM	MIMviewer
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	SPECT, PET, CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	No
Operating Platform	Apple® iOS	Windows® 2000/XP MacOS X® 10.4+ Linux®
Hardware Requirements	Apple® iOS handheld devices	Pentium® 4+ G4+

Substantial Equivalence

The comparison chart above provides evidence to facilitate the substantial equivalence determination between Mobile MIM and our chosen predicate device, MIMviewer (K062163)

The differences in the Indication Statements between Mobile MIM and MIMviewer describe specific restrictions on how Mobile MIM is to be used, given the hardware and portability differences between these two devices. Mobile MIM adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography.

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K103785

The technological characteristics between Mobile MIM and MIMviewer are different, as the software operates on different hardware. These differences are addressed through the labeling and additional software features of Mobile MIM.

Performance Data

MIM Software Inc. has conducted display performance testing using Mobile MIM software on various portable devices, both prior to and after utilizing the application's calibration procedure. Testing measured contrast response and evaluated test patterns for luminosity, resolution, and noise according to IEC 62563-1 and TG18 guidelines. All testing passed requirements following the Mobile MIM's calibration procedure.

MIM Software Inc. also performed multiple studies with qualified radiologists using a variety of modalities, specifically MRI, CT, SPECT, and PET, under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

Furthermore, MIM Software Inc. has conducted verification, validation, and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM provides a diagnostic viewer of medical images substantially equivalent to the MIMviewer software, with portable device characteristics and functionality.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Hanigan
Quality Manager
MIM Software
25200 Chargrin Blvd., Suite 200
CLEVELAND OH 44122

FEB - 4 2011

Re: K103785
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2010
Received: December 27, 2010

Dear Ms. Hanigan:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K103785

Device Name: Mobile MIM

Indications for Use:

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103785

K103785

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FDA CDRH DMC

DEC 27 2010

Received

Date: Dec 22, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Submission (21 CFR 807.90(e))

Trade Name: Mobile MIM **Common Name: Medical Imaging Software**

Submitter: MIM Software Inc.

Contact Person: Lynn Hanigan
Quality Manager
216-455-0600

Alternate Contact Person: Mark Cain
Chief Technical Officer
216-455-0600

Dear Sir or Madam,

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, MIM Software Inc. hereby submits this premarket notification at least ninety days before the Company intends to market its Mobile MIM in the United States. This is a Traditional 510(k) submission of a new device. Our recommended classification for Mobile MIM is a Class II Device under 21 CRF 892.2050; product code LLZ.

Prior to this submission, formal correspondence with the FDA for the Mobile MIM included: 510(k)091895, (k)082495, and pre-IDEs I100652, I090140, I090102, I080742.

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

mim SOFTWARE

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Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

MIM Software believes that Mobile MIM is substantially equivalent to a legally marketed device which has been granted marketing clearance by FDA under the 510(k) premarket notification process. This device is substantially equivalent to a device currently in commercial distribution within the United States, in both technological characteristics and in intended function and use. Additionally, it raises no new questions pertaining to safety or effectiveness.

Information to demonstrate the substantial equivalence of this device is included in the subsequent sections. We trust that the information included will be sufficient to enable the FDA to find Mobile MIM substantially equivalent to the predicate device referenced within this submission.

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MIM Software believes, to the best of its knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted. Additionally, MIM Software considers its intent to market this product to be confidential information and requests that it be considered confidential by FDA.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Should you have any questions concerning this submission, please contact me at 216-455-0600 or by fax at 216-455-0601.

Sincerely,

Lynn Hanigan

Lynn Hanigan
Quality Manager

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

VOL 001

001_TABLE OF CONTENTS

TABLE OF CONTENTS

510(k) INFORMATION RECOMMENDED BY:

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – May 11, 2005

VOL 002 - ADMINISTRATIVE

001_MEDICAL DEVICE USER FEE COVER SHEET

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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MIM SOFTWARE INC
25200 Chagrin Blvd. Suite 200
Cleveland OH 44122
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Lynn Hanigan

2.1 E-MAIL ADDRESS
lhanigan@mimsoftware.com

2.2 TELEPHONE NUMBER (include Area code)
216-455-0600

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
216-455-0601

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:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD118145

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?
[X] 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.)
[ ] 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.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] 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).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
06-Dec-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

VOL 002 - ADMINISTRATIVE

002_PREMARKET REVIEW SUBMISSION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/22/2010	MD6053131-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: MIM Software Inc.	Establishment Registration Number *(if known)*: 3004363352		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 216-455-0600		
Street Address: 25200 Chagrin Blvd. Suite 200	FAX Number *(including area code)*: 216-455-0601		
City: Cleveland	State / Province: Ohio	ZIP/Postal Code: 44122	Country: USA
Contact Name: Lynn Hanigan			
Contact Title: Quality Manager	Contact E-mail Address: lhanigan@mimsoftware.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 Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

FORM FDA 3514 (3/08)

PSC Graphics (301) 443-1090 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LLZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K062163	1	MIMviewer	1	MIM Software Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1	Mobile MIM	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 I100652	2 K091895	3 I090140	4 I090102	5 I080742	6 K082495
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	C.F.R. Section *(if applicable)*	Device Class
LLZ	892.2050	[ ] Class I [x] Class II
Classification Panel: Radiology		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.
Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.
This device is not to be used for mammography.

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3004363352	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: MIM Software Inc.		Establishment Registration Number: 3004363352		
Division Name *(if applicable)*		Phone Number *(including area code)*: 216-455-0600		
Street Address: 25200 Chagrin Blvd. Suite 200		FAX Number *(including area code)*: 216-455-0601		
City: Cleveland		State / Province: Ohio	ZIP Code: 44122	Country: USA
Contact Name: Lynn Hanigan	Contact Title: Quality Manager	Contact E-mail Address: lhanigan@mimsoftware.com		

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 Code	Country
Contact Name	Contact Title	Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 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:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

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VOL 002 - ADMINISTRATIVE

003_COMPLIANCE WITH CLINICAL TRIALS

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

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
MIM Software Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
12/22/2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
25200 Chagrin Blvd., Suite 200
Cleveland, OH 44122
US

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (216) 455-0600
(Fax) (216) 455-0601

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)

Mobile MIM

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)*

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)
Lynn Hanigan
Quality Manager

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Lynn Hanigan
(Title) Quality Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
25200 Chagrin Blvd., Suite 200
Cleveland, OH 44122
US

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (216) 455-0600
(Fax) (216) 455-0601

15. DATE OF CERTIFICATION
12/22/2010

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

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. If there is no such number, leave this field blank.
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 of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   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, on the date the certification is signed, 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, as of the date the certification is signed, 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 the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been 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. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
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 numbers 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 address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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Form FDA 3674 (11/08) (BACK)

VOL 003

001_510(k) COVER LETTER

MIM SOFTWARE

25200 Chagrin Blvd.
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Cleveland, OH 44122

866.421.2536
www.mimsoftware.com

Date: Dec 22, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Submission (21 CFR 807.90(e))

Trade Name: Mobile MIM **Common Name: Medical Imaging Software**

Submitter: MIM Software Inc.

Contact Person: Lynn Hanigan
Quality Manager
216-455-0600

Alternate Contact Person: Mark Cain
Chief Technical Officer
216-455-0600

Dear Sir or Madam,

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, MIM Software Inc. hereby submits this premarket notification at least ninety days before the Company intends to market its Mobile MIM in the United States. This is a Traditional 510(k) submission of a new device. Our recommended classification for Mobile MIM is a Class II Device under 21 CRF 892.2050; product code LLZ.

Prior to this submission, formal correspondence with the FDA for the Mobile MIM included: 510(k)091895, (k)082495, and pre-IDEs I100652, I090140, I090102, I080742.

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

25200 Chagrin Blvd.
Suite Ten 200
Cleveland, OH 44122

866.481.2656
www.mimsoftware.com

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

MIM Software believes that Mobile MIM is substantially equivalent to a legally marketed device which has been granted marketing clearance by FDA under the 510(k) premarket notification process. This device is substantially equivalent to a device currently in commercial distribution within the United States, in both technological characteristics and in intended function and use. Additionally, it raises no new questions pertaining to safety or effectiveness.

Information to demonstrate the substantial equivalence of this device is included in the subsequent sections. We trust that the information included will be sufficient to enable the FDA to find Mobile MIM substantially equivalent to the predicate device referenced within this submission.

MIM SOFTWARE

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MIM Software believes, to the best of its knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted. Additionally, MIM Software considers its intent to market this product to be confidential information and requests that it be considered confidential by FDA.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Should you have any questions concerning this submission, please contact me at 216-455-0600 or by fax at 216-455-0601.

Sincerely,

Lynn Hanigan

Lynn Hanigan
Quality Manager

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

VOL 004

001_INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): TBD

Device Name: Mobile MIM

Indications for Use:

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

VOL 005

001_510(k) SUMMARY

510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: Dec 22, 2010

Device Name

Trade Name: Mobile MIM
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Device

K062163 MIMviewer 1.0 MIM Software Inc. (formerly MIMvista Corp.)

Intended Use / Indications for Use

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device Description

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Substantial Equivalence

Mobile MIM is substantially equivalent to MIMviewer software (K062163).

Mobile MIM provides a portable diagnostic viewer of medical images substantially equivalent to the MIMviewer software.

Performance Data

MIM Software Inc. has conducted performance and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

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Tel: 866-421-2536
Fax: 216-455-0601

VOL 006

001_TRUTHFUL AND ACCURACY STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Quality Manager of MIM Software Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for Mobile MIM is truthful and accurate and that no material fact has been omitted.

Lynn Hanigan
(Signature)

12/22/2010
(Date)

Lynn Hanigan
Quality Manager
MIM Software Inc.

VOL 010

001_Executive Summary

EXECUTIVE SUMMARY

Device Description:

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Device Comparison Table between new device and predicate:

ITEM	Mobile MIM	MIMviewer
Intended Use / Indications For Use	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI. Mobile MIM provides wireless and portable access	MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities. The MIMviewer software

ITEM	Mobile MIM	MIMviewer
	to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	program is used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	Yes	Yes
Multi-Planar Reconstruction (MPR)	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Standardized Uptake Value (SUV)	Yes	Yes

ITEM	Mobile MIM	MIMviewer
Distance Measurements	Yes	Yes
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	SPECT, PET, CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	No
Operating Platform	Apple® iOS	Windows® 2000/XP MacOS X® 10.4+ Linux®
Hardware Requirements	Apple® iOS handheld devices	Pentium® 4+ G4+

Substantial Equivalence Discussion:

The comparison chart above provides evidence to facilitate the substantial equivalence determination between Mobile MIM and our chosen predicate device, MIMviewer.

There is a direct correlation between the Indication Statement / Intended Use of Mobile MIM with MIMviewer. Both devices are software applications used by medical professionals in the diagnosis of patients by means of medical images. They both display, register and fuse medical images from SPECT, PET, CT and MRI modalities.

The differences in the Indication Statements between Mobile MIM and MIMviewer describe specific restrictions on how Mobile MIM is to be used, given the hardware and portability differences between these two devices. Mobile MIM adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography.

For a complete discussion of these differences see the *Device Use-Safety* discussion in the *Software* section of this 510(k) premarket notification. A summary of the results of the testing done during Alpha and Beta development stages demonstrate that the device, when used according to operating instructions, can be used safely and effectively.

The technological characteristics between Mobile MIM and MIMviewer are different, as the software operates on different hardware. These differences are addressed through the labeling and additional software features (e.g. Calibration, lighting verification) and evidenced by the results of the Image Quality Evaluation testing performed. See the *Device Use-Safety* section in the *Software* portion of this 510(k) premarket notification for a complete discussion of the descriptive characteristics.

Therefore, from all evidence gathered, it is our belief that Mobile MIM provides a diagnostic viewer of medical images substantially equivalent to the MIMviewer software, with portable device characteristics and functionality.

Summary of Testing:

MIM Software Inc. has conducted performance and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

VOL 011

001_Device Description

DEVICE DESCRIPTION

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

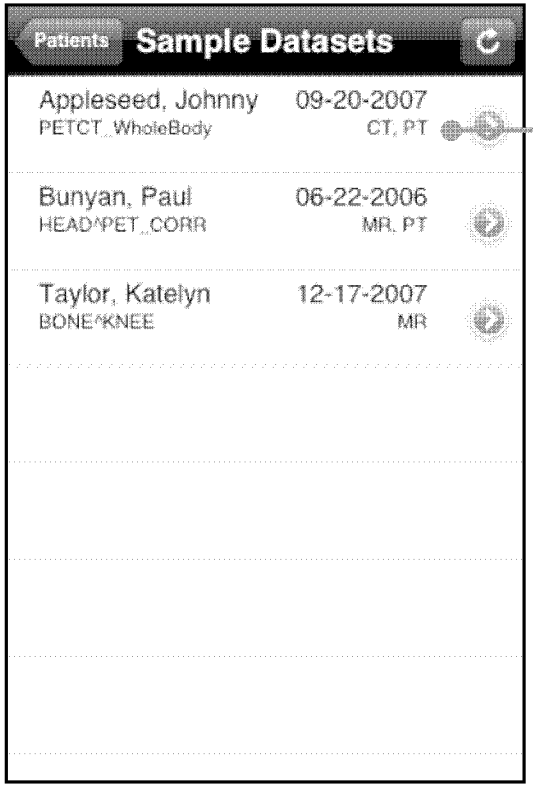
Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Mobile MIM provides the following during processing of medical image data:

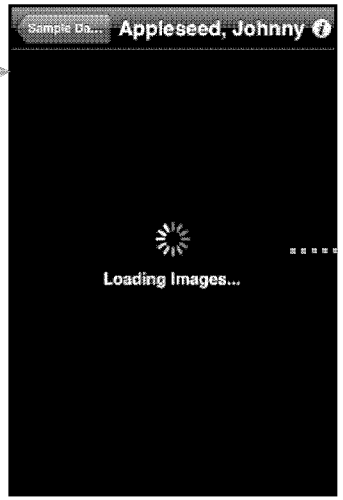
1. Data is downloaded to hand-held device.
2. Meta information for the data is listed along with all other series available on device.
3. User selects series.
4. Data read into memory.
5. Data is sliced from the stored arrays in 3 orthogonal views for multi-planar reconstruction, or directly from single image for 2D viewing.
6. Contrast is applied to the slice.

7. Color lookup table is applied to the contrasted slice.
8. Result is displayed.
9. Any overlays with same DICOM coordinates of displayed slice are rendered as line and text graphical elements as is appropriate for the type of overlay.
10. User interacts with interface using gestures for zoom/pan, contrast, traversing through slices.
11. Each user control change results in adjustment to appropriate parameter and control returns to step 5.

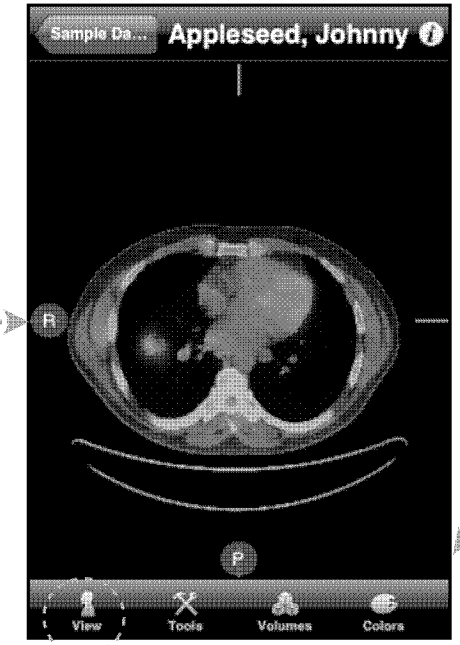
Data Set Image Rendering

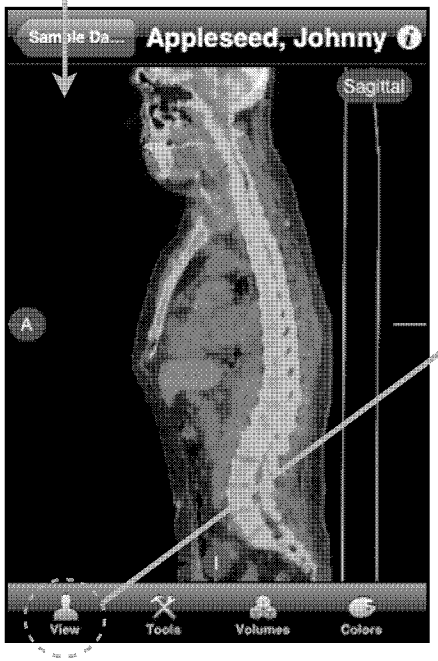


Local Data Sets

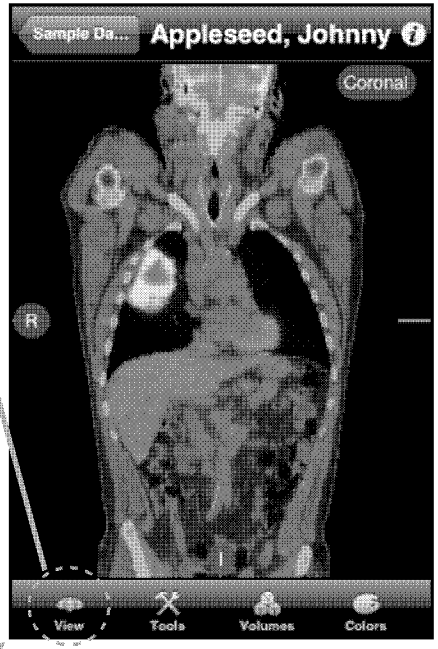


Images Rendered





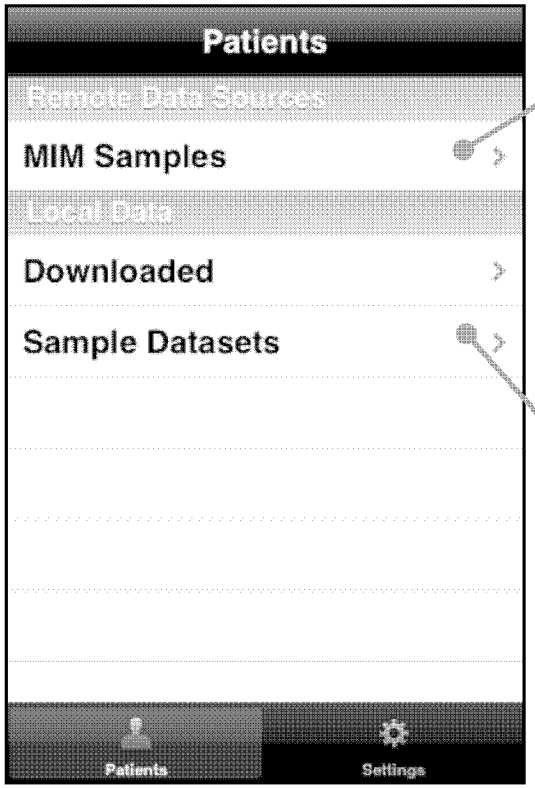
Same Modalities from Multiple Views

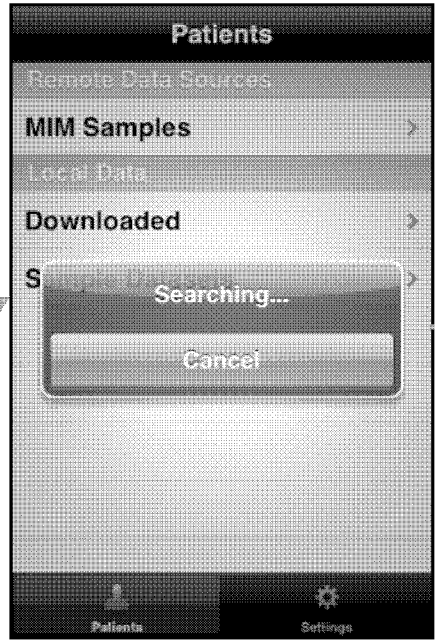


PS - 0005 21.1

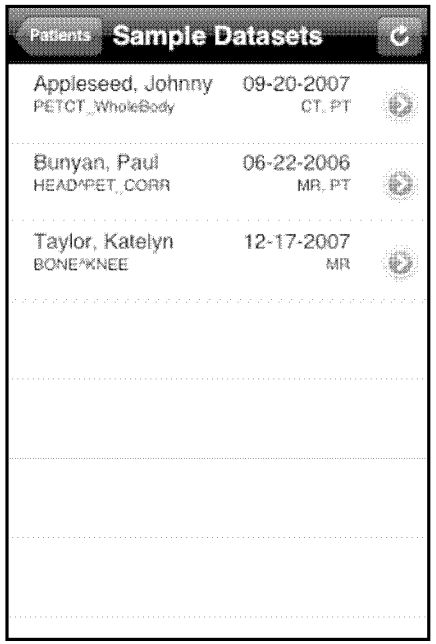
Data Set Browser/Manager

Main Screen





Remote Source



Local Source

PS - 0005 21.2

Data Transfer to Mobile Device

Remote Data Sets

Data Set Transfer in Progress

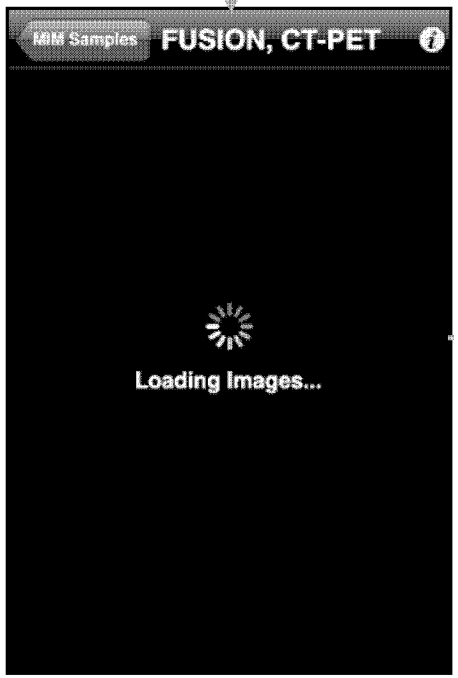
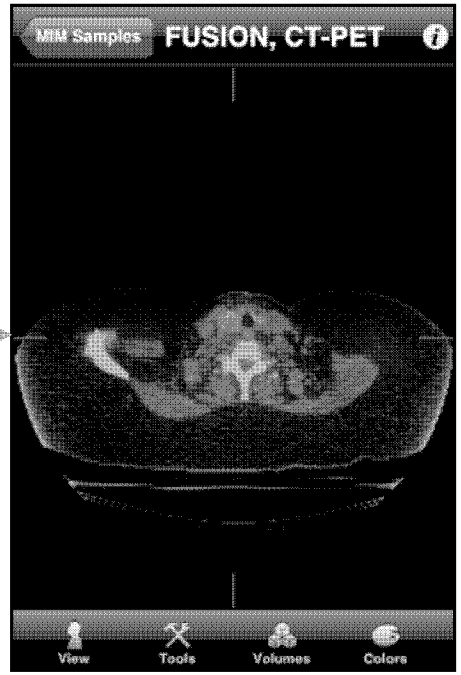


Image Rendered

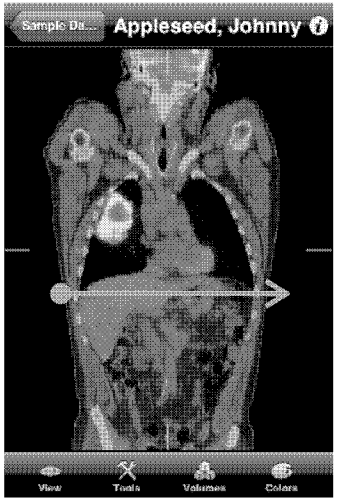


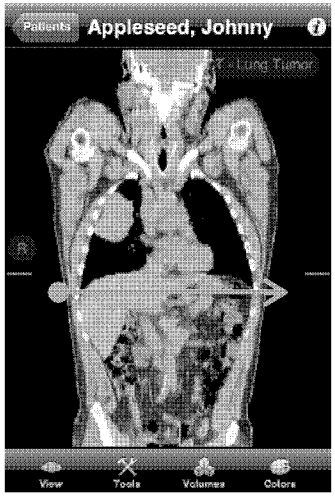
PS - 0005 21.3 (1 of 2)

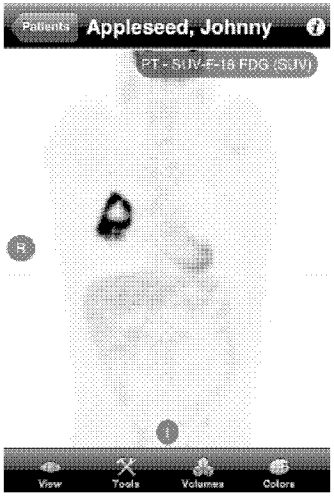
Data Transfer to Mobile Device

(b)(4)

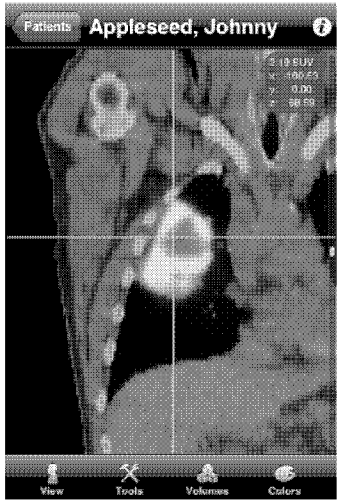
User Interaction



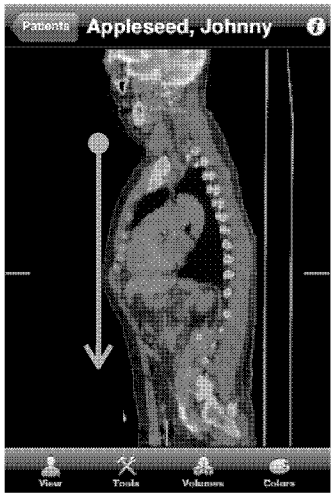




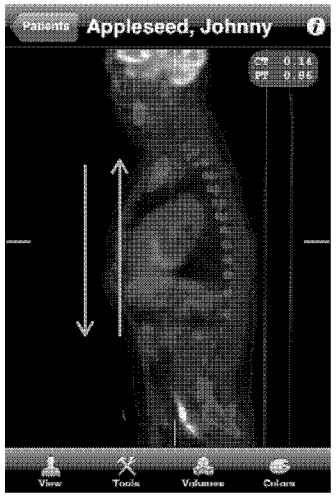
Swipe left/right change modality



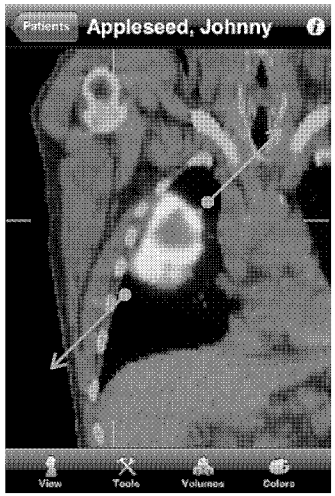
Touch and Hold - Drag to localize

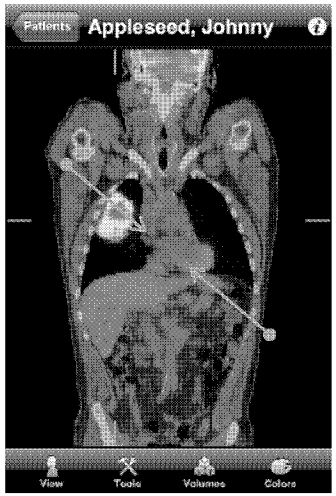


Swipe up/down change view



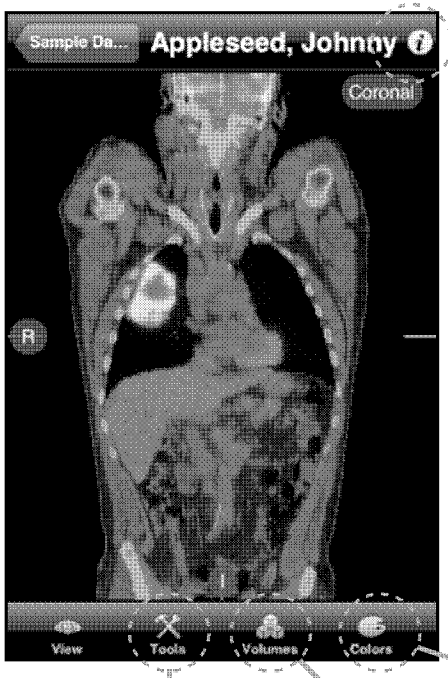
Drag, change blend/contrast



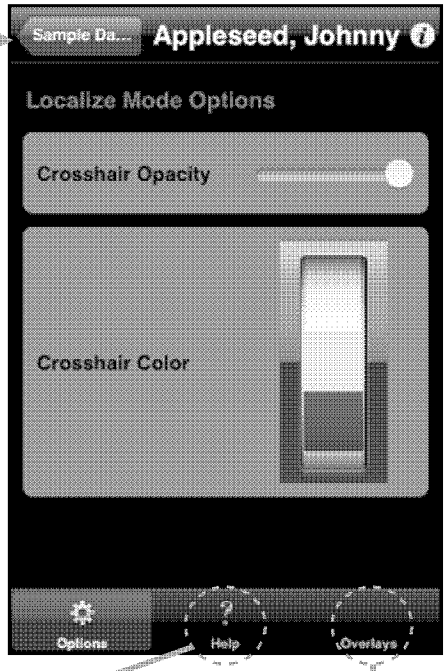


Pinch to zoom, moving apart to zoom in and together to zoom out

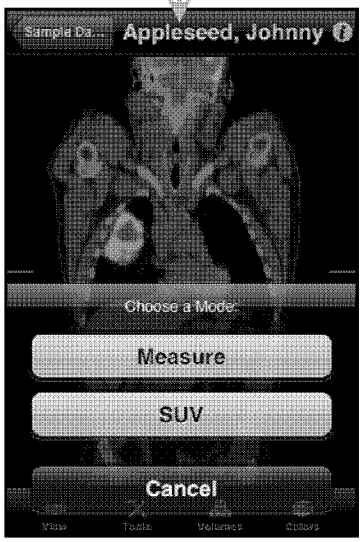
User Interface



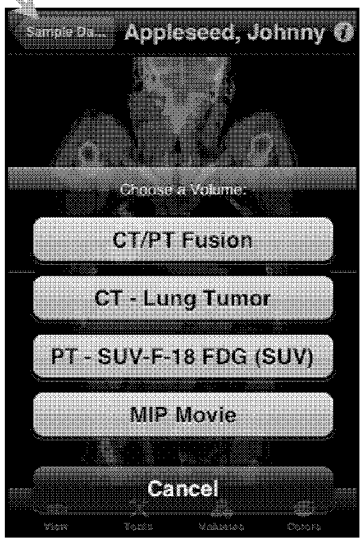
Main Layout



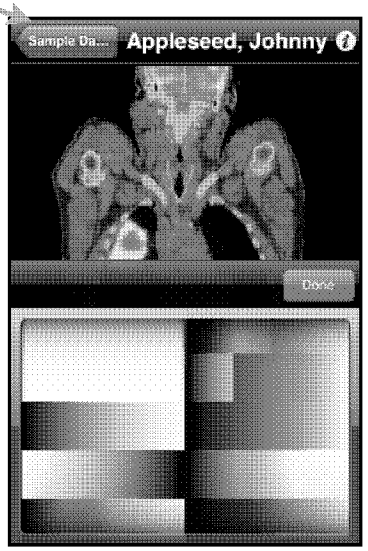
Flipped View



Tool Selection

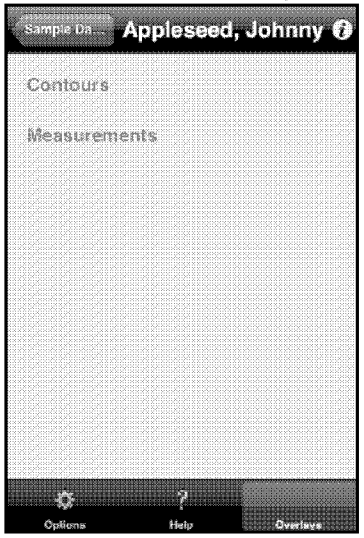


Volume Selection



Color Table Selection

Help Screen

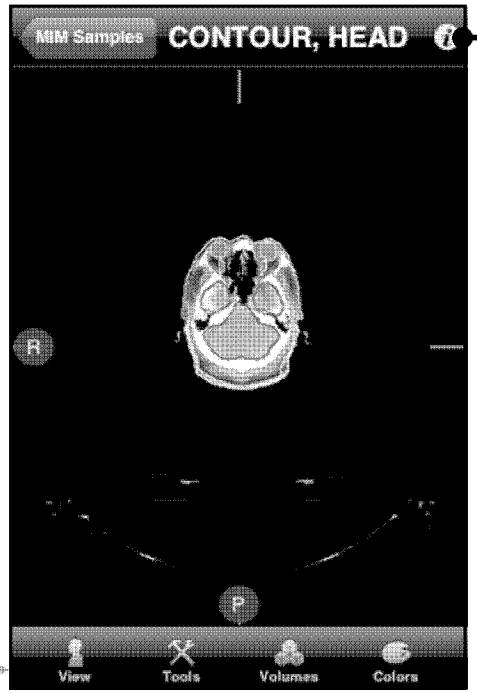


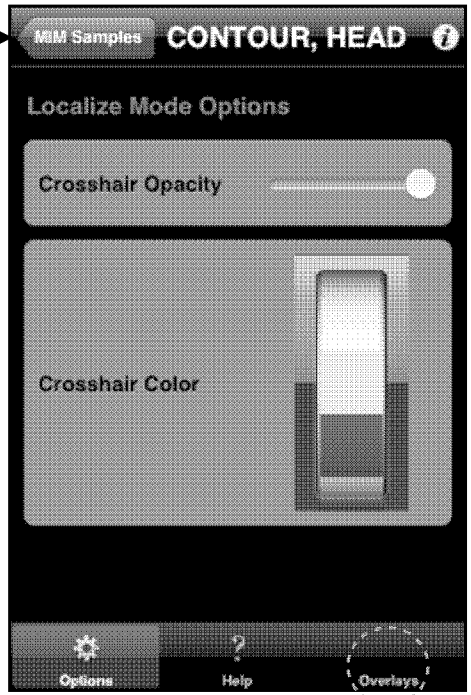
Overlay Control

Overlay and Control Framework

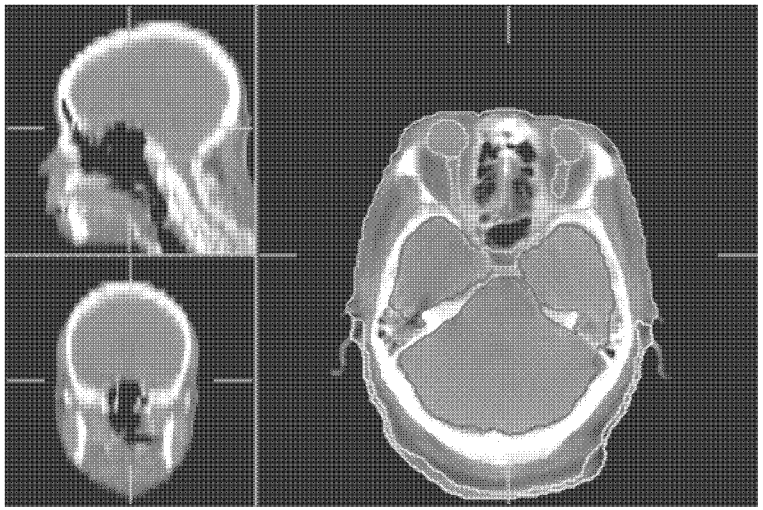
Remote Data Sets

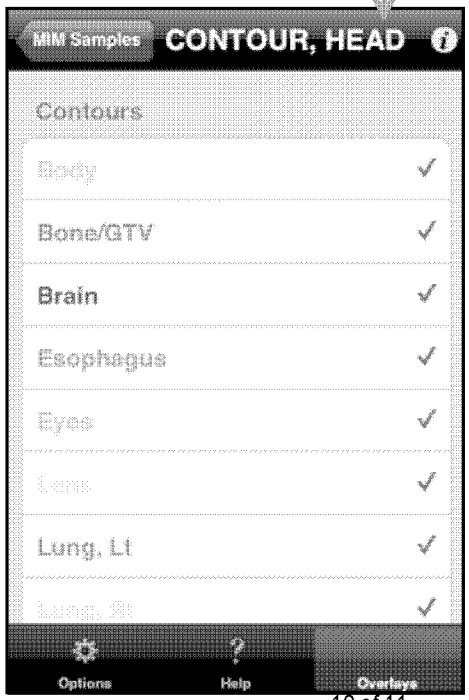
Data Set Info





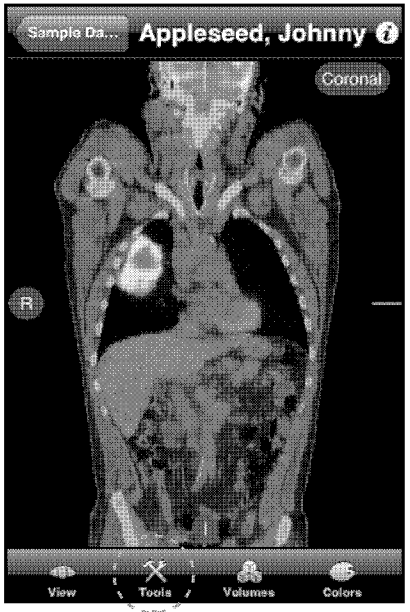
Rotate Device Orientation
For Different Layouts

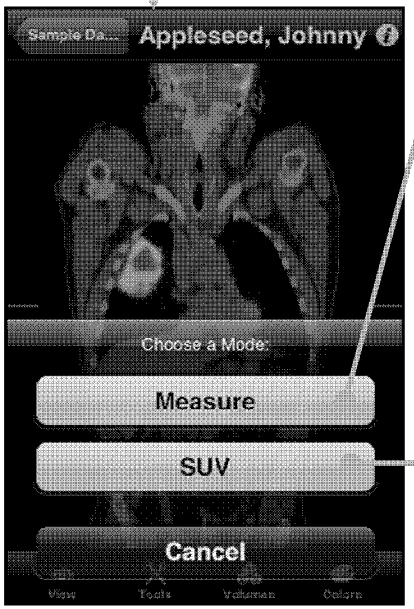




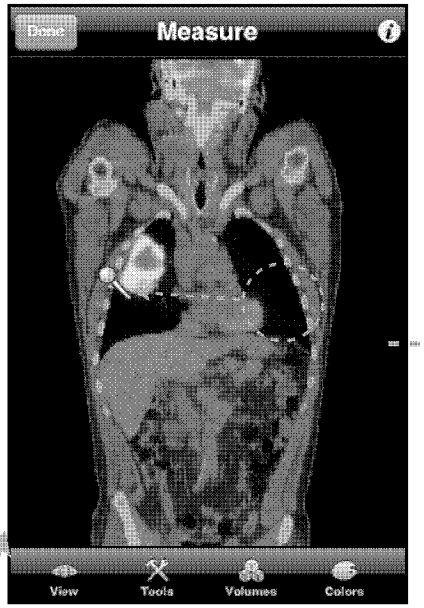
Overlay Control

Tool Framework

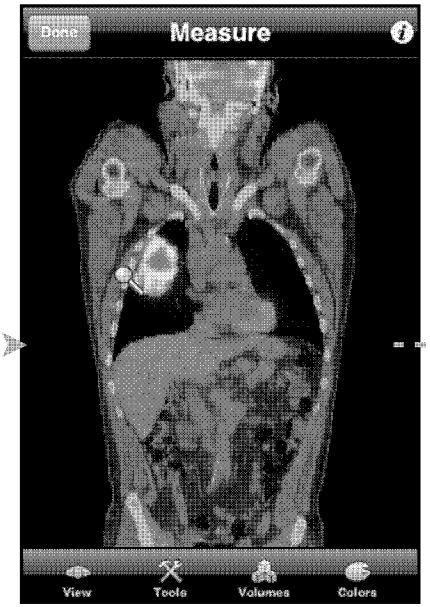




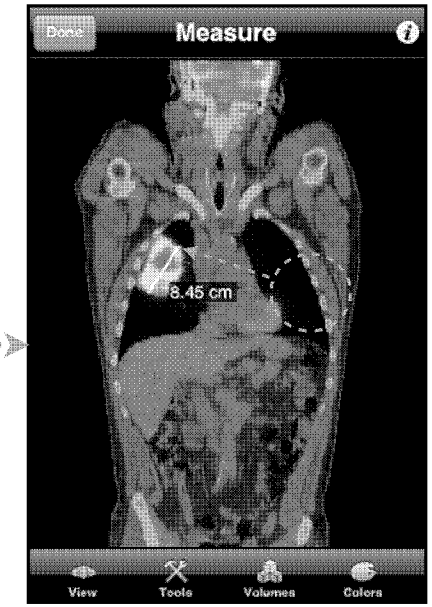
Select Tool



Drag to Move Pin

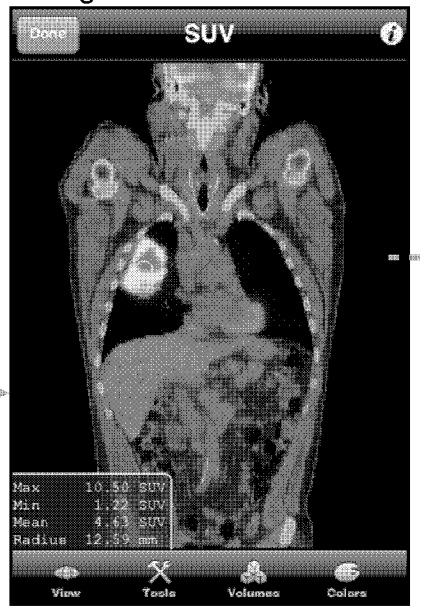


Release to Set Pin

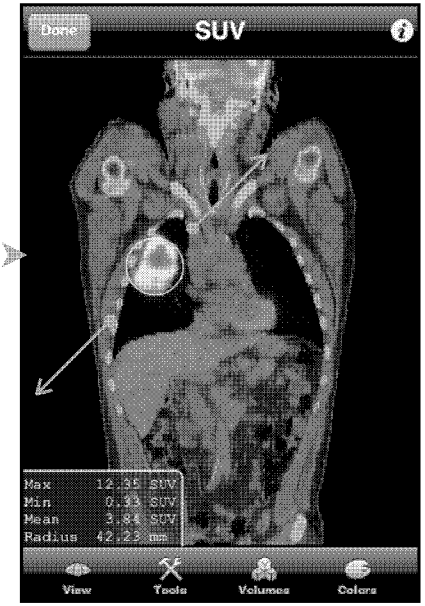


Repeat to Draw Line

Drag to Position SUV Ball



Pinch to Shrink/Grow



PS - 0005 21.7

VOL 012 – SUBSTANTIAL EQUIVALENCE DISCUSSION

001_SE Matrix

Substantial Equivalence Discussion

COMPARISON TO PREDICATE DEVICE

ITEM	Mobile MIM	MIMviewer
510(k) Accession Number	TBD	K062163
Clearance Date	TBD	09-22-2006
Intended Use / Indications For Use	The Mobile MIM software program is used for the registration, fusion, and/or diagnostic display of medical images from only the following modalities: SPECT, PET, CT, and MRI. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities. The MIMviewer software program is used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes

ITEM	Mobile MIM	MIMviewer
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	Yes	Yes
Multi-Planar Reconstruction (MPR)	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Standardized Uptake Value (SUV)	Yes	Yes
Distance Measurements	Yes	Yes
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	SPECT, PET, CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	No

ITEM	Mobile MIM	MIMviewer
Operating Platform	Apple® iOS	Windows® 2000/XP MacOS X® 10.4+ Linux®
Hardware Requirements	Apple® iOS handheld devices	Pentium® 4+ G4+

Discussion:

The comparison chart above provides evidence to facilitate the substantial equivalence determination between Mobile MIM and our chosen predicate device, MIMviewer.

There is a direct correlation between the Indication Statement / Intended Use of Mobile MIM with MIMviewer. Both devices are software applications used by medical professionals in the diagnosis of patients by means of medical images. They both display, register and fuse medical images from SPECT, PET, CT and MRI modalities.

The differences in the Indication Statements between Mobile MIM and MIMviewer describe specific restrictions on how Mobile MIM is to be used, given the hardware and portability differences between these two devices. Mobile MIM adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography.

For a complete discussion of these differences see the *Device Use-Safety* discussion in the *Software* section of this 510(k) premarket notification. A summary of the results of the testing done during Alpha and Beta development stages demonstrate that the device, when used according to operating instructions, can be used safely and effectively.

The technological characteristics between Mobile MIM and MIMviewer are different, as the software operates on different hardware. These differences are addressed through the labeling and additional software features (e.g. Calibration, lighting verification) and evidenced by the results of the Image Quality Evaluation testing performed. See the *Device Use-Safety* section in the *Software* portion of this 510(k) premarket notification for a complete discussion of the descriptive characteristics.

Conclusion:

Therefore, from all evidence gathered, it is our belief that Mobile MIM provides a diagnostic viewer of medical images substantially equivalent to the MIMviewer software, with portable device characteristics and functionality.

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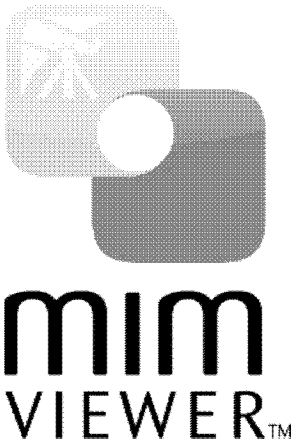
VOL 012 – SUBSTANTIAL EQUIVALENCE DISCUSSION

002_PREDICATE LABELING (MIMviewer)



USER'S GUIDE

Version 2.1 (Pro and Non-Pro)

12-14-2010

Image Manipulation

The image manipulation tools appear on the left side of the MIMviewer window.

Localize (Default Mode)

- Triangulate on any of the images, including the MIP Movie, with a left-click.
- Change slices using the mouse scroll wheel or a right-click drag.

Scroll

- Left-click drag over an image to traverse slices in that plane.

Contrast

- Left-click drag over an image to adjust the window/level in any view.
- To set contrast based on a region, right-click drag over an area. The contrast will be set according to the data within the rectangle.
- Adjusting the contrast on a fusion will adjust the secondary (PET) series.

Hover Zoom

- Apply a zoom to the area where the mouse is hovering.
- Mouse over any scan or MIP movie.

Zoom

- Left-click drag up/down over an image to zoom.
- To reset the zoom and pan of an image, right-click on the Zoom Icon.

Pan

- Left-click drag over an image to pan (image must be zoomed).
- To reset (center) the pan, right-click on the Pan Icon.

Measure *(Professional Version Only)*

- Left-click to set a starting point; left-click again to set an end point.
- Or, left-click drag across a distance and release the mouse button.
- To reposition the line, left-click drag on the label.
- Delete the measurement by right-clicking on the label.

SUV *(Professional Version Only)*

- Position the SUV ball with a left-click or left-click drag.
- To resize the SUV ball, right-click drag up/down.
- SUV statistics are displayed in the lower right-hand corner of a PET or fusion volume.

Blend *(Professional Version Only)*

- Adjust the blending of the two series in a fusion by left-click dragging up and down.
- Or, use the Blend Menu (top left) to see a list of quick blend settings.

MIP Movie Controls

The MIP Movie Controls appear to the right of the MIP movie when displayed.

	Play		Pause
	Reverse Direction		Increase/Decrease Speed

- Manually rotate by using the mouse scroll wheel or a right-click drag over a stopped movie.
- Triangulate in corresponding planes with a left-click or a left-click drag over the movie.
- A MIP is shown by default on both fusion and PET presentations.

Presentation Tools

Presentation tools are located in the top left corner.

Layout

- Cycle through the available layout options by left-clicking on the menu.
- Choose a specific layout using the dropdown.
- Available layouts vary based on the volume displayed.
- See the description of Cycle Views for more about display.

Color Table

- Select a color scale with a left-click.
- Color scales are available based on the displayed modalities.
- Submenus are used when there are multiple displayed modalities.

Show/Hide MIP

- To toggle the visibility of the MIP Movie, left-click on the Show/Hide MIP Icon.
- Showing or hiding the MIP will affect the layout.

Presets/Reset

- CT contrast presets are available with a left-click whenever a CT is displayed.
- Reset the PET contrast with a left-click when a PET is displayed.
- Submenus are used when there are multiple displayed modalities.
- See the Contrast section under Image Manipulation for more contrast control.

Cycle Views

- If views are only shown in one plane, left-click to cycle all views together through the axial, sagittal, and coronal planes. The appearance of the MIP will not change.
- If views in all planes are shown, left-click to change which plane is dominant in the layout.

Blend

- Cycle through the available blend options by left-clicking on the menu.
- Choose a specific blend setting using the dropdown.
- Blend settings are applied to the visible fusion.

Utilities

The utilities are found at the top right and help manage data within the software.

Patient

- See a list of available patients with a left-click on the Patient Icon.
- Select a patient to see the series in the study.
- An individual series can be selected with a left-click.
- Burn series to one or more CDs using the options under "CD Burning."
- Move series to other locations by clicking on "Send To..."
- Hide the patient list with another left-click on the Patient Icon.

Options

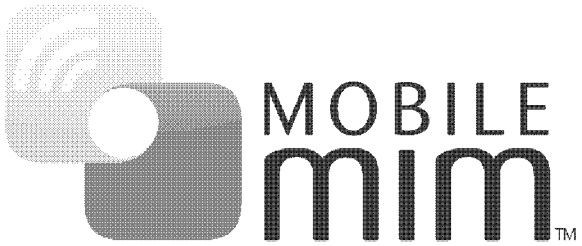
- Access General and MIP Movie Preferences with a left-click.
- Several language options are also available.

Capture

- To save a screen capture to a file, select "Capture to File" from the Capture Menu. When prompted, browse for a location and select a name for the file.
- The "Capture to Clipboard" option copies the screen capture to the system clipboard. Once in the clipboard, the capture can be pasted into another program.
- The "Print" command opens a dialog to send the capture to a selected printer.

VOL 013 – PROPOSED LABELING

001_Mobile MIM User's Guide (draft)



USER'S GUIDE

version 2.1

version 2.1

TBD - Draft

Mobile MIM Hardware Requirements

Apple devices running iPhone OS, such as iPhone, iPod touch, or iPad.
Operating System: iOS 3.2 / 4.0 / 4.1 / 4.2

Mobile MIM Software Requirements

Mobile MIM is available from the App Store on iTunes or directly from the phone. An iTunes account is required to download the application.
Operating System: iOS 3.2 / 4.0 / 4.1 / 4.2

MIM Workstation/Server Systems Recommendations and Guidelines

PC

Intel Core i7 (Quad Core)
8+ GB 800+ MHz RAM
16x DVD+/-RW Drive
1 TB Hard Drive
512 MB Dual DVI Graphics Card
One 24" LCD or Two 19" LCDs
(HP LP2475w, HP LP1965)
Gigabit Ethernet
Microsoft Windows 7 Professional 64-bit or
Microsoft Windows Vista Business 64-bit

Mac

iMac 27-inch Intel Core i7/Mac Pro–Intel Quad-Core Xeon
8+ GB RAM
SuperDrive
1 TB Hard Drive
512MB ATI or NVIDIA Graphics Card
Apple Display(s)
Mac OS X 10.6
AppleCare

CE 0120

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邮箱 info@mimsoftware.com

MOBILE MIM USER'S GUIDE

Indications For Use / Intended Use

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

contents

MOBILE MIM 2.1

MOBILE MIM 2.1

Mobile MIM is a multi-modality imaging application for the Apple iPhone, iPod Touch, and iPad. This innovative software allows a referring physician to view medical images remotely.

Mobile Device Setup

Mobile MIM is available from the App Store on iTunes or directly from the mobile device. An iTunes account is required to download the Mobile MIM application.

The Mobile Device must be connected to either Wi-Fi or the cellular network. If connected to the cellular network, the server must have a public IP address.

Install the Mobile MIM Application

From the iTunes store, either search for Mobile MIM by typing in the upper right, or browse to find Mobile MIM in the Medical category.

Left click Get App, and wait for the download to finish.

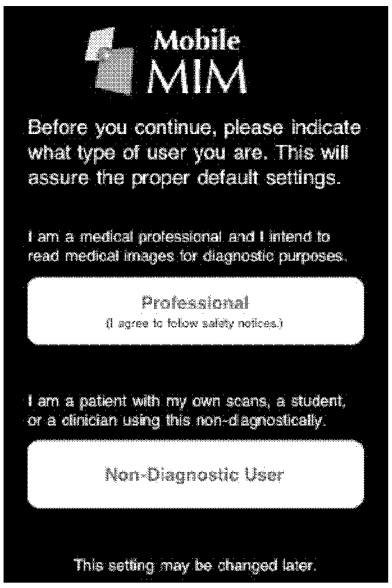
Sync your mobile device with iTunes. Once complete, Mobile MIM will appear on the home page.

Mobile MIM may be downloaded directly from the App Store on the Mobile Device as well, and can similarly be found with a search or in the Medical category.

Selecting User Type

Mobile MIM can be used by professionals and non-professionals. The first time Mobile MIM runs, it will ask you to select which type of user you are. Choose Professional if you intend to read medical images for diagnostic purposes. Otherwise, choose Non-Diagnostic User.

As a Professional user, you will have additional safety features enabled by default. Also, you will be required to register your software with MIM Software Inc. This enables MIM Software to contact you with important information regarding Mobile MIM, including recall notices and critical version updates. Please be aware that this is a regulatory requirement in many countries.



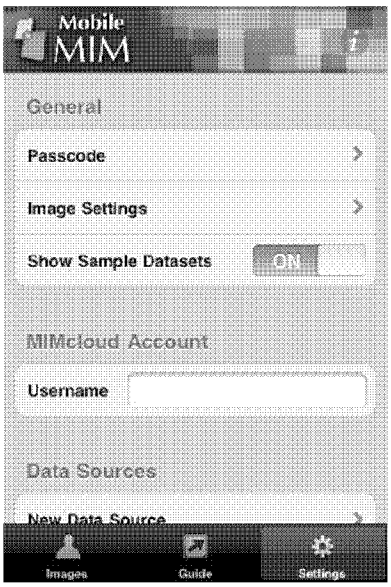
Configure Image Access

There are two ways to get images to Mobile MIM. First, Mobile MIM can connect to MIMcloud.com, a secure, Internet-based medical imaging service that provides a central, easily accessible resource for storing, sharing, and viewing. Visit www.mimcloud.com to learn more and create an account.

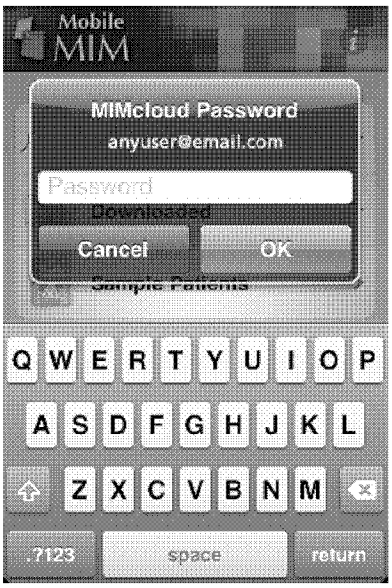
The second is by connecting to a MIMfusion workstation through a Wi-Fi network.

Connecting to MIMcloud

Tap the Mobile MIM logo to launch the application, then tap Settings in the lower right corner. Enter the MIMcloud username that you set up at www.mimcloud.com. The user name is the e-mail address for the account.



Next, tap the MIMcloud item on the Images page. It will ask for your MIMcloud account password. It does not write that password to disk, for security reasons, and will ask you once each time you run Mobile MIM.

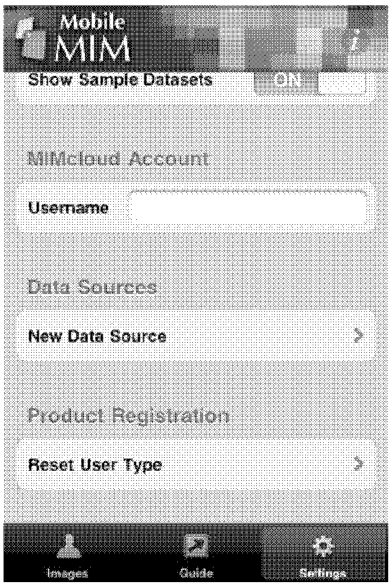


Connecting to a MIMfusion Workstation

Mobile MIM can also connect to a configured MIMfusion workstation. A network connection to this workstation is required to download images. If not on the same network (for example: at home accessing a MIM workstation at the office), then a VPN may be required. If so, work with a network administrator. To connect to the VPN from the Mobile Device, tap Settings, then General, then Network, then VPN.

See Mobile MIM Mobile Supplement Guide for instructions on setting up the MIMfusion workstation and exporting data to your device.

Tap on Settings in the lower right corner. Touch and drag to scroll down to the section called Data Sources.

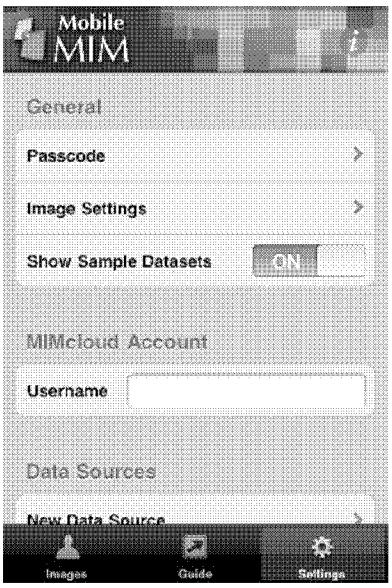


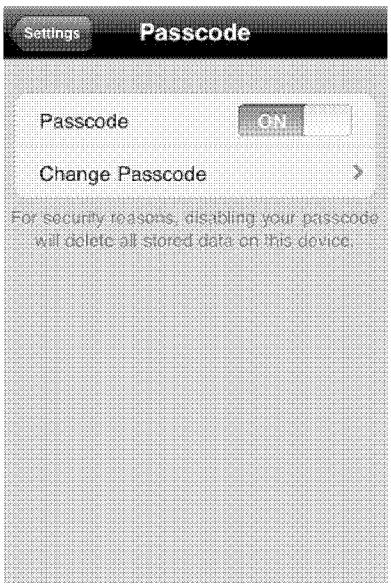
Tap New Data Source, and type the Source Name (this can be arbitrary) and enter the IP address or host name of the server. Type the username and password that was created on the server for this user. Tap Save in the upper right corner to complete.

Create a Passcode

Mobile MIM allows you to protect sensitive information through the use of a passcode. All the personal information in the downloaded medical images will be encrypted by that passcode. Mobile MIM will require you to enter the passcode upon launch. The encryption is 128 bit AES. You can set up the passcode in the Settings section of the main page.

Tap Passcode from the Settings page and turn it on.





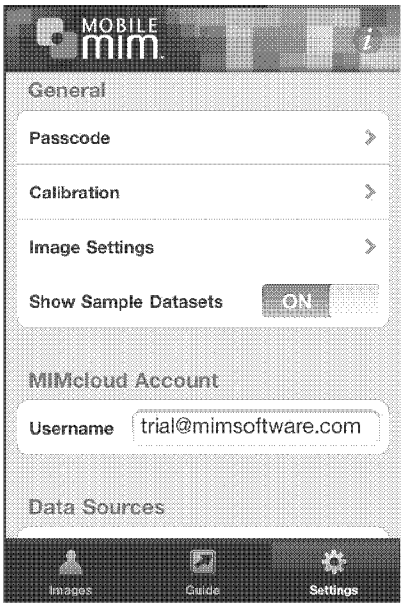
Type the passcode twice to be sure it is entered correctly.

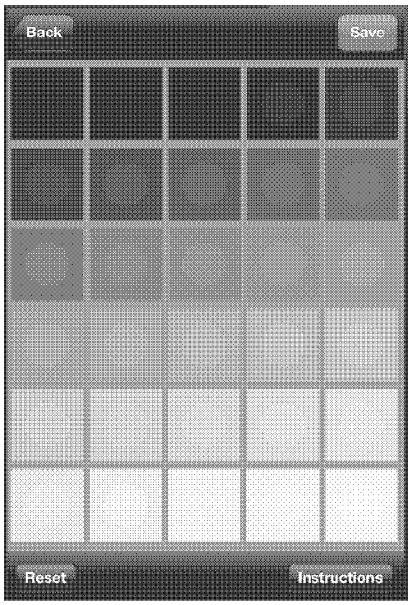
⚠ If you do not set a passcode, data downloaded will not be encrypted. As an additional security measure, if you have a passcode and later remove it, all data is deleted from the device.

You can change the passcode at any time by returning to Passcode and tapping Change Passcode. Changing the passcode will not delete any of the images already downloaded.

Calibration

Look at the display of circles on squares. Notice the relative contrast of each circle over its square. Tap the squares where the circle seems dim or faint in comparison to others.





It is recommended to first scan visually across the rows, looking for obviously dimmer circles. Tap them until they have more contrast and seem similarly contrasted with those in same row.

Next, scan up and down over the columns. Are the circles in the second row more obvious than those in the bottom row? Then tap on the bottom square. After each tap, see if it is better balanced with the others in the column.

Now that you've changed one, re-check its row. The rest of the row may need to be adjusted to match the one you just fixed.

Repeat a few times.

Finally, look at the whole field of circles. Try not to focus on any particular circles, almost like you are looking through the screen, not directly at it. Are all the circles visible? None seem too dim? Then you're done. Save it.

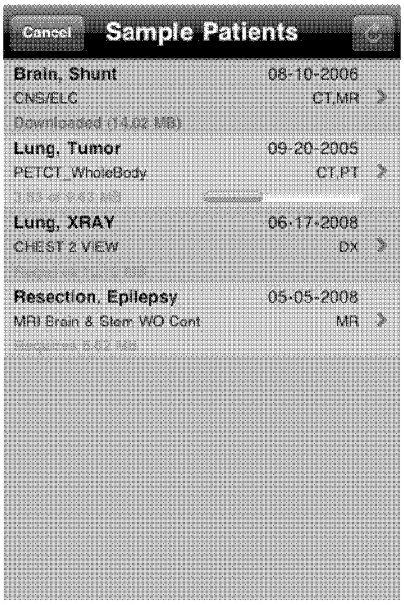
You can reset at any time and start over, using the Reset button at the bottom.

Managing Images

Download/View Images

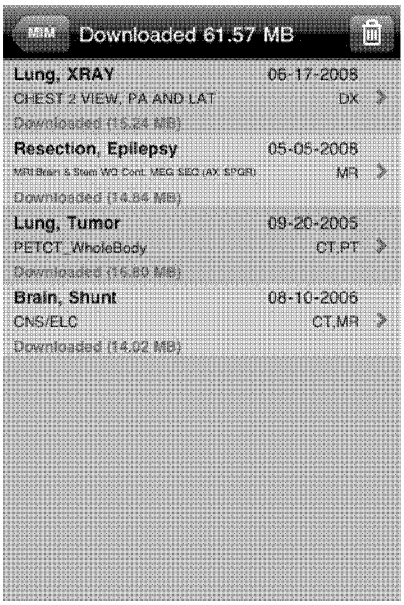
Launch Mobile MIM from the home screen which will default to the Images Screen. Tap the data source you would like to use, whether MIMcloud, Downloaded images, Sample Patients, or a configured MIMfusion Workstation.

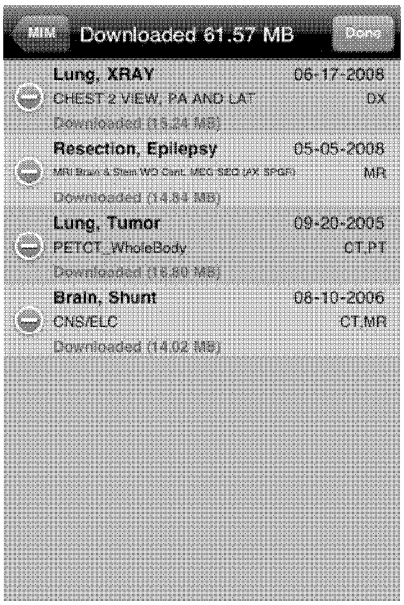
The data source will be accessed and a list of studies will appear. If the study is already downloaded, it will note that in the listing. Tap a study to begin downloading a new study. After the transfer is complete, the study will open for review.

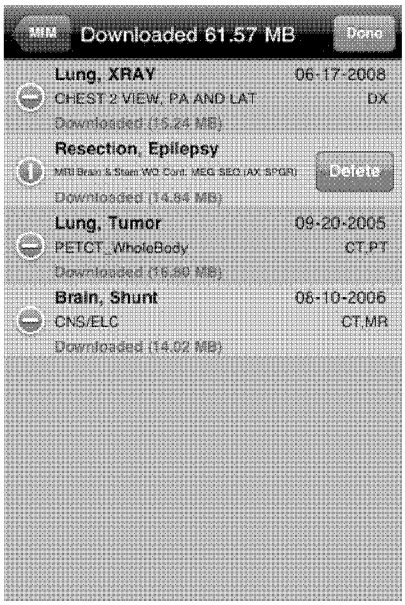


Delete Images

To delete images from the Mobile Device, tap Downloaded. Images can be deleted with the normal delete swipe function. Alternately, tap the trash can in the upper right and select images to delete.





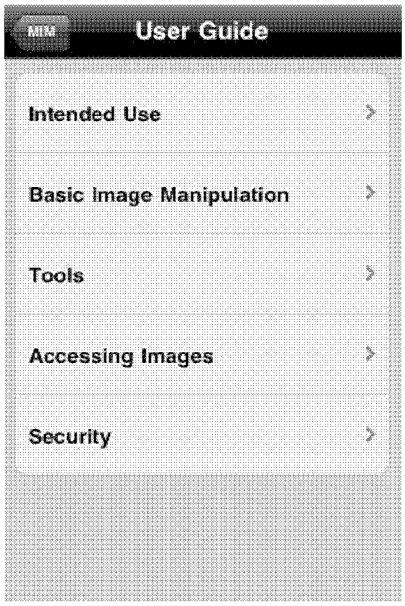


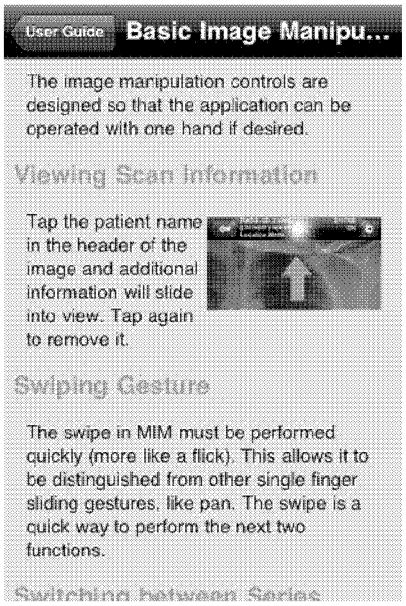
User Guide for Interacting with Mobile MIM

The application comes with a User Guide, accessible by tapping Guide on the main screen.

From there you can access the User Guide, Safety information, Frequently Asked Questions and Support for contact information.

The User Guide includes a section for Basic Image Manipulation which describes how you interact with the images while viewing them (e.g. Window/Level, Zoom and Pan).





The User Guide includes other information as well, including details on accessing image data.

Basic Image Manipulation

The image manipulation controls are designed so that the application can be operated with one hand if desired.

Viewing Scan Information

Tap the patient name in the header of the image and additional information will slide into view. Tap again to remove it.

Swiping Gesture

The swipe in Mobile MIM must be performed quickly (more like a flick). This allows it to be distinguished from other single finger sliding gestures, like pan. The swipe is a quick way to perform the next two functions.

Switching between Series

To cycle between different image series, or volumes, swipe left/right with one finger, or select a series from the "Volumes" button on the toolbar.

Switching Between Viewing Planes/Images

To cycle between axial, sagittal, and coronal planes of reconstructed image sets (not 2D), swipe up/down with one finger, or press the "Views" button on the toolbar.

With 2D images, the swipe moves between images in the series.

Contrast Adjustment

While viewing a single modality (CT, PET, etc.) slide one finger over the image. The contrast setting appears in the upper right corner during manipulation.

- Up/down changes the window.
- Left/right changes the level.

Tap the screen with two fingers at once to reset it to the initial contrast.

Fusion Blending

While viewing a fusion volume, slide one finger up and down over the image to change the percentage of blend between primary and secondary volumes.

Zoom

To magnify a portion of an image, use the pinch gesture. Alternately, double-tap on an area to zoom and localize the crosshairs at the same time. For large images, the double-tap zooms directly to a 1:1 resolution. Double-tap again to zoom out.

Pan

While zoomed in on a portion of an image, pan by sliding with one finger. Note that panning too quickly can trigger a swipe gesture.

Contrast/Blending when Zoomed

When zoomed in, one finger becomes pan. Therefore, to access the contrast and blending, slide two fingers together instead of one.

Localization

Localize the crosshairs to a new position on the volume by touching and holding still for a brief moment. When the crosshairs expand, slide them to the desired position and lift your finger.

Double-tap while crosshairs are still expanded to zoom to that exact point.

Scroll through Slices

To scroll through slices, slide one finger up and down in the scroll area at the right edge of the screen. This area is dedicated to scrolling and functions no matter which viewing plane is displayed. A scroll indicator shows the relative position of the current slice.

The scroll area is also present when viewing in landscape orientation (MPR), but only on the large view on the right.

Multi-planar Reconstruction (MPR)

Turn the device sideways to view "volumetric" data as a multi-planar reconstuction. Gestures, such as localization or swiping to change volumes/views, will continue to function.

Skip to a Slice

To skip directly to a slice, double-tap the scrollbar at the right edge of the screen at the desired position.

Go One Slice Up/Down

To go up or down one slice at a time, tap above or below the middle of the scrollbar. However, if you do this too quickly, Mobile MIM will treat it like a double-tap and skip to the slice.

Tools

Safety Tools

Additionally there is a section in the on-screen user guide which describes the Safety Tools (for aiding in assuring safety and effectiveness), and Tool Modes for measurements (i.e. length and SUV).

Read Map

When the Read Map is enabled, it aids in reviewing large matrix 2D images by giving a visual indication of what has and what has not been reviewed at full 1:1 resolution. Areas that have been viewed at 1:1 resolution or greater will not be tinted when zoomed out. Use this to assure adequate reading coverage of large images that greatly exceed the screen resolution.

Verify Lighting

This tool brings up the ambient light verification tool. Use this to evaluate the brightness of the area in which you are using Mobile MIM.

If you are unable to pass the check, a warning icon will show in the header. Pass the test and the warning will be removed.

If you do not see the low contrast square, there is guidance available at that time to help you make sure all conditions have been accounted for.

Tool Modes

Most tools function as a mode. The name of the tool is displayed in the header along with a "Done" button to leave the mode.

Measure

Slide one finger to drag the start of the measurement line. Repeat to position the endpoint. Place as many lines on as many slices or planes as desired.

Tap on a line to allow repositioning of its endpoints. Tap on the image (away from a line) to cycle through each measurement for review.

SUV

The SUV tool measures the maximum, minimum, and mean SUV value of PET scans within a dynamically sized sphere.

Slide one finger to position the SUV measurement sphere. Pinch to resize the sphere. Localization is locked to the center of the sphere, so you can easily cycle views and review it in three planes.

This tool only measures values for functional modalities, like PT and NM. This tool reports the values in the units of the scan (SUV is a unit of PET scans).

Annotate

Slide one finger to position the tip of the annotation arrow. Repeat to position the endpoint of the arrow. A keyboard will appear to enter your annotation. Place as many annotations as you desire. Tap on the image (away from the annotation) to cycle through each annotation for review.

Safety Guide

Tap Safety on the Guide page to view the Safety Guide. These instructions review important safety information for using Mobile MIM in a safe and effective way. The red warning badge will appear on each safety topic that has not yet been reviewed.

The topics covered by the Safety Guide include: Ambient Light, Screen Brightness, Careful Use, Distracting Environments, Dirty Screen, Viewing Angle, Compromised Mental Clarity, Screen Protectors, Motion, Poor Vision, Shaky Hands, Cracked Screen, Wireless Access, Damage (e.g. Crushing, Mutilation, Submersion, and Incineration), Battery Life, Lack of Training, Lack of Information, and New Hardware and Operation System Changes.

USER'S GUIDE

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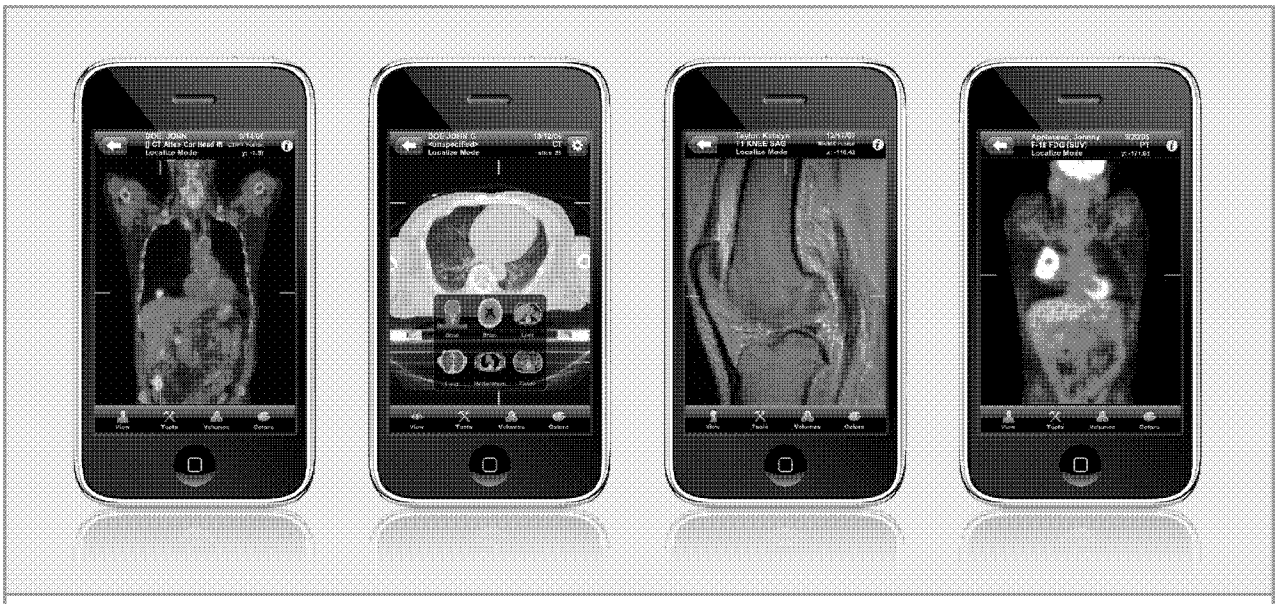
VOL 013 – PROPOSED LABELING

002_Mobile MIM Marketing Sheet (draft)



Remote Medical Imaging for the iPhone

- ✓ Remote imaging on the iPhone®, iPod touch®, or iPad®
- ✓ Multi-planar reconstruction of data sets including SPECT, PET, CT, and MRI
- ✓ Multi-touch interface including zoom, fusion, blending, and window/level
- ✓ Data encryption ensures patient privacy
- ✓ Includes sample images
- ✓ Available from the Apple App Store
- ✓ Requires MIMcloud or MIM Workstation

DRAFT

to see how Mobile MIM can improve your interface with remote medical imaging, visit www.mimsoftware.com

 Rev. Date Draft TBD

VOL 016 - SOFTWARE

001_LEVEL OF CONCERN

LEVEL OF CONCERN

MIM Software has determined the level of concern of this device to be minor. This is consistent with FDA Guidance Document *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)."* Justification and rationale for this determination is included in Table 1 and Table 2 below.

Table 1 – Major Level of Concern

Question 1: Does the Software Device qualify as Blood Establishment Computer Software?

Response: *No. Mobile MIM is a standalone software program, designed for use in medical device imaging management.*

Question 2: Is the Software Device an accessory to a medical device that has a Major Level of Concern?

Response: *No. Mobile MIM is standalone software. It is not an accessory.*

Question 3: Prior to mitigation of hazards, could a failure of the Software Device result in a death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining device?

Response: *No. Mobile MIM is not used in a life supporting or life sustaining application.*

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such a radiation treatment systems, defibrillators, and ablation generators?

Response: *No. Mobile MIM does not contain or control any potential sources of harmful energy.*

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

Response: *No. Mobile MIM does not control the delivery or treatment of any therapy.*

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

Response: *No. Mobile MIM does not "directly" drive a decision but assists the operator in making decisions.*

e. Does the Software Device provide monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

Response: *No. Mobile MIM is not a monitoring device.*

Table 2 – Moderate Level of Concern

Question 1: Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

Response: *No. Mobile MIM is standalone software. It is not an accessory.*

Question 2: Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

Response: *No. Mobile MIM does not "directly" drive a decision but assists the operator in making decisions.*

Question 3: Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

Response: *No. A malfunction of Mobile MIM would not cause a delay of appropriate medical care since a malfunction would result in the operator using traditional methods to make a medical decision. A malfunction is recognized by the operator since the operator has the responsibility to review Mobile MIM functionality and make appropriate changes when necessary. The delay in making a medical decision would only be the several minutes necessary to load a patient and initiate the Mobile MIM functionality to detect the malfunction. Mobile MIM is not used for medical decisions that are made in near real time.*

Conclusion: Minor Level of Concern

VOL 016 - SOFTWARE

002_PRODUCT SPECIFICATION

VOL 016 - SOFTWARE

003_DEVICE HAZARD ANALYSIS

DEVICE USE-SAFETY

GENERAL NOTE:

THE INFORMATION INCLUDED IN THIS SECTION WAS DEVELOPED IN ACCORDANCE WITH FDA GUIDANCE ENTITLED: "MEDICAL DEVICE USE-SAFETY: INCORPORATING HUMAN FACTORS ENGINEERING INTO RISK MANAGEMENT" (JULY 18, 2000). THIS GUIDANCE DESCRIBES HOW HAZARDS RELATED TO MEDICAL DEVICE USE SHOULD BE ADDRESSED DURING DEVICE DEVELOPMENT AS PART OF THE RISK MANAGEMENT PROCESS.

ESSENTIAL COMPONENTS CONSIDERED WHEN ADDRESSING USE-RELATED HAZARDS INCLUDED: DEVICE USERS, TYPICAL AND ATYPICAL DEVICE USE, DEVICE CHARACTERISTICS, CHARACTERISTICS OF THE ENVIRONMENT IN WHICH THE DEVICE WILL BE USED AND INTERACTION BETWEEN USERS, DEVICES AND ENVIRONMENTS.

BY DOCUMENTING THE FOLLOWING OUR AIM IS TO PROVIDE EVIDENCE THAT MOBILE MIM IS SAFE AND EFFECTIVE AND THAT ANY MITIGATING RISK ASSOCIATED WITH THE USE OF THE DEVICE IS OUTWEIGHED BY THE CLINICAL BENEFIT IT PROVIDES.

DEVICE OVERALL

Purpose and operation

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Population on which it is used

Mobile MIM provides display of medical images on a portable device for viewing by trained medical professionals. It is not used on patients directly, but is used for diagnosis and review of images by physicians.

Definitions, Software and Hardware

The Mobile MIM "device" is software and not hardware. It operates on off-the-shelf hardware manufactured by Apple. Because it is closely tied to the hardware, the information that follows will include discussions about the hardware and its characteristics. These details are important to understand the technical characteristics that Mobile MIM incorporates.

For the remainder of this document, the term "device" will refer to the off-the-shelf hardware manufactured by Apple (iPhone, iPod touch, and iPad). The term "Mobile MIM" will be used to describe the software, the object of this 510(k) submission. This distinction is necessary in order to simplify the discussion of the hardware, in which the term "device" will often stand for the list of similar portable devices made by Apple.

Hardware (Physical) Device

The hardware device provides a screen on which Mobile MIM displays medical images and computing hardware which runs the device's operating system (iOS) and the Mobile MIM software.

The iPhone™, iPod®, and iPad® are hand held electronic devices powered by battery. They function as portable computers, having all the components of workstations in smaller form: CPU, long term storage memory, RAM memory, user input mechanisms, display screen, fully functional operating system (Apple® iOS™), and network connectivity (wireless).

The screen on the earlier devices (1st, 2nd, 3rd Generation iPod touches and iPhone 2, 3, and 3GS) is 3.5 inches diagonal with 480 by 320 pixels at 163 pixels per inch. The later devices (4th Generation iPod, and iPhone 4) use Apple's Retina display which is 3.5 inches diagonal with 640 by 960 pixels at 326 pixels per inch. The iPad has a 9.7 inch screen, 1024 by 768 pixels, and 132 pixels per inch.

Brightness of the screen backlight is adjustable at a system level. Set at their brightest (recommended), measurements with a photometer have shown that maximum luminosity varies across devices from 224 to 317 cd/m^2, and the minimum luminosity from 0.4 to 3.9 cd/m^2. The contrast ratios range from 81:1 (an iPhone 3GS) to 523:1 (an iPhone 4). When converted to Just Noticeable Differences according to the GSDF, the number of

JND values displayed for the device with 81:1 ratio was 494 JND, and for the device with 523:1 ratio it was 574 JND.

Future devices will certainly be produced by Apple which differ from these models. As a general rule (and as evidenced by the iPhone 4 and iPad), it can be anticipated that the specifications of these devices will continue to improve, and that they will generally exceed the requirements specified here. Nevertheless, the risk exists that a future device's hardware specifications will not meet the levels verified against in this submission. To mitigate this risk, a mechanism is in place to notify users of unverified hardware or OS versions. This is described in the Use-Related Hazards below.

Comparison of Mobile MIM Use with Similar Devices

As Mobile MIM is being used for viewing of medical images, a specific description in terms of medical displays is warranted and include in the following:

Medical Display Characteristics

The differences between Mobile MIM and standard medical viewing systems raise the same questions that are a part of the dialog of the radiological industry as a whole, in that image characteristics have consistently pressed the limits of existing hardware. These questions have, and continue to be, effectively answered by software.

The digital radiography guidelines put forth by the American College of Radiology (ACR) describe medical displays in two contexts: small matrix size (e.g., CT, MRI, Ultrasound, nuclear medicine, and digital fluorography) and large matrix size (e.g., digital radiography, digitized radiographic films, and digital mammography). Mobile MIM does not include CR in its intended use. However, the ACR guideline is still pertinent in that it describes the situations that arise when the image dimensions exceed those of the physical display, as is commonly the case for large matrix digital radiography. This is the situation that will often occur when using a small device for small matrix modalities like CT and MR. Therefore, large matrix image guidelines will be the focus of the discussion, in terms of safety and effectiveness.

It is understood that Mobile MIM operates on devises with displays that do not meet all of the recommended guidelines for medical displays put forth by the ACR. This limitation not inherently mean that diagnostic capability is absent, but underscores the fact that *CARE SHOULD BE TAKEN* to mitigate the risk involved.

The ACR acknowledges the clinical necessity of tools which operate outside of their guidelines:

"The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines." (ACR Practice Guideline for Digital Radiography, 2007, p. 23)

It is with the understanding that physicians can, and do, encounter situations which require tools outside of the expressed guidelines, that we placed great importance on developing features to mitigate the associated risks. Doing so provides a tool to the physician which both fits the criteria for "responsibly adopting a course of action different from ... the guidelines" and provides the physician a device that has undergone scrutiny and testing in order to verify that it is safe and effective for just such a purpose.

The ACR lists several characteristics of medical image displays which are pertinent to Mobile MIM.

Screen Size

Typical diagnostic workstations utilize large format viewing displays. Many medical imaging modalities can be rendered on these displays with minimal or no zooming and panning. Large matrix size images, however, can regularly exceed the pixel dimensions of these monitors. Mobile MIM provides the proper software compensatory tool needed when the screen is smaller than the image, as described by the ACR:

"For those images, zooming and roaming display functions are required to achieve a correspondence between the detector element matrix and the display pixel matrix, so that resolution of the display monitor does not limit the resolution of the partially displayed image. This is true for any size image where the detector element matrix size exceeds the display pixel matrix size." (ACR Practice Guideline for Digital Radiography, 2007, p.39)

The earlier model iPod and iPhone screens are 320x480 pixels, smaller than typical CT scans (512x512) and several times less than digital x-rays which can be 2000x2000 or greater. (b)(4)
(b)(4)
(b)(4)

Maximum and Minimum Luminance

The ACR recommends a ratio of maximum to minimum luminance to be at least 50. Mobile MIM operates on devices which have contrast ratios greater than this, averaging well over 100. Additionally, the ACR states that the maximum luminance should be at least 250 cd/m^2. Measurements indicate that the iPhone and iPod touch generally exceed this as well, with only one of the six devices tested falling slightly below that at 224 cd/m^2 and with upper measurements reaching about 320 cd/m^2.

Contrast Response

The ACR recommends that the contrast response of the display should comply with the AAPM Task Group 18 recommendations, not deviating from the DICOM Grayscale Standard Display Function by more than 10%. Mobile MIM operates on devices which do not, in their native contrast response, meet this guidance.

(b)(4)
(b)(4)

Ambient Lighting

The ACR recommends that the effect of ambient lighting on the display should be included in luminance measurements and that reflections from ambient light sources be kept at a minimum. Mobile MIM operates on portable devices which cause environmental conditions to be inconsistent and impractical to measure. To accomplish full compliance with the ACR guideline, one would have to carry a photometer and, when the need arises to view the medical image, first perform a calibration with the meter to correct for whatever the current environment may be.

This is completely impractical. (b)(4) (b)(4)

1) (b)(4)

2)

3)

Bit Depth

The ACR recommends 8-bit luminance resolution (bid depth). The screens on the earlier iPhone and iPod touch models (iPod touch 1st/2nd/3rd Generations and iPhone, iPhone 3G, and iPhone 3GS) have less than this, though the exact bit depth is not made public by manufacturer. What is known is that the hardware uses an unspecified dithering technique (temporal, spatial or a combination of the both) to produce the effect of 8-bit depth. These devices, when tested using TG18-MP test pattern, matched the 8-bit resolution markers (see 002_Non-Clinical Data Report in VOL 021-OTHER). Later models (iPad, iPhone 4, and iPod touch 4th Generation) are most likely native 8-bit screens. They also match the 8-bit patterns on TG18-MP. (b)(4) (b)(4)

Device Addresses Needs of Intended User

The device addresses the needs of the intended user in one primary way: providing means to visualize medical images when there is no access to a workstation. This has application in three general situations: 1) When there are no workstations accessible, 2) when time doesn't allow for access to a workstation, and 3) when a expert or peer consultation is desired and that individual may not have access to a workstation.

No Access to a Workstation

Situations will arise when there will not be any medical imaging tools available for the physician who requires them. For example, if the physician is located in remote locations, rural, or underserved populations. Mobile MIM addresses this need.

No Timely Access to a Workstation

Medical professionals can routinely be found in situations where there is no convenient access to medical imaging workstations (attending classes, conferences, at restaurants, on vacations, etc.). Workstations would be available, but the time it would take to access them would not be deemed acceptable in terms of patient care.

Expert or Peer Consultation

On occasion, the professional advice of a peer or an expert is needed by the physician during the course of patient care. Such third-party involvements are typically inconvenient due to coordination efforts to get the expert to a workstation in a timely manner and to assure the expert has access to the images needing reviewed.

DEVICE USER INTERFACE

Mobile MIM is software that operates on the iOS™ operating system which uses a touch screen interface for its primary user interaction. Users can touch the screen with one, two or more fingers and the application can detect and respond to those events, much like typical workstation software responds to mouse events. The touch interface has been fully developed by Apple® and incorporates a set of gestures which are used consistently throughout the applications that Apple® provides on the device, as well as the applications of 3rd party developers.

Mobile MIM takes full advantage of the common gesture framework to provide control actions which are consistent with users' abilities, expectations, and likely behaviors.

Of primary importance on a device with a small display is the ability to zoom and pan the images. (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

A description of the gestures and tool usage functionality is available within the application, easily accessible from the main image viewing display. Other tools are described there as well, among them, the single finger slide to change contrast (window/level), the contrast reset gesture, blending percentage adjustment for multi-modality fusion studies, the measurement tools, and color lookup table selection.

Operating instructions for safe and effective use are available from the primary application screen, and are presented to the user when application is used the first time.

MOBILE MIM USE

Mobile MIM provides the user with two means for access to data.

First, the Mobile MIM settings panel has a place to enter a MIMcloud account. The MIMcloud account is setup outside of Mobile MIM. Data is placed into that account by several means outside the scope of Mobile MIM. Data available to the MIMcloud account holder will be available to him or her through the configuring of that account into Mobile MIM.

Second, from settings the user can access a Data Source setup panel where the user enters the username, password, and network address of the MIM Workstation server which provides the data to the device.

Both methods provides access to the data through the wireless network. The user touches the configured data source and sees a list of all the studies that have been made available to the user from the server. Selecting a study initiates a secure wireless download and finally displays the first series of that study.

The user manipulates the image data as needed to visualize the information therein, and can touch a button to reveal a selection list of the other series contained in that study. Meta information about all the series in the study can be viewed by touching the patient info header atop each view.

The medically pertinent image review tasks performed by the professional is the scrolling through the slices of data, the zooming and panning to visualize all of the pixels, and the changing of contrast to visualize the range of data contained in the pixels. For large matrix planar images, the user would additionally see and utilize the "Read Map" overlay to identify the areas of the image not yet visualized at 1:1 resolution (see Use-Related Hazards Section, below, for description of "Read Map" and other risk mitigating features).

DEVICE USER POPULATION

The intended population of users is medical professionals who desire or require remote and portable access to medical image data as a part of their responsibilities for providing patient care. These users are trained to interpret medical images and must have the visual acuity (whether with or without corrective lenses) to see the information presented on a computer screen.

Of specific concern for these users are the differences that a portable device presents as compared with their everyday reading workstation used in a controlled environment. Some users may be at least familiar with the issues surrounding portable devices because they have opted to use laptops or netbooks to accommodate their professional duties. For others, a portable imaging solution will be a new and unique experience. Therefore, we consider our user population to be somewhat unaware of the risks associated with portable devices, and mostly unfamiliar with the experience of working outside of their typical, controlled, workstation environment.

All users will be instructed to step through several pages of training and operating instructions which warn about the potential risks associated with portable viewing (visual on screen aides help guide the user through this). These instructions furthermore describe the tools which will help assure safe and effective use. These will be discussed in detail in the Use-Related Hazards section of this document.

DEVICE USE ENVIRONMENTS

Mobile MIM is intended to be used in many locations and environments, provided they meet the recommended viewing conditions specified in the operating instructions, and that they do not impose any of the other disruptive situations explained within the operating instructions. Mobile MIM is unsuited for environments where those conditions are not met. The user is instructed to leave the unsuited environment before attempting to use the software.

Due to the portable characteristic of this device, the use environments make up a significant portion of the Use-Related Hazards and are therefore discussed below.

USE-RELATED HAZARDS

Use-Related Hazards associated with use of Mobile MIM can be divided into two general categories, those that are typical to any medical image viewing device, and those that are specific to the small and portable nature of Mobile MIM. This document will focus on the latter, as those issues are more unique to this device. However, a complete analysis and mitigation of risks of both types can be found in the Product Assessment and Hazard Identification and the Risk Analysis Evaluation Matrix documents.

Process used to identify and prioritize use-related hazards

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The identified use-related hazards

Mobile MIM diverges from the user's typical reading room situation in that it is a tool that is accessible from almost anywhere. This presents a host of new potential risks that the average physician who views medical images has never had to consider. The risks that arise from a mobile viewing tool are those that would interfere with the process of diagnosing medical images. Therefore, the operating instructions are designed to provide a broad list of situations which can interfere with the physician's ability to see the images, interpret the images, or otherwise think clearly during image review.

The following warnings are presented to the user in a series of screens as a part of the standard operation of the software, each screen addressing each item. By including this in the software we prevent the loss of manuals or materials, and thus eliminate the "lack of instructions" hazard.

1. Warning about environmental lighting

   Ambient light can significantly reduce the contrast of the device, reducing your ability to perceive subtle image detail. Mobile MIM provides a means to Calibrate the device to adjust for its display characteristics, as well as a Verify Lighting tool to test your current environment and help ensure it is within acceptable levels.

   Calibration, accessible from Mobile MIM settings, provides an interface to adjust the grayscale lookup table specific to your device. Perform the Calibration in the recommended viewing conditions:

   Recommended Viewing Conditions are in a dimly lit office environment avoiding overhead fluorescent lights and exterior windows. This is an environment similar to a Radiology Reading Room.

   The Verify Lighting tool presents a low contrast square in the dark background. If you can see and tap the square, then the ambient lighting in your environment is acceptable. If you cannot see the square, you have the opportunity to move to a better location and try again. As an aide, a sequence of dialogs lists factors which may be interfering. If you are unable to pass the lighting verification, then the device, in the given environment, is not intended to be used as a diagnostic tool.

   When the Verify Lighting Automatic Check is active, the test will slide into view if it has been twenty minutes since you last used the app. The tool can also be run manually at any time from the Tools menu.

2. Warn about level of screen brightness and auto-dim

   To ensure proper luminance during the reading of an image, the device brightness should be set to maximum, and the Auto-Brightness feature should be disabled. This must be configured in your device Settings, not in Mobile MIM. The Verify Lighting check will help you notice if the brightness is too low, because the low contrast square will be very hard to see.

3. Warning about distracting environments

   Unlike a radiology reading room in a clinical environment, you may find yourself in situations which can be chaotic, noisy, or otherwise cognitively disruptive. You must be aware of this potential risk and remove yourself from the situation before attempting to diagnose the medical images.

4. Warning about viewing angle

   This device uses a Liquid Crystal Display (LCD), which will not display a uniform gradient of intensity values when viewed from an angle. You should always view the device directly, perpendicular to the surface of the display. Do not angle the device in an effort to try to perceive what may be a subtle intensity variation. Doing so will create arbitrary and artificial contrast characteristics which are not part of the medical image. Always use contrast (window/level) adjustments to reveal the more subtle details of a medical image.

5. Warning about dirty screen

   A touch screen is susceptible to dirt and oils and other foreign matter which can be transferred from fingers to the screen surface. These will obscure the image data and reduce contrast. Always be aware of your screen and wipe it before and during use if necessary. Carrying a lens cloth is recommended, although many types of clothing are effective at removing foreign matter.

6. Warning about compromised mental clarity

   As a portable device can be with you anywhere and in any circumstance, it is reasonable to expect that at some point you may need to use it when you are in a state of reduced mental clarity. For example, you may be asked to read medical images while you are drinking at a party or you may be roused from a deep sleep. Do not attempt to provide diagnostic review when you are in this state.

7. Warning about motion

   Unlike a workstation monitor which sits upon a desk, this device is very mobile. Do not attempt to use Mobile MIM if you are in an unsteady environment. For example, if you are the passenger in a car which is traversing rough terrain, have the driver pull over to provide you a still environment in which to read the medical images.

8. Warning about poor vision

   If you suffer from any visual impairment which requires you to use corrective lenses to view objects near you, then the possibility exists that you may be called upon to review an image when you do not have your corrective lenses with you. Do not attempt to read the images if you cannot see them clearly. If you expect to be on call for emergency reading of images, bring your corrective lenses with you.

9. Warning about screen protector

   Screen protectors are thin transparent films which many people apply to the surface of their device to protect from scratches, to reduce the visibility of finger prints, or to reduce glare. These external devices are not recommended as they may obstruct the image data or diffuse the clarity of the image. The screen is made of durable material which is not easily scratched and can optionally be protected in other ways, like cases, which when opened or removed, provide no obstruction to the viewing of the screen.

10. Warning about shaky hands

    Since Mobile MIM operates on handheld devices, if you suffer from or experience hand tremors, you should not attempt to read medical images without placing the device against a stable surface.

11. Warning about lack of other information

    Information that is typically accessible at work, like reports, lab results, and even the patient, may not be readily available outside of the workplace. Some decisions may require additional data, and therefore may have to be delayed despite having access to the medical image data.

12. Warn about cracked screen

    There have been many reported cases in which the glass on the screen has cracked and the device has continued to function. Cracks are an obstruction to viewing the medical image. Replace or repair the device; do not use it as a diagnostic tool while still cracked.

13. Warn about need to patiently zoom and pan large images

    Use of zoom and pan is vital for diagnostic use, because the smaller screen is incapable of displaying the entirety of some medical imaging modalities. Pinch to zoom or double-tap to quickly zoom in to a target area.

    A Read Map function aids in providing visual indications on large images. Areas that have been viewed at 1:1 resolution or greater will not appear tinted when zoomed out. You can quickly see if there are still areas that should be considered at 1:1 resolution.

14. Warn about need to use contrast

    Calibration improves the contrast response to a level that permits sufficient display for the intended use. However, the contrast response of this device is not equivalent to that of a medical grade diagnostic workstation. Therefore, you should use contrast adjustments more extensively than you would on a typical workstation.

    Remember that contrast adjustments are simple and easy on Mobile MIM. When viewing a single modality (not fusion), sliding one finger up/down and right/left will adjust window and level, respectively. If you are zoomed in, sliding one finger adjusts pan, so slide two fingers together instead.

15. Warn about lack of training

    If you are going to be placed in situations where you may have to read images diagnostically on this device, then you should practice using the device ahead of time in the following manner. Take the opportunity to look at the same cases on both the device and the workstation, so that you may compare the two and, by practice, become familiar with the zoom/pan and contrast requirements to accurately visualize the image data.

16. Warn about battery life

    If you are responsible for being available to review images where you do not have access to workstations, it is vitally important that you maintain the charge of the device or have a power supply within easy access. Become familiar with the battery life of your device under your typical use patterns so you can better anticipate and prevent this problem from occurring.

17. Warn about difficulties of wireless access

    If you are expected to be available in situations where you have no access to a workstation, you should become aware of the wireless signal strengths in the areas you frequent, whether Wi-Fi or through the cellular network. If you are in an area of which you are not familiar, you should regularly glance at the device and take note of the network signal indicator.

    Download time depends on your network speed. Large scans can take a significant amount of time on slow networks. For example, a 40 slice CT can range from 9 seconds, when connected to a local workstation on Wi-Fi, to 5 minutes on a 3G network, to 30+ minutes when downloading over the Edge network.

    Understand that network capability will affect your availability for medical image viewing.

18. Warn about environmental damage

    Given that the device is an electronic device, it is susceptible to all the environmental hazards which are common to computers. Care should be taken to not expose the device to strong magnetic fields, excessive moisture, or other environmental situations which would damage computing equipment.

19. Warn about new hardware or new versions of the OS (Operating System)

    New hardware models and new versions of the iOS Operating System may prevent the device from performing according to its intended use. To ensure that you are aware of these changes, Mobile MIM regularly queries the MIM Software server (accessible through the internet) and transmits your current hardware, OS version, and Mobile MIM version.

    When your hardware or OS does not match a list of those already validated, you will receive a notification explaining the situation. Typically OS software changes will not produce these notifications, as MIM Software has already tested the OS as a part of its development process using release candidate OS software prior to its general release.

    Hardware changes, however, will require validation at the time the hardware becomes available. This may take several days, after which time you will receive a follow up notification of the results of the validation for your particular hardware.

No personal information is transmitted to the MIM Software server, only the information necessary to assure safe and effective use of the device, accounting for future changes that are unable to be addressed in advance. This mechanism may also be used for other safety notifications regarding the software, should the need arise.

How significant use-related hazards were mitigated or controlled

Section 21.8 of the Product Specification (PS-0005 21.8) describes the steps to mitigate the use-related hazards. We approached the issues from the perspective of the four risk mitigation steps from the Medical Device Use-Safety Guidance:

1. Modify design to remove hazard
2. Make design error tolerant
3. Detect and alert user to hazard
4. Develop written procedures/training for safe operation

We were able to address risks using all four steps.

Modify design to remove hazard

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Make the design error tolerant

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Detect and alert user to hazard

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Develop written procedures

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Why strategies used are appropriate

These strategies are thorough and address, through various means, the use-related hazards identified during testing. The effectiveness of these strategies is supported by the successful results of the testing performed.

VERIFICATION AND VALIDATION

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VOL 016 - SOFTWARE

004_Traceability Analysis Matrix of ECOs

VOL 016 - SOFTWARE

005_Development

SOFTWARE CERTIFICATION STATEMENT

As Quality Manager of MIM Software Inc., I hereby certify that the software information provided in the 510(k) Premarket Notification for Mobile MIM is accurate and its design, development and testing was done in accordance to the following procedures. In addition, all subsequent revisions to Mobile MIM will abide by the same guidelines.

Lynn Hanigan _____ 12/22/2010 _____

(Signature) *(Date)*

Lynn Hanigan
Quality Manager
MIM Software Inc

VOL 016 - SOFTWARE

007_Revision Level History

VOL 016 - SOFTWARE

008_Unresolved Anomalies and ECOs

VOL 021 - OTHER

001_Non-Clinical Data Discussion

VOL 021 - OTHER

002_Non-Clinical Data Report