U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (szs)

FOLDER: K112930 - 403 pages

COMPANY: MIM SOFTWARE INC. (MIMSOFT)

PRODUCT: SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)

SUMMARY: Product: MOBILE MIM

DATE REQUESTED: Apr 24, 2012

DATE PRINTED: Apr 24, 2012

Note: Printed

DEC - 2 2011

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:	Sept 30, 2011

Device Name

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

Predicate Device

K103785	Mobile MIM	MIM Software Inc.
K042956	Vision	Varian Medical System

Intended Use / Indications for Use

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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

Mobile MIM (RT) extends the Mobile MIM software application previous cleared under K103785. In addition to SPECT, PET, CT, MRI modalities, Mobile MIM can be used for the viewing and/or display for diagnosis of X-ray and Ultrasound medical images.

It also provides functionality for the review of medical images, contours, DVH, and isodose curves from radiation treatment plans. In addition, Mobile MIM (RT) will allow permitted users the ability to approve reviewed radiation treatment plans.

Substantial Equivalence

Mobile MIM is substantially equivalent to Mobile MIM software (K103785) and portions of the Vision product (K042956). It extends Mobile MIM functionality by adding 2 additional image modalities to its indication and having the capability to serve as a mobile reviewing device for radiation treatment plans.

Performance Data

MIM Software Inc. has performed multiple studies with qualified radiologists, dosimetrists and radiation oncologists. Radiologists tested Mobile MIM by evaluating the image quality of the two additional modalities of X-ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

MIM Software also orchestrated radiation therapy plan review tests evaluating multiple areas of treatments by trained medical professionals using plan data from 3 major vendors, and using both smaller format (iPhone and/or iPod touch) and larger format (iPad) devices. The results indicated the display quality for of isodose curves, DVH graphs, and contours was of acceptable quality for review and approval of radiation therapy plans, and were equivalent to those viewed on a full workstation.

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.

25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

www.mimsoftware.com

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

Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM (RT) provides a safe and effective diagnostic viewer of the following medical imaging modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. It also is safe and effective in that it is substantially equivalent to the radiation treatment plan review functionality of Vision (K042956), allowing for portable device characteristics and accessibility when there is no access to a full workstation.

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Fax: 216-455-0601

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, Inc.
25200 Chagrin Blvd, Suite 200
CLEVELAND OH 44122

DEC - 2 2011

Re: K112930
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ & MUJ
Dated: September 30, 2011
Received: October 3, 2011

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.

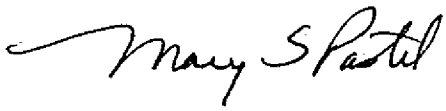
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 S. Pastel, Sc.D.
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 K112930

Device Name: Mobile MIM

Indications for Use:

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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) K112930

RH/D02AB

K112930

Date: Sept 30, 2011

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: 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 new version of Mobile MIM (RT) in the United States. This is a Traditional 510(k) submission extending the indications of the original Mobile MIM device (K103785). Our recommended classification for Mobile MIM (RT) remains a Class II Device under 21 CRF 892.2050; product code LLZ.

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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.

mim SOFTWARE

25800 Science Park Drive
Suite 225
Cleveland, OH 44122

216-521-4000
www.mimsoftware.com

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 (RT) is substantially equivalent to legally marketed devices which have been granted marketing clearance by the FDA under the 510(k) premarket notification process. This device is substantially equivalent to devices 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 (RT) substantially equivalent to the predicate devices referenced within this submission.

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.

MIM SOFTWARE

[illegible]
[illegible]
Cleveland, OH 44122

866-421-2546
www.mimsoftware.com

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

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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. 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
24-Aug-2011

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: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
9/30/2011	MD6057356-956733	

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: OH	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:		

PSC Publishing Services (301) 443-6740 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

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

- [ ] Response to FDA correspondence:

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

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

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

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

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

- [ ] 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)

- [ ] New Device
- [x] 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	LLZ	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	K103785	1	Mobile MIM	1	MIM Software Inc.
2	K042956	2	Vision	2	Varian Medical System
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	11104302	2		3		4	
5		6		7		8	
9		10		11		12	

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LLZ	892.2050	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Radiology

Indications *(from labeling)*

The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound.
Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans.
Mobile MIM can be used to approve these plans. 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 the information entered in Section H does not affect the need to submit device establishment registration.	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 OH	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.

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

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 Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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
9/30/2011

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
9/30/2011

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

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

VOL 003

001_510(k) COVER LETTER

25200 Chagrin Blvd.
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Date: Sept 30, 2011

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: 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 new version of Mobile MIM (RT) in the United States. This is a Traditional 510(k) submission extending the indications of the original Mobile MIM device (K103785). Our recommended classification for Mobile MIM (RT) remains a Class II Device under 21 CRF 892.2050; product code LLZ.

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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.

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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 (RT) is substantially equivalent to legally marketed devices which have been granted marketing clearance by the FDA under the 510(k) premarket notification process. This device is substantially equivalent to devices 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 (RT) substantially equivalent to the predicate devices referenced within this submission.

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.

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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.
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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 viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound.

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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: Sept 30, 2011

Device Name

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

Predicate Device

K103785	Mobile MIM	MIM Software Inc.
K042956	Vision	Varian Medical System

Intended Use / Indications for Use

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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

Mobile MIM (RT) extends the Mobile MIM software application previous cleared under K103785. In addition to SPECT, PET, CT, MRI modalities, Mobile MIM can be used for the viewing and/or display for diagnosis of X-ray and Ultrasound medical images.

It also provides functionality for the review of medical images, contours, DVH, and isodose curves from radiation treatment plans. In addition, Mobile MIM (RT) will allow permitted users the ability to approve reviewed radiation treatment plans.

Substantial Equivalence

Mobile MIM is substantially equivalent to Mobile MIM software (K103785) and portions of the Vision product (K042956). It extends Mobile MIM functionality by adding 2 additional image modalities to its indication and having the capability to serve as a mobile reviewing device for radiation treatment plans.

Performance Data

MIM Software Inc. has performed multiple studies with qualified radiologists, dosimetrists and radiation oncologists. Radiologists tested Mobile MIM by evaluating the image quality of the two additional modalities of X-ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

MIM Software also orchestrated radiation therapy plan review tests evaluating multiple areas of treatments by trained medical professionals using plan data from 3 major vendors, and using both smaller format (iPhone and/or iPod touch) and larger format (iPad) devices. The results indicated the display quality for of isodose curves, DVH graphs, and contours was of acceptable quality for review and approval of radiation therapy plans, and were equivalent to those viewed on a full workstation.

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.

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Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM (RT) provides a safe and effective diagnostic viewer of the following medical imaging modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. It also is safe and effective in that it is substantially equivalent to the radiation treatment plan review functionality of Vision (K042956), allowing for portable device characteristics and accessibility when there is no access to a full workstation.

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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)

9/28/2011

(Date)

Lynn Hanigan
Quality Manager
MIM Software Inc.

VOL 009 – Declaration of Conformity and Summary

001_Statement of Non Use of Standards

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MIM Software, Inc. claims no conformance to any standards.

Note that for our previous Mobile MIM 510(k)-103785 aspects of the IEC 62563 - 1 standard (Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods) and the TG18 test pattern were used as guidelines for our non-clinical testing of luminosity, resolution, and noise on a limited number of specific models of iPod, iPhone and iPad, we do not claim conformance to this standard as we do not manufacture the off-the-shelf hardware on which the Mobile MIM application runs.

VOL 010

001_EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

Device Description:

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

Mobile MIM can be used to approve these plans. 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.

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 predicates:

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Clearance Date	TBD	2/4/2011	3/11/2005
Intended Use / Indications For Use	The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans.	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.	The Vision product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, and plan verification and treatment. Vision also stores the treatment histories including dose delivered to defined sites, and ***provides tools to verify*** performed treatments. ***Vision is designed to assist the radiation therapy staff to prepare and approve treatment plans, and to perform quality assurance of the treatments***. The preparation tasks include image acquisition, viewing and manipulation, treatment plan definition, manipulation and scheduling.

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
	Mobile MIM can be used to approve these plans. 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.	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.	
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes	Yes

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes	No
Image Fusion	Yes	Yes	No
Multi-Planar Reconstruction (MPR)	Yes	Yes	No
Maximum Intensity Projection (MIP)	Yes	Yes	No
Standardized Uptake Value (SUV)	Yes	Yes	No

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Distance Measurements	Yes	Yes	Yes
Window/Level	Yes	Yes	Yes
Zoom/Pan	Yes	Yes	Yes
User Authentication	Yes	Yes	Yes
Modalities	SPECT, PET, CT, MRI X-Ray, Ultrasound	SPECT, PET, CT, MRI	CT, MRI, X-Ray
Remote Handheld Viewing Device	Yes	Yes	No

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Display contours	Yes	Yes	Yes
Review isodose curves from RTP	Yes	No	Yes
Review DVH	Yes	No	Yes
Approve RTP via an authorized user	Yes	No	Yes
Patient setup	No	No	Yes
Scheduling and business information management	No	No	Yes

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Plan simulation and modification	No	No	Yes
Operating Platform	Apple® iOS	Apple® iOS	Windows 95,XP,NT
Hardware Requirements	Apple® iOS handheld devices	Apple® iOS handheld devices	PC Server/Workstation

Substantial Equivalence Discussion:

The comparison chart above provides evidence to facilitate the substantial equivalence determination between the expanded indications of Mobile MIM and our chosen predicate devices, Mobile MIM (K103785) and Vision (K042956).

There is a direct correlation between the Intended Use/ Indications For Use statement of Mobile MIM (RT) and its predicate Mobile MIM (K103785) as the indications of this current submission extend those of Mobile MIM (K103785) by adding two additional image modalities, X-Ray and Ultrasound. All of the other functionality of the original Mobile MIM is maintained. The Indications for Use also extend to allow medical professionals the ability to review and approve radiation treatment plans which is substantially equivalent to comparable features of Vision (K042956).

The differences between Mobile MIM (RT) and Vision (K042956) include the functionalities that Vision (K042956) provides, that of Patient setup, Scheduling and business information management, and Plan simulation and modification. Mobile MIM (RT) does not provide these functionalities.

There are no new technological characteristics that affect safety and effectiveness for this Mobile MIM as the software operates on the same Apple hardware and operating system as the original Mobile MIM submission.

For a complete summary of the testing results done during Alpha development stages, see section *VOL 016 – Software 000 006_Verification and Validation Testing*. Testing summaries and subsequent discussion and feedback gathered from the testers provided ample evidence when used according to operating instructions Mobile MIM can be used safely and effectively.

Therefore, from all evidence gathered, it is our belief that these expanded of indications for Mobile MIM (RT) provide a safe and effective mobile diagnostic viewer of medical images that can be used to review and approve radiation treatment plans when the user does not have access to a full workstation.

Summary of Testing:

MIM Software Inc. performed multiple studies with qualified radiologists using the additional modalities of X-Ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

Additionally, radiation therapy users (radiation oncologists, physicists, and dosimetrists) compared Mobile MIM (RT) with three major manufacturers of TPS systems validating that the mobile device display was equivalent to the TPS workstation displays.

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.

VOL 011

001_DEVICE DESCRIPTION

DEVICE DESCRIPTION

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions and points 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.

Mobile MIM also provides the following workflow when review radiation treatment plans if connected to an OEM TPS.

1. Mobile MIM sets up connectivity to OEM TPS.
2. User will login using appropriate credentials on Mobile MIM.
3. Mobile MIM sends login information (authentication request) through Mobile MIM Service to OEM TPS.
4. OEM TPS grants/denies login with appropriate user type
   a. Reviewer
   b. Authorizer (i.e. able to approve plan after review)
5. Mobile MIM requests treatment plan list to Mobile MIM Service.
6. Mobile MIM Service requests treatment plan list from OEM TPS.
7. OEM TPS sends treatment plan list to Mobile MIM Service.
8. Mobile MIM Service sends treatment plan list to Mobile MIM.
9. Mobile MIM scans/searches treatment plan list for patient plan on Mobile MIM device.
10. Mobile MIM requests patient treatment plan from Mobile MIM Service.
11. Mobile MIM Service begins bundling patient treatment plans for storage and quicker retrieval.
12. Mobile MIM Service checks if patient plan is current.
13. Plan is downloaded to mobile device.
14. User reviews plan.
15. User accesses toolbar to choose Authorize (approve).
16. User verifies patient demographics.
17. User chooses a treatment site.
18. If desired, user approves plan by touching Authorize (approve) button.
19. Response is returned indicating success or failure to complete authorization (approval) of plan.

Note: Throughout this submission there are references to two builds of the Mobile MIM software. Both builds are based on the same code and are generated with identical version and build number. There are minor differences between the two builds, predominantly with regard to User Interface. There are additional options to select for Authorization (i.e. approval), which brings up the authorization dialog. Additionally, the OEM build displays a login dialog before accessing data. Unless otherwise specified, all information provide applies equally to both builds, as it is the same exact logic.

VOL 012 – SUBSTANTIAL EQUIVALENCE DISCUSSION

001_SE MATRIX

Substantial Equivalence Discussion

COMPARISON TO PREDICATE DEVICES

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Clearance Date	TBD	2/4/2011	3/11/2005
Intended Use / Indications For Use	The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be	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.	The Vision product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, and plan verification and treatment. Vision also stores the treatment histories including dose delivered to defined sites, and ***provides tools to verify*** performed treatments. ***Vision is designed to assist the radiation therapy staff to prepare and approve treatment plans, and to perform quality assurance of the treatments***. The preparation tasks include image acquisition, viewing and manipulation, treatment plan definition, manipulation and scheduling.

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
	used to approve these plans. 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.	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.	
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes	Yes

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes	No
Image Fusion	Yes	Yes	No
Multi-Planar Reconstruction (MPR)	Yes	Yes	No
Maximum Intensity Projection (MIP)	Yes	Yes	No
Standardized Uptake Value (SUV)	Yes	Yes	No

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Distance Measurements	Yes	Yes	Yes
Window/Level	Yes	Yes	Yes
Zoom/Pan	Yes	Yes	Yes
User Authentication	Yes	Yes	Yes
Modalities	SPECT, PET, CT, MRI X-Ray, Ultrasound	SPECT, PET, CT, MRI	CT, MRI, X-Ray
Remote Handheld Viewing Device	Yes	Yes	No

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Display contours	Yes	Yes	Yes
Review isodose curves from RTP	Yes	No	Yes
Review DVH	Yes	No	Yes
Approve RTP via an authorized user	Yes	No	Yes
Patient setup	No	No	Yes
Scheduling and business information management	No	No	Yes

ITEM	Mobile MIM (RT)	Mobile MIM (K103785)	Vision (K042956)
Plan simulation and modification	No	No	Yes
Operating Platform	Apple® iOS	Apple® iOS	Windows 95,XP,NT
Hardware Requirements	Apple® iOS handheld devices	Apple® iOS handheld devices	PC Server/Workstation

Discussion:

The comparison chart above provides evidence to facilitate the substantial equivalence determination between the expanded indications of Mobile MIM and our chosen predicate devices, Mobile MIM (K103785) and Vision (K042956).

There is a direct correlation between the Intended Use/ Indications For Use statement of Mobile MIM (RT) and its predicate Mobile MIM (K103785) as the indications of this current submission extend those of Mobile MIM (K103785) by adding two additional image modalities, X-Ray and Ultrasound. All of the other functionality of the original Mobile MIM is maintained. The Indications for Use also extend to allow medical professionals the ability to review and approve radiation treatment plans which is substantially equivalent to comparable features of Vision (K042956).

The differences between Mobile MIM (RT) and Vision (K042956) include the functionalities that Vision (K042956) provides, that of Patient setup, Scheduling and business information management, and Plan simulation and modification. Mobile MIM (RT) does not provide these functionalities.

There are no new technological characteristics that affect safety and effectiveness for this Mobile MIM as the software operates on the same Apple hardware and operating system as the original Mobile MIM submission.

For a complete summary of the testing results done during Alpha development stages, see section: *VOL_016_ Software-006_Verification and Validation Testing*. Testing summaries and subsequent discussion and feedback gathered from the testers provided ample evidence when used according to operating instructions Mobile MIM can be used safely and effectively.

Therefore, from all evidence gathered, it is our belief that these expanded of indications for Mobile MIM (RT) provide a safe and effective mobile diagnostic viewer of medical images that can be used to review and approve radiation treatment plans when the user does not have access to a full workstation.

Conclusion:

MIM Software Inc. performed multiple studies with qualified radiologists using the additional modalities of X-Ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

Additionally, radiation therapy users (radiation oncologists, physicists, and dosimetrists) compared Mobile MIM (RT) with three major manufacturers of TPS systems validating that the mobile device display was equivalent to the TPS workstation displays.

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.

VOL 012 – SUBSTANTIAL EQUIVALENCE DISCUSSION

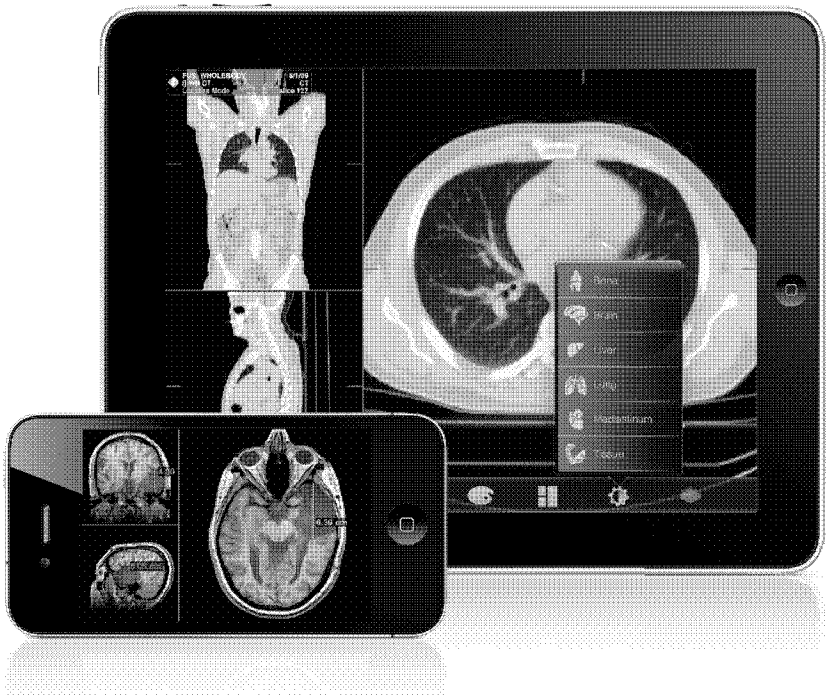
002_PREDICATE LABELING (MOBILE MIM)


MOBILE
mim™

Imaging Anywhere

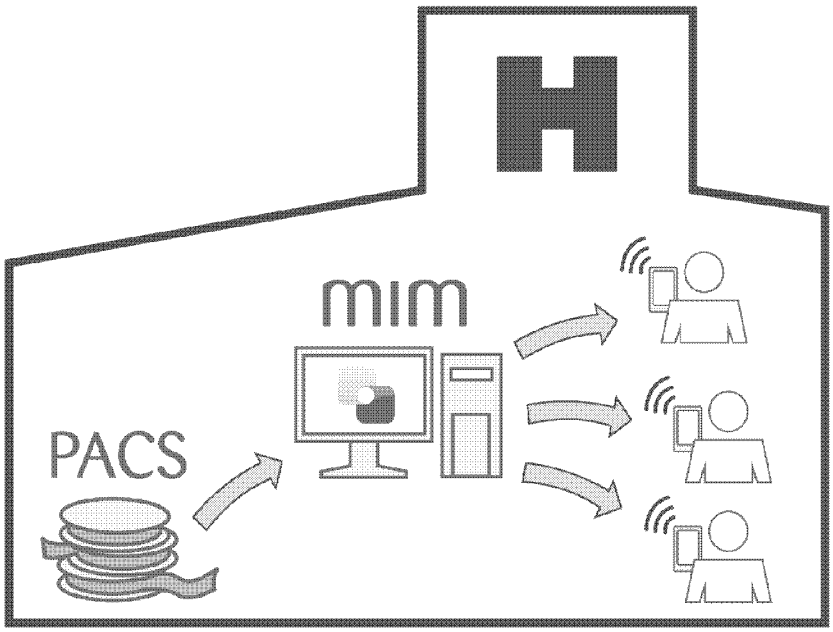
Open up new possibilities with Mobile MIM.

- Mobile MIM is a diagnostic imaging app for the iPad®, iPhone®, and iPod touch®.
- Imaging professionals now have a portable solution away from their workstations.
- Consult with peers for difficult cases and overreads.
- Reduce image distribution delays.
- Enhance referring physician and patient interaction.
- Never rely on ad hoc mobile viewing solutions again.
- Bypass the cost and headache of CDs.
- Give hands-on image access to tumor board or class members.



Access your PACS with a MIM server solution.

- A MIMpacs™ server can function as an imaging server for Mobile MIM.
- Configure MIM software to cache a subset of PACS data for mobile access.
- Access patient studies with fast searching and viewing.
- Keep data within your local network.
- Access data off-site with VPN or other network extensions.



Simplify Using MIMpacs

With MIMpacs as your primary image storage solution, the setup is even simpler. Every study in MIMpacs is immediately accessible.

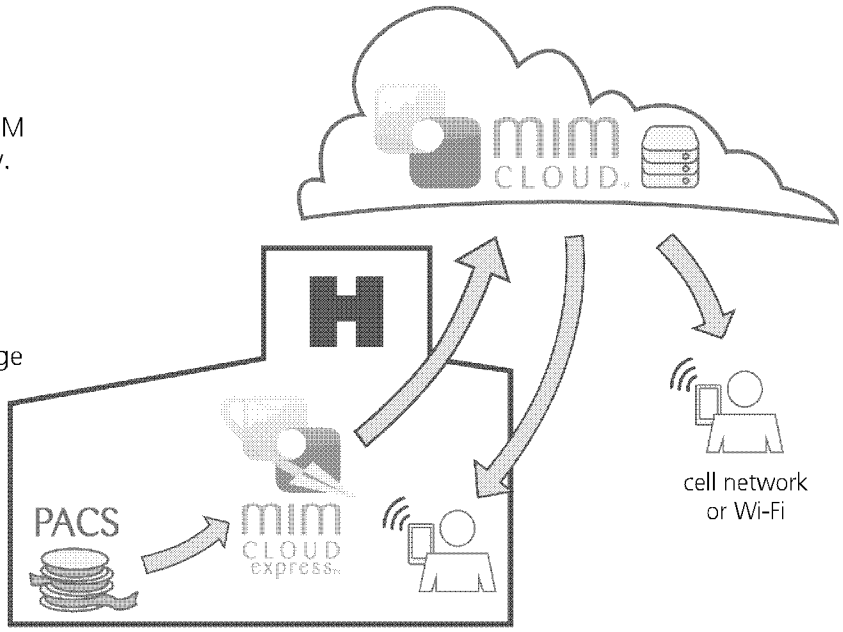
Imaging Everywhere

Extend your PACS with MIMcloud™ and MIMcloud Express™.

- MIMcloud securely hosts image data so users can maintain access while off-site.
- The free MIMcloud Express automatically routes PACS data transfers to MIMcloud.
- MIMcloud Express accepts standard DICOM transfers for institution-wide compatibility.
- MIMcloud Express is vendor-neutral and compatible with PC and Mac.
- A single server can route to multiple MIMcloud users or groups.
- All PHI is encrypted for transfer and storage (for HIPAA compliance).

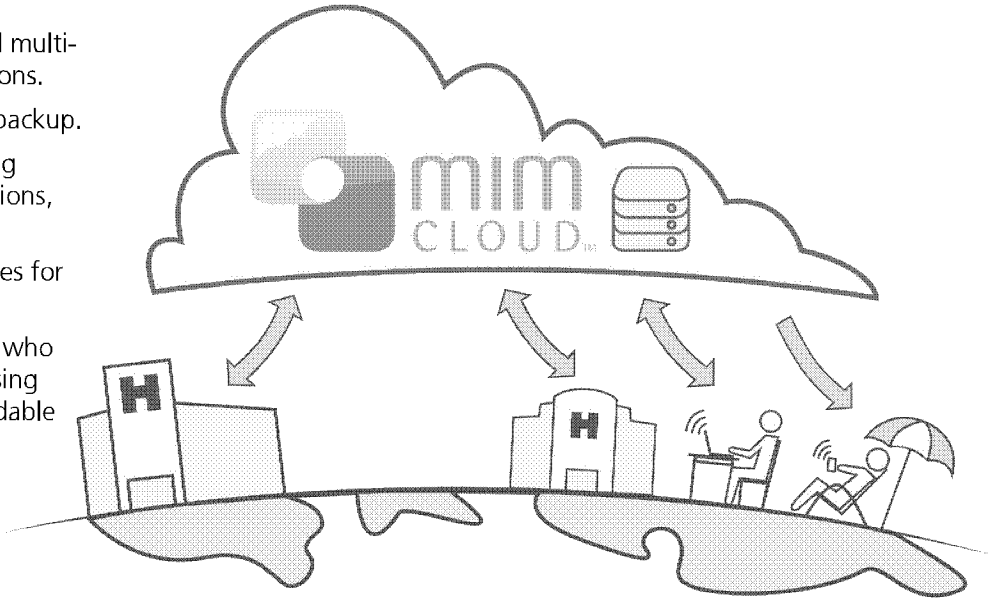
MIM 5 Integrates with MIMcloud

MIMcloud compatibility is built-in to every MIM 5 workstation, allowing you to manage studies, push and pull images, and easily share studies with others inside or outside your institution.



Broaden your horizons with MIMcloud.

- Access images from any Internet connection.
- Enhance teleradiology and multi-institution reading operations.
- Use MIMcloud as off-site backup.
- Share images with referring physicians, partner institutions, and patients.
- Collect or contribute images for clinical trials.
- Distribute images to users who don't have Mobile MIM using the MIMviewer® downloadable desktop software.



per-user configuration

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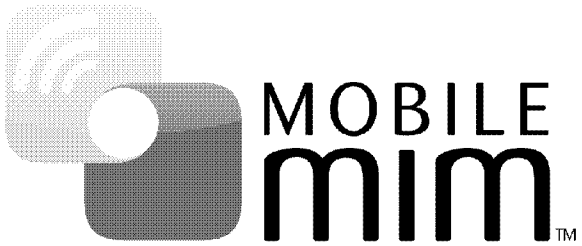
CE 0120



USER GUIDE

version 2

version 2

04-18-2011

Mobile MIM Hardware Requirements

Apple devices such as iPhone, iPod touch, or iPad.
Operating System: iOS 4.0.x / 4.1.x / 4.2.x / 4.3.x

Mobile MIM Software Requirements

Mobile MIM is available from the App Store on iTunes or directly from the mobile device (see page 8). An iTunes account is required to download the application.

MIM Workstation/Server System Recommendations and Guidelines

PC

Intel Core i7 (Quad Core)
8+ GB 800+ MHz RAM
16x DVD+/-RW Drive
2-8 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

Mac Pro – Intel Quad-Core Xeon / iMac 27-inch - Intel Core i7
8+ GB RAM
SuperDrive
2-8 TB Hard Drive
512 MB ATI or NVIDIA Graphics Card
Apple Display(s)
Mac OS X 10.6

Caution:

Federal law restricts this medical device to sale to, or on order of, a physician.

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Cleveland, OH 44122
866-421-2536
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info@mimsoftware.com

Beijing MIM Software Corp. Ltd.
北京明维视景医疗软件开发有限公司
地址：北京市海淀区苏州街29号
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CE 0120

MOBILE MIM USER GUIDE

Indications For Use / Intended Use

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

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.

Recommended Viewing Conditions

Recommended Viewing Conditions are in a dimly lit office environment, away from overhead fluorescent lights and exterior windows. This is an environment similar to a radiology reading room.

Reading rooms are typically less than 300 LUX. Testing revealed that the contrast response could degrade at levels higher than this.

contents

MOBILE MIM 2

MOBILE MIM 2

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.

Installing 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.

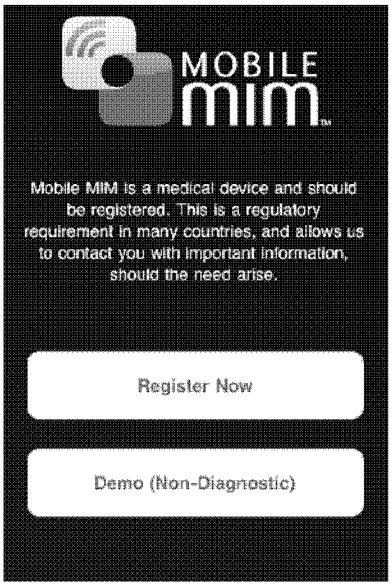
Mobile MIM may be downloaded directly from the App Store onto the mobile device as well, and can similarly be found with a search or in the Medical category.

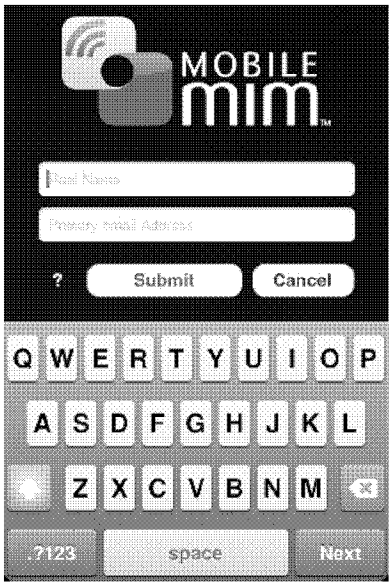
Device Registration

The first time Mobile MIM runs, it will ask you to register your device with MIM Software Inc. Providing this contact information allows MIM Software to notify you of any important information regarding your Mobile MIM device, including recall notices and critical version updates. Please be aware that registration is a regulatory requirement in many countries.

If you do not register your device, you should only use Mobile MIM for non-diagnostic purposes.

Contact information can be updated at any time.





Configuring Image Access

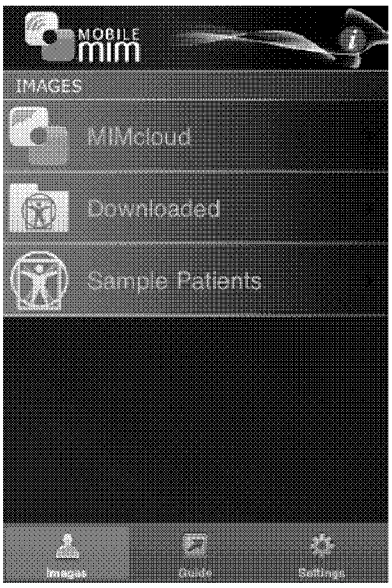
There are two ways to get images to Mobile MIM. First, Mobile MIM can connect to MIMcloud.com, a secure, Internet-based medical imaging service that provides a central, easily accessible location for storing, sharing, and viewing images. Visit www.mimcloud.com to learn more and create an account.

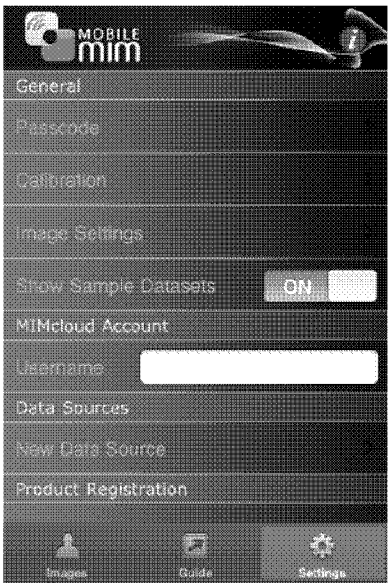
Secondly, Mobile MIM can connect to a MIM workstation through a Wi-Fi network.

IMPORTANT: Mobile MIM is only intended to be used for diagnosis when you do not have access to a workstation. If you are in a hospital or clinical setting, you should use the workstations that are at that site. The presence of a wireless network in the facility does not alter this intended use.

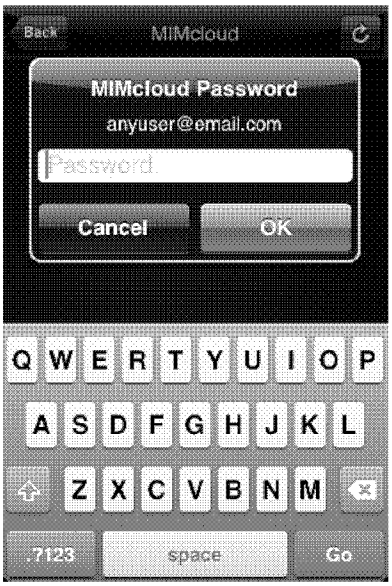
Connecting to MIMcloud

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 username is the e-mail address for the account.





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

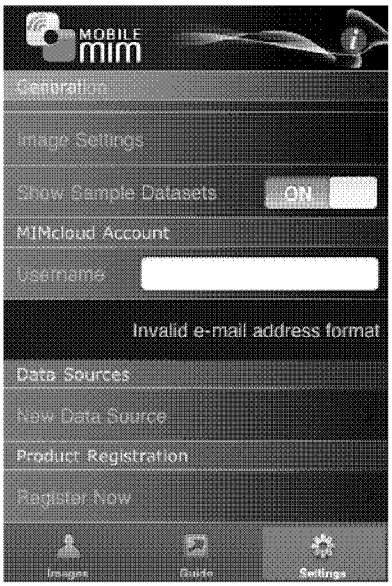


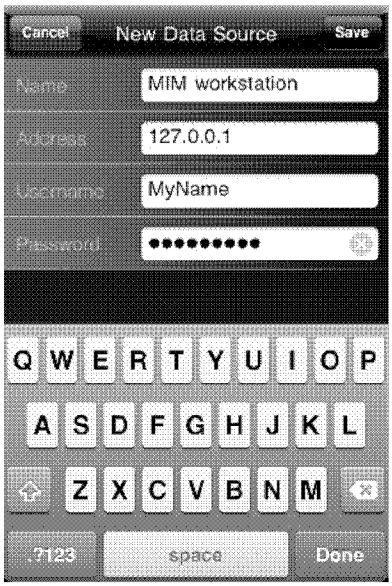
Connecting to a MIM Workstation

Mobile MIM can also connect to a configured MIM workstation. A network connection to this workstation is required to download images. If Mobile MIM is not on the same network as the workstation (for example, when accessing a MIM workstation at the office from home), then a VPN may be required. If so, work with a network administrator. To connect to the VPN, use the Settings for your mobile device (outside of Mobile MIM).

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

Once a connection is established, tap on Settings in the lower right corner. Touch and drag to scroll down to the section called Data Sources.



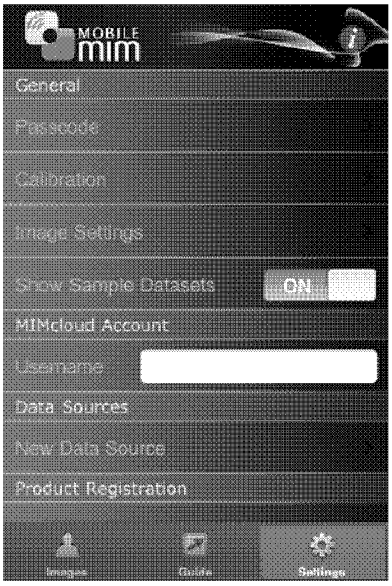


Tap New Data Source, type the source name (this can be arbitrary), and enter the IP address or hostname of the server. Type the username and password that was created on the server for you. Tap Save in the upper right corner to complete.

Creating 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 uses 128-bit AES. You can set up the passcode in the Settings tab of the main page.

Tap Passcode from the Settings tab and turn it on. Type the passcode twice to be sure it is entered correctly.



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

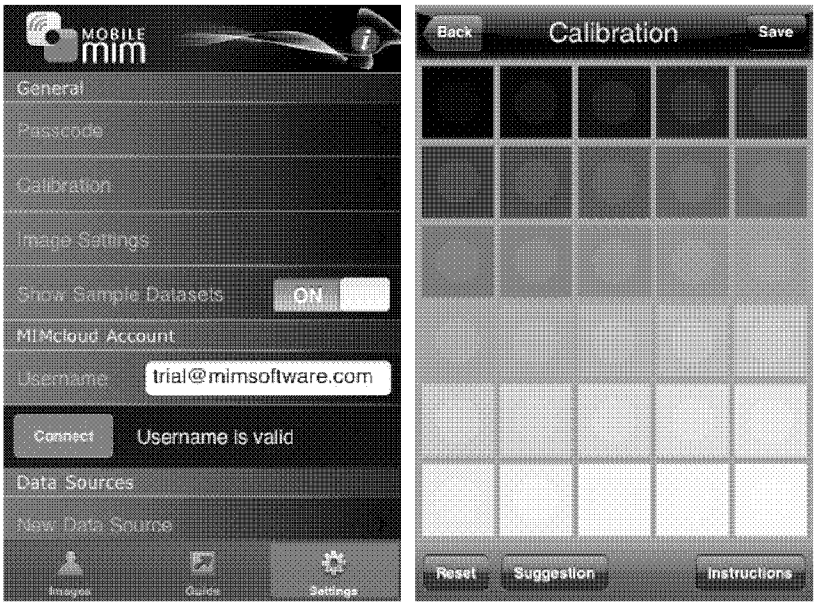
Calibrate your device under the Recommended Viewing Conditions with the device brightness set to maximum.

Recommended Viewing Conditions are in a dimly lit office environment, away from overhead fluorescent lights and exterior windows. This is an environment similar to a radiology reading room.

Reading rooms are typically less than 300 LUX. Testing revealed that the contrast response could degrade at levels higher than this.

Instructions

Select the Settings tab on the main screen, and then select Calibration.



The screen displays 30 squares, each containing a circle that is slightly brighter than the square. The squares represent the gray scale range from black to white. Calibration ONLY affects the gray scale color tables.

- Notice the relative contrast of each circle to its square.
- Tap the squares which have the lowest contrast circles (those that appear dimmer in comparison to other circles).
- Each tap increases the contrast of that circle.
- Continue tapping low contrast circles until all the circles have a similar contrast.

Tap the Suggestion button for an approximate configuration for your device. Examine the result and make further adjustments as described above.

Tap the Reset button to return the screen to an uncalibrated state.

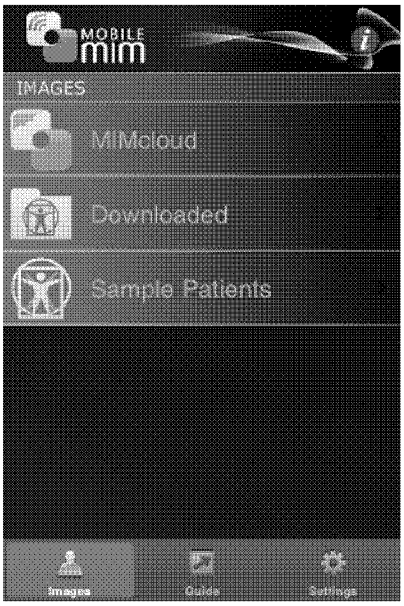
Tap the Save button at the top to finish, or tap the Back button to exit without saving the changes.

Managing Images

Downloading/Viewing Images

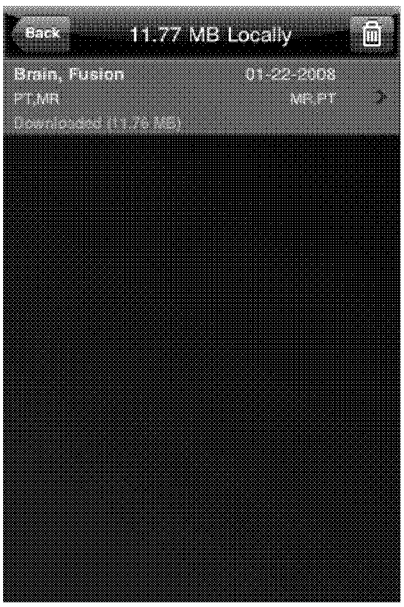
Launch Mobile MIM from the home screen to access the Images tab. Tap the data source you would like to use, such as MIMcloud, Downloaded, Sample Patients, or a configured MIM workstation.

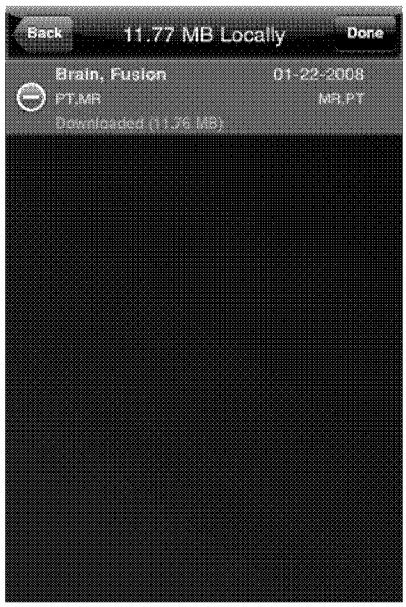
The data source will be accessed and a list of studies will appear. If the study is already downloaded, it will note that in the listing. Tap a study to begin downloading a new study. After the transfer is complete, the study will open for review.

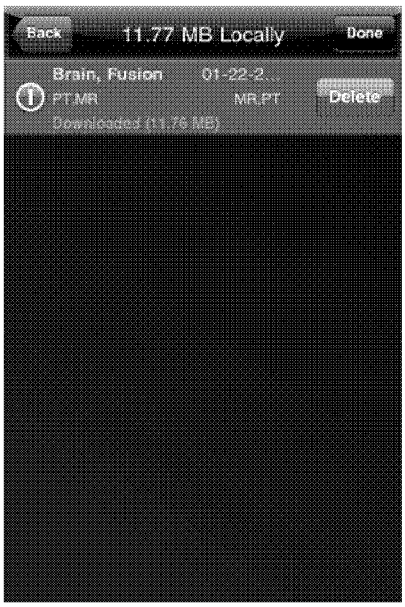


Deleting Images

To delete images from the mobile device, tap the Downloaded data source. Images can be deleted with the normal delete swipe function. Alternatively, tap the trash can in the upper right and select images to delete.





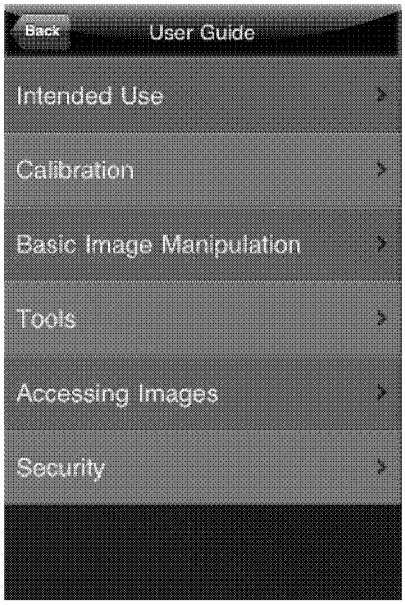


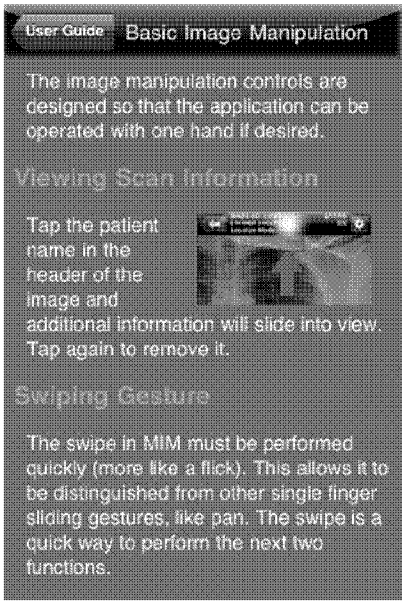
User Guide for Interacting with Mobile MIM

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

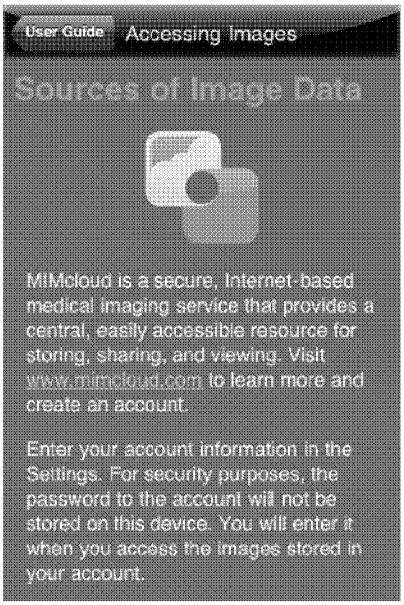
From there you can access the User Guide, Safety information, Frequently Asked Questions, and Support (contains contact information).

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

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 switch between series, planes, and images.

Switching between Series

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

Switching between Viewing Planes/Images

With non-2D images, cycle between axial, sagittal, and coronal planes or reconstructed image sets by swiping up/down with one finger. Or press the View 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 series, slide one finger up and down over the image to change the blend percentages between the primary and secondary series.

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 series by touching the screen and holding that position for a brief moment. When the crosshairs expand, slide them to the desired position and lift your finger. Double-tap while the crosshairs are still expanded to zoom to that exact point.

Scrolling 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.

When viewing a multi-planar reconstruction, scrolling works only on the rightmost viewport.

Multi-Planar Reconstruction (MPR)
Turn Volumetric data can be displayed as a multi-planar reconstruction. On the iPad, tap the Layouts button on the toolbar. All the Layouts with three viewports are MPRs. On the iPhone or iPod touch, turn the device sideways to show MPRs. Gestures, such as localization or swiping to change series/views, will continue to function.

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

Moving 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 the Tool Modes for measurements (e.g., 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 functionality to assure adequate reading coverage of large images that greatly exceed the screen resolution.

Verify Lighting
Use this tool to evaluate the ambient lighting of the area in which you are using MIM. A low contrast square is positioned randomly on a dark background. If you can see the square and tap it, then the environment is not too bright.

Calibrate Mobile MIM to get a low contrast square which is most appropriate for this hardware.

If you do not see the low contrast square, steps will be provided to help you check all relevant conditions.

The automatic Verify Lighting check presents the ambient light test after a period of inactivity (e.g., quitting Mobile MIM, using other apps while Mobile MIM is in the background, or simply putting the device to sleep). This helps to ensure that your current environment is acceptable for diagnostic use, given that you may have changed locations during the period of inactivity.

Upon passing the lighting verification, the automatic check will recur following 20 minutes or more of inactivity. This safety feature helps maintain the diagnostic integrity of the device.

If you cannot see the square and/or cannot tap it successfully, you also have the option to select "Read Non-diagnostically." By doing so, the yellow warning badge will appear at the top of the image display. This warning badge will remain until a subsequent Verify Lighting test is passed.

⚠ By choosing to read non-diagnostically, the automatic check will not recur for a span of 4 hours. The badge will remain as a visible reminder. The Verify Lighting tool may be manually run at any time in order to reevaluate the environment.

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 all lines) to cycle through each measurement for review.

To delete lines, tap the gear at the top right. Turn on Shake to Delete in the Options tab, or delete with the usual swipe gesture in the Overlays tab.

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 the sphere 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

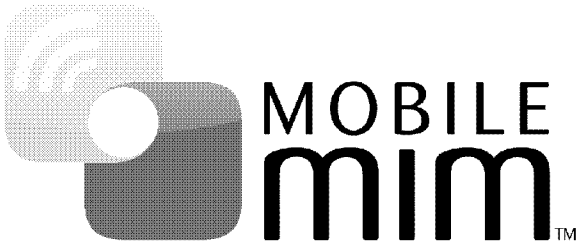
Slide one finger to position the tip of the annotation arrow. Repeat to position the endpoint of the arrow. A keyboard will appear to enter your annotation. Place as many annotations as you desire. Tap on the image (away from all annotations) to cycle through each annotation for review.

To delete annotations, tap the gear at the top right. Turn on Shake to Delete in the Options tab, or delete with the usual swipe gesture in the Overlays tab.

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.



USER GUIDE

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VOL 012 – SUBSTANTIAL EQUIVALENCE DISCUSSION

003_PREDICATE LABELING (VISION)

INFORMATICS

A revolution in oncology information systems

A revolution is happening in oncology care, facilitated by advances in informatics. Varian's VARiS Vision™ Oncology Information System makes it possible for oncology departments to streamline clinical processes, improve workflow, eliminate paper charts, share data across the health enterprise, and generally improve the quality of patient care by automating many aspects of complex treatment deliveries.

"VARiS Vision is a comprehensive database and information system that can drive every step of the clinical process, from initial consultation through treatment and follow-up," says Charmaine Lawrence, Varian product manager. "Every piece of needed information is easily accessible to the medical staff. No one has to search for paper charts or worry that information will get lost."

Today, the staff spends more time with patients and less time entering data. "The system provides us with accurate information for audit, clinical trials, and research purposes," says Mehta. "It accurately identifies the patient pathway, allowing us to instigate ongoing improvements in the radiotherapy process and assess their effectiveness. There is little doubt that a networked information management and imaging system has transformed the lives of everybody working here."

> "With the introduction of IMRT, the savings are significantly more. These treatments involve six, eight, ten fields, and we still can do them in standard 15-minute time slots."
>
> —*Ian Hudson, Tom Baker Cancer Center*

According to Lawrence, hospitals that set up paperless and filmless procedures using VARiS Vision are able to automate many functions and enhance intradepartmental communication, which results in greater efficiency.

Randy Holt, PhD, chief medical physicist in the radiation oncology department at Enloe Medical Center in Chico, California, agrees. "VARiS Vision has helped us reduce our costs by introducing efficiencies—over and above those we're seeing thanks to the new 4D console," he says (see story on page 2). "We have shown a 15 percent improvement in overall departmental efficiency, looking at FTEs used relative to charges billed. We were pleasantly surprised to see that we could eliminate constant overtime."

The clinical team at the Tom Baker Cancer Center in Calgary, Canada, has also realized important efficiencies with VARiS Vision capabilities. Sue Merritt, radiotherapy manager, reports that RV Mode-Up, a feature that links the record-and-verify database to the treatment machine so that radiation therapists need not input treatment parameters, combined with auto field sequencing (AFS), decreased treatment time by up to three minutes per patient—a 20 percent time savings. "The AFS loads one field after another, and the gains add up. We went from treating four to treating five patients every hour."

"With the introduction of IMRT, the savings are significantly more," adds Ian Hudson, radiotherapy manager. "These treatments involve six, eight, ten fields. And we still can do them in standard 15-minute time slots, thanks to automation features in VARiS Vision."

Late last year, the Royal Free Hampstead Trust became the first hospital in Great Britain to implement the latest version of VARiS Vision from scratch, rather than as an upgrade. According to Kashmira Mehta, radiotherapy manager, the radiotherapy department had been working "with no networked system whatsoever. Everything was done manually."

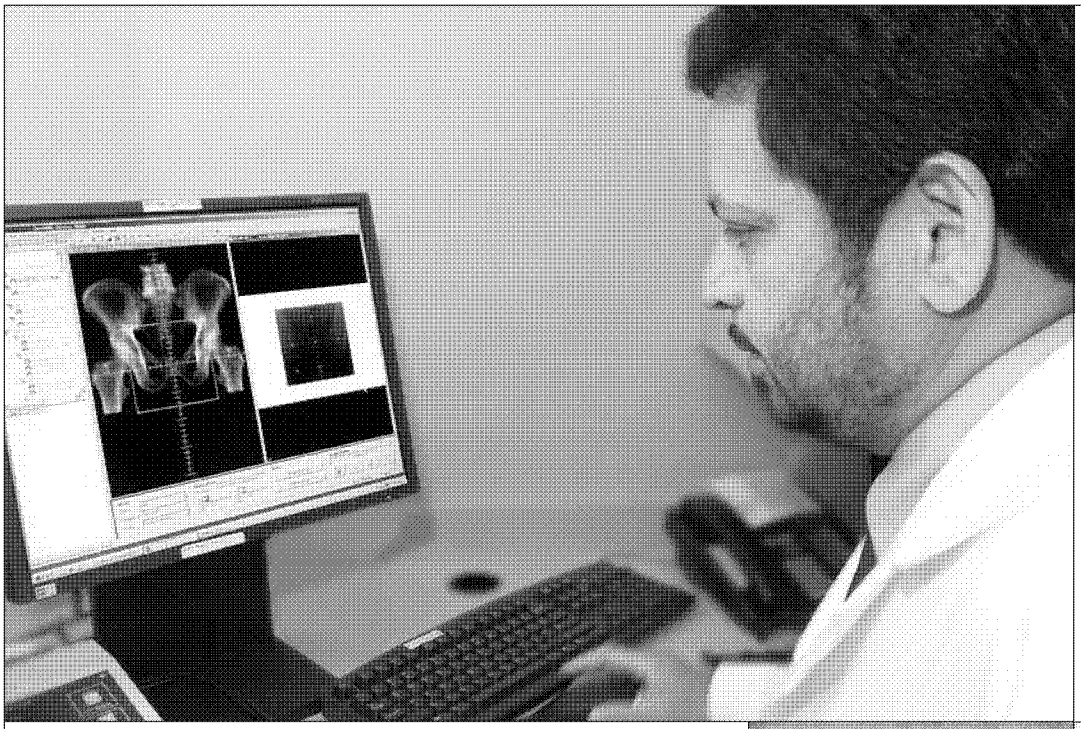
Expanded functionality

Recently the VARiS Vision system was updated with new clinical management tools that expand the patient's chart into a complete electronic health record. Among the new features are:

- New tools in the Patient Manager™ module that document and manage diagnosis and staging. These include a Smart Staging™ feature that can guide physicians through the staging process, according to current clinical guidelines, to arrive at an optimal treatment approach.
- A Clinical Assessment™ module that documents and manages the patient's medical, family, and social history; physical exams; vital signs; lab results; counseling and education; and medications.
- Standard templates that users can customize and autopopulate with existing data, as well as prompted activities that streamline workflow.

According to Roy Lowe, medical physicist at Rock Hill Radiation Therapy Center in Rock Hill, South Carolina, VARiS Vision's user interface is easier to use than ever before. "People with limited computer experience won't be intimidated," Lowe says. "VARiS Vision is now a wonderful Windows-based product that works like other popular software programs that people are used to seeing. It isn't scary. It looks familiar."

Among Lowe's favorite features are Patient Check-In™ and Time Planner™. "We love that patients can check themselves in electronically when they arrive," he said. "It alerts every person in the clinic that the patient is here and ready for treatment. And the Time Planner module allows us to arrange our own tabs to customize our screens. The physicians see the information that is important to them, and the therapist has the same ability. Everyone in the clinic has made their own customized screen."

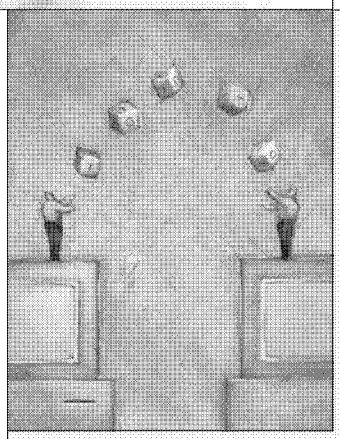


Deepak Pradhan, MD, medical director at the Josephine Cancer Center Downriver, part of the Henry Ford Health System in Detroit, Michigan, uses the VARiS Vision system to review information about a patient's treatment.

The Patient Manager module incorporates a summary tab that gives a snapshot of all the clinical aspects of a patient's treatment—contact information, the diagnosis, the treatment plan, a digital photo, and more are visible in one place. "The subsequent tabs let you get into deeper detail," Lowe explains. "We have a registration tab and a care-path tab that let us quickly review how many treatments there will be, prescription information, charging codes. There's a really nice little tab at the top that takes you right into RT Chart™ without having to open another application. That's where you see the patient's radiotherapy prescriptions, the fields being treated, reference points to multiple treatment sites, and all the scheduled treatments. It's very intuitive and simple for people to pick up."

"Users can save care paths in template format," Lawrence adds. "For instance, if you have a care path you usually use for prostate cancer patients, you can attach that to a patient's record and automatically schedule everything that patient will need in the weeks to come. You can edit the care path if you need to, but it's a simple way to capture everything without reinventing the entire wheel every time."

"The system is very well integrated," observes Holt. "All the data is in one place, and you have multiple ways of accessing it and interacting with it. We're finding that, by using VARiS Vision, we've become far more trusting of the electronic information, and paper is a habit that we're falling out of." •



News from Varian's Oncology Information Systems group

New data protection service

Varian has launched a new data protection service, High Availability and Rapid Recovery Protection (HARRP). HARRP is designed to enable treatment centers to recover VARiS Vision™ data quickly and easily if network servers go down. With HARRP technology, if a server fails, a treatment center can be back up within an hour. In the event of a primary server outage, the software enables a secondary server to stand in with the push of a button.

Varian acquires Sigma Micro Informatique Conseil

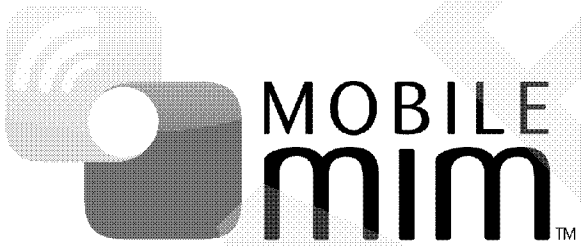
Early this year, Varian acquired Sigma Micro Informatique Conseil, a company that supplies information management and electronic health record software for radiation and medical oncology departments in France and other European nations. Sigma Micro software supports billing in many different reimbursement schemes and works with equipment from multiple vendors. It can be purchased, installed, commissioned, and serviced over the web, and contributes significantly to Varian's informatics portfolio. •

VOL 013 – PROPOSED LABELING

001_MOBILE MIM 3 USERS GUIDE (draft)

Note regarding Draft User Guide:

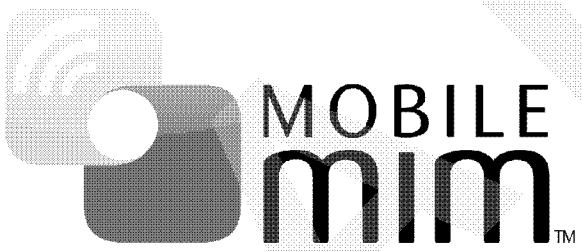
This draft User Guide represents the proposed marketing material that will be available to Mobile MIM users. As already noted earlier, the OEM vendor will be using a build with a few additional User Interface elements. The vendor has requested to produce their own User Guide which includes these dialogs. For that reason, login and authorization/approval screens are not described in this User Guide. Those will only be seen in the OEM build. Furthermore, those dialogs do not represent the core functionality of the software, which is covered in the draft User Guide provided here.



USER GUIDE

version 3

version 3



TBD

Mobile MIM Hardware Requirements

Apple devices such as iPhone, iPod touch, or iPad.
Operating System: iOS 4.0.x / 4.1.x / 4.2.x / 4.3.x

Mobile MIM Software Requirements

Mobile MIM is available from the App Store on iTunes or directly from the mobile device (see page 8). An iTunes account is required to download the application.

MIM Workstation/Server System Recommendations and Guidelines

PC

Intel Core i7 (Quad Core)
8+ GB 800+ MHz RAM
16x DVD+/-RW Drive
2-8 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

Mac Pro – Intel Quad-Core Xeon / iMac 27-inch - Intel Core i7
8+ GB RAM
SuperDrive
2-8 TB Hard Drive
512 MB ATI or NVIDIA Graphics Card
Apple Display(s)
Mac OS X 10.6

Caution:

Federal law restricts this medical device to sale to, or on order of, a physician.

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MOBILE MIM USER GUIDE

Indications For Use / Intended Use

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

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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.

Recommended Viewing Conditions

Recommended Viewing Conditions are in a dimly lit office environment, away from overhead fluorescent lights and exterior windows. This is an environment similar to a radiology reading room.

Reading rooms are typically less than 300 LUX. Testing revealed that the contrast response could degrade at levels higher than this.

contents

MOBILE MIM 3

MOBILE MIM 3

Mobile MIM is a multi-modality imaging application for the Apple iPad, iPhone, and iPod touch. 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.

Installing 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.

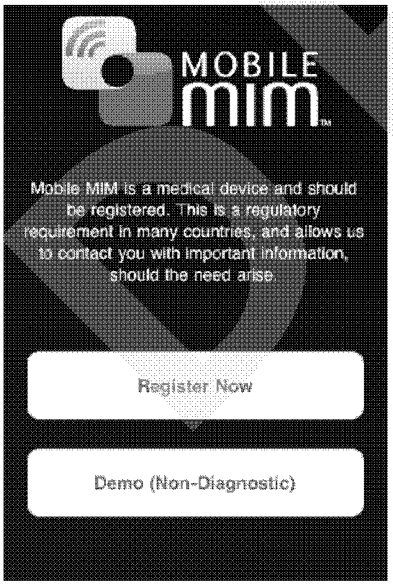
Mobile MIM may be downloaded directly from the App Store onto the mobile device as well, and can similarly be found with a search or in the Medical category.

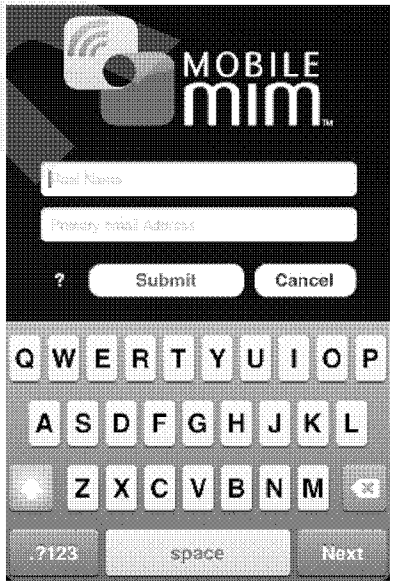
Device Registration

The first time Mobile MIM runs, it will ask you to register your device with MIM Software Inc. Providing this contact information allows MIM Software to notify you of any important information regarding your Mobile MIM device, including recall notices and critical version updates. Please be aware that registration is a regulatory requirement in many countries.

If you do not register your device, you should only use Mobile MIM for non-diagnostic purposes.

Contact information can be updated at any time.





Configuring Image Access

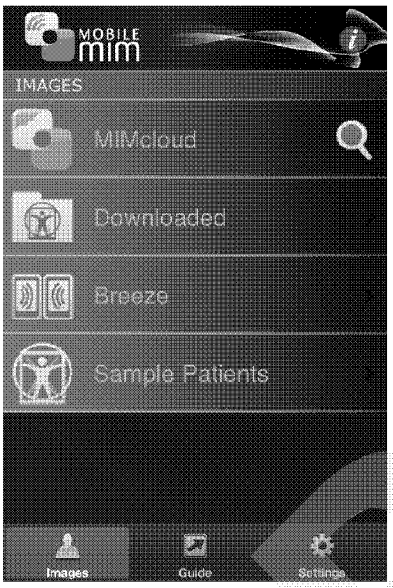
There are two ways to get images to Mobile MIM. First, Mobile MIM can connect to MIMcloud.com, a secure, Internet-based medical imaging service that provides a central, easily accessible location for storing, sharing, and viewing images. Visit www.mimcloud.com to learn more and create an account.

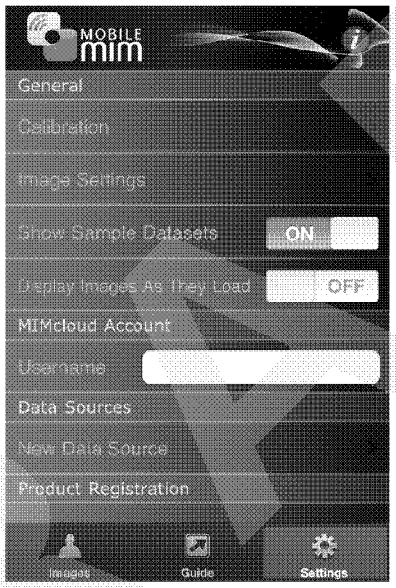
Secondly, Mobile MIM can connect to a MIM workstation through a Wi-Fi network.

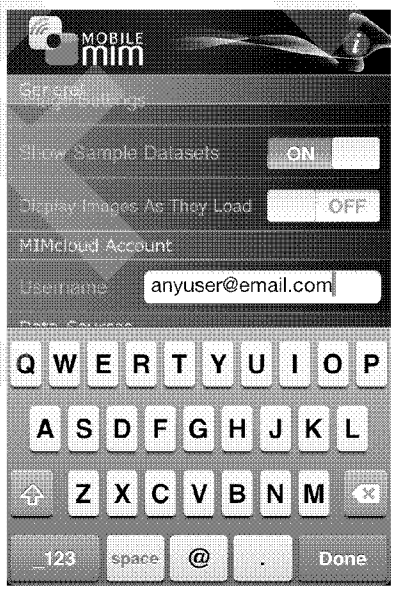
IMPORTANT: Mobile MIM is only intended to be used for diagnosis when you do not have access to a workstation. If you are in a hospital or clinical setting, you should use the workstations that are at that site. The presence of a wireless network in the facility does not alter this intended use.

Connecting to MIMcloud

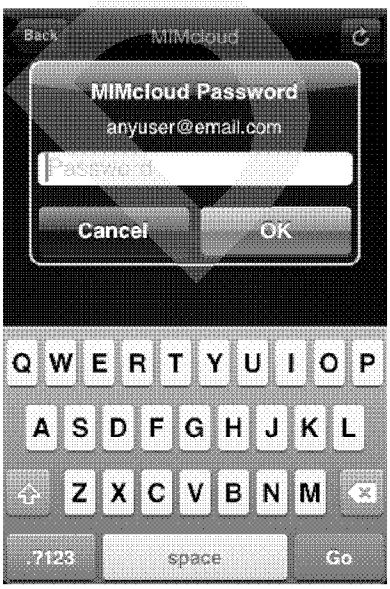
Tap the Mobile MIM logo to launch the application, then tap Settings in the lower right corner. Enter the MIMcloud username that you set up at www.mimcloud.com. The username is the e-mail address for the account.







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

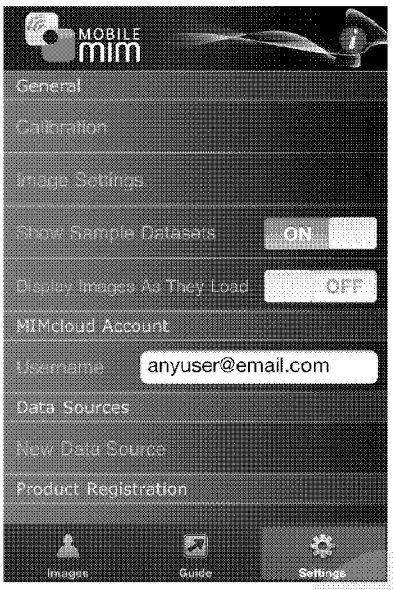


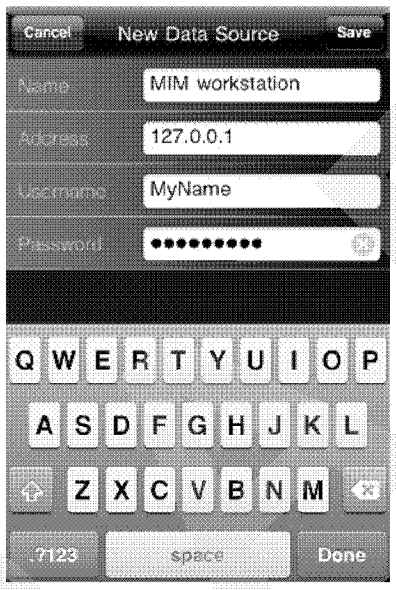
Connecting to a MIM Workstation

Mobile MIM can also connect to a configured MIM workstation. A network connection to this workstation is required to download images. If Mobile MIM is not on the same network as the workstation (for example, when accessing a MIM workstation at the office from home), then a VPN may be required. If so, work with a network administrator. To connect to the VPN, use the Settings for your mobile device (outside of Mobile MIM).

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

Once a connection is established, tap on Settings in the lower right corner. Touch and drag to scroll down to the section called Data Sources.





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

Calibration

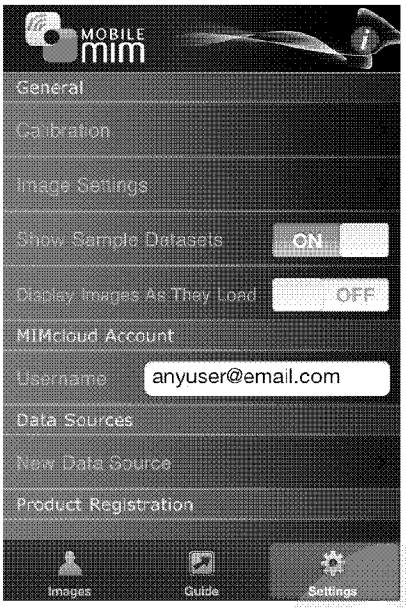
Calibrate your device under the Recommended Viewing Conditions with the device brightness set to maximum.

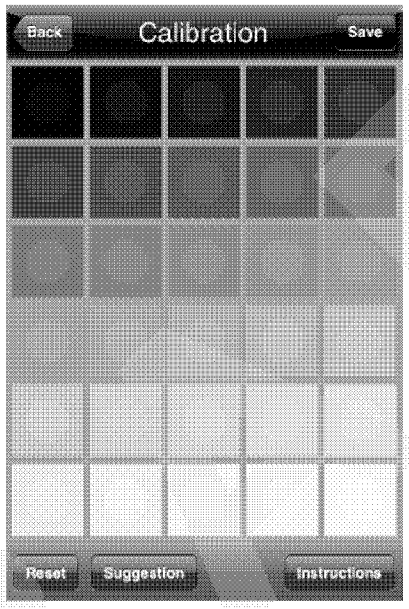
Recommended Viewing Conditions are in a dimly lit office environment, away from overhead fluorescent lights and exterior windows. This is an environment similar to a radiology reading room.

Reading rooms are typically less than 300 LUX. Testing revealed that the contrast response could degrade at levels higher than this.

Instructions

Select the Settings tab on the main screen, and then select Calibration.





The screen displays 30 squares, each containing a circle that is slightly brighter than the square. The squares represent the gray scale range from black to white. Calibration ONLY affects the gray scale color tables.

- Notice the relative contrast of each circle to its square.
- Tap the squares which have the lowest contrast circles (those that appear dimmer in comparison to other circles).
- Each tap increases the contrast of that circle.
- Continue tapping low contrast circles until all the circles have a similar contrast.

Tap the Suggestion button for an approximate configuration for your device. Examine the result and make further adjustments as described above.

Tap the Reset button to return the screen to an uncalibrated state.

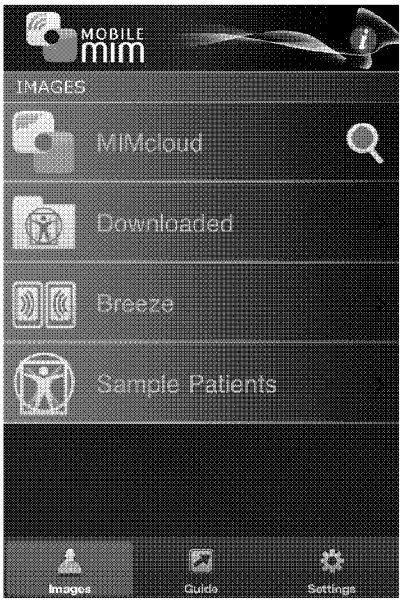
Tap the Save button at the top to finish, or tap the Back button to exit without saving the changes.

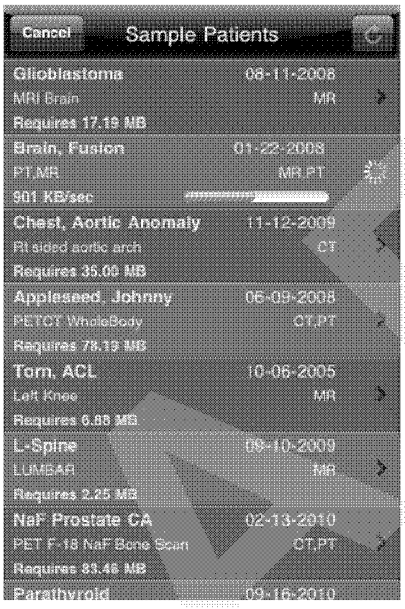
Managing Images

Downloading/Viewing Images

Launch Mobile MIM from the home screen to access the Images tab. Tap the data source you would like to use, such as MIMcloud, Downloaded, Sample Patients, or a configured MIM workstation.

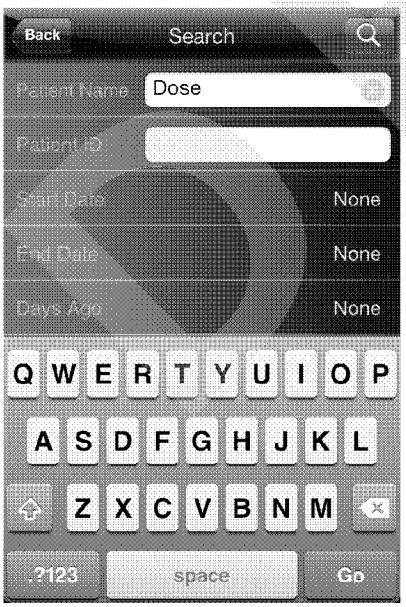
Tapping the data source will initiate a default search. This returns a list of studies based on the date at which the studies were added to that data source, most recent at the top. If a study is already downloaded, it will note that in the listing. Tap a study to begin downloading a new study. After the transfer is complete, the study will open for review.

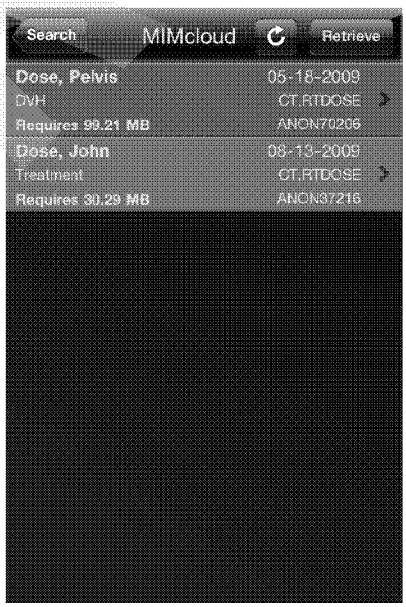




Searching for Studies

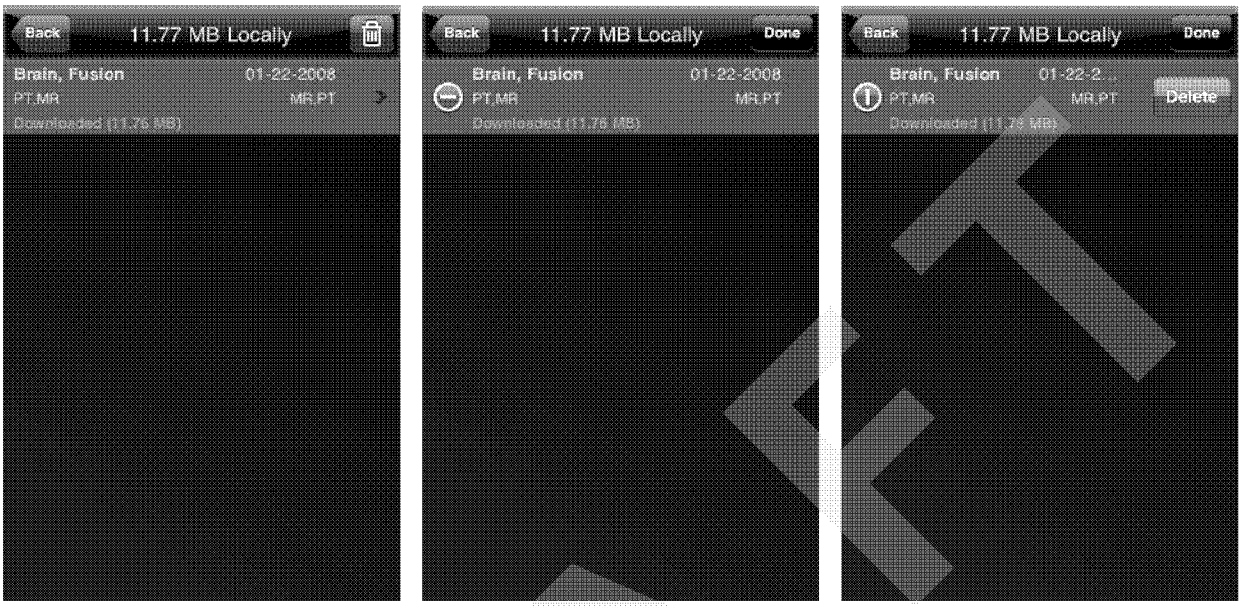
Tap the search magnifying glass icon to search for specific studies. Enter information to narrow the search, then tap "Perform Search" to get a list of results matching your parameters.





Deleting Images

To delete images from the mobile device, tap the Downloaded data source. Images can be deleted with the normal delete swipe function. Alternatively, tap the trash can in the upper right and select images to delete.



Breeze Image Transfer

Breeze lets you transfer images between two devices running Mobile MIM over a local area network, or through bluetooth when in close proximity. Each user must tap the Breeze label on the main screen, then select whether they are sharing or receiving data. Each user should identify how their device will appear to others by filling in the nickname field.

The sender will see a list of studies on the device and must select one of them. The screen will show a randomly created 5 digit pin number. The sender will tell this number to the receiver.

The receiver will see a list of users currently available from which to receive data. These potential senders are listed by the nickname they selected. When the sender is selected, the receiver must type in the 5 digit pin code provided by the sender in order to initiate the transfer.

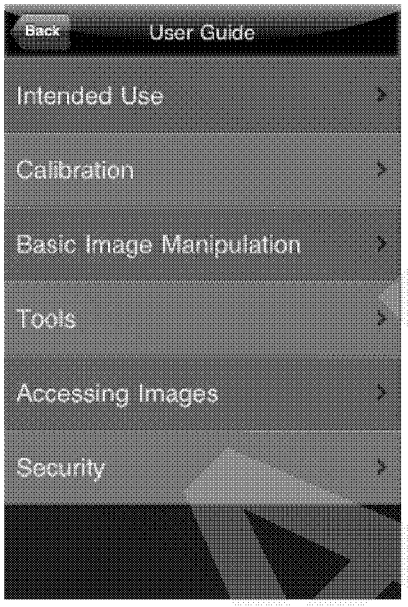
When the transfer is completed, the data will appear in the Downloaded listing. The sender can terminate the sharing at any time, but may chose to share the pin number with others for additional sharing.

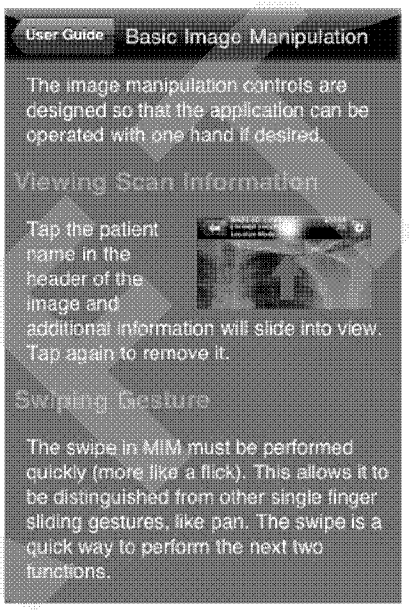
Interacting with Mobile MIM

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 (contains 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

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 switch between series, planes, and images.

Switching between Series

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

Switching between Viewing Planes/Images

With non x-ray and ultrasound images, cycle between axial, sagittal, and coronal planes or reconstructed image sets by swiping up/down with one finger. Or press the View button on the toolbar.

With x-ray and ultrasound 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 series, slide one finger up and down over the image to change the blend percentages between the primary and secondary series.

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 series by touching the screen and holding that position for a brief moment. When the crosshairs expand, slide them to the desired position and lift your finger. Double-tap while the crosshairs are still expanded to zoom to that exact point.

Scrolling 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.

When viewing a multi-planar reconstruction, scrolling works only on the rightmost viewport.

Multi-Planar Reconstruction (MPR)

Turn Volumetric data can be displayed as a multi-planar reconstruction. On the iPad, tap the Layouts button on the toolbar. All the Layouts with three viewports are MPRs. On the iPhone or iPod touch, turn the device sideways to show MPRs. Gestures, such as localization or swiping to change series/views, will continue to function.

Skipping to a Slice

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

Moving 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 the Tool Modes for measurements (e.g., length and SUV).

Read Map

When the Read Map is enabled, it aids in reviewing large matrix x-ray and ultrasound 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 functionality to assure adequate reading coverage of large images that greatly exceed the screen resolution.

Verify Lighting

Use this tool to evaluate the ambient lighting of the area in which you are using MIM. A low contrast square is positioned randomly on a dark background. If you can see the square and tap it, then the environment is not too bright.

Calibrate Mobile MIM to get a low contrast square which is most appropriate for this hardware.

If you do not see the low contrast square, steps will be provided to help you check all relevant conditions.

The automatic Verify Lighting check presents the ambient light test after a period of inactivity (e.g., quitting Mobile MIM, using other apps while Mobile MIM is in the background, or simply putting the device to sleep). This helps to ensure that your current environment is acceptable for diagnostic use, given that you may have changed locations during the period of inactivity.

Upon passing the lighting verification, the automatic check will recur following 20 minutes or more of inactivity. This safety feature helps maintain the diagnostic integrity of the device.

If you cannot see the square and/or cannot tap it successfully, you also have the option to select "Read Non-diagnostically." By doing so, the yellow warning badge will appear at the top of the image display. This warning badge will remain until a subsequent Verify Lighting test is passed.

⚠ By choosing to read non-diagnostically, the automatic check will not recur for a span of 4 hours. The badge will remain as a visible reminder. The Verify Lighting tool may be manually run at any time in order to reevaluate the environment.

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 all lines) to cycle through each measurement for review.

To delete lines, tap the gear at the top right. Turn on Shake to Delete in the Options tab, or delete with the usual swipe gesture in the Overlays tab.

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 the sphere 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 all annotations) to cycle through each annotation for review.

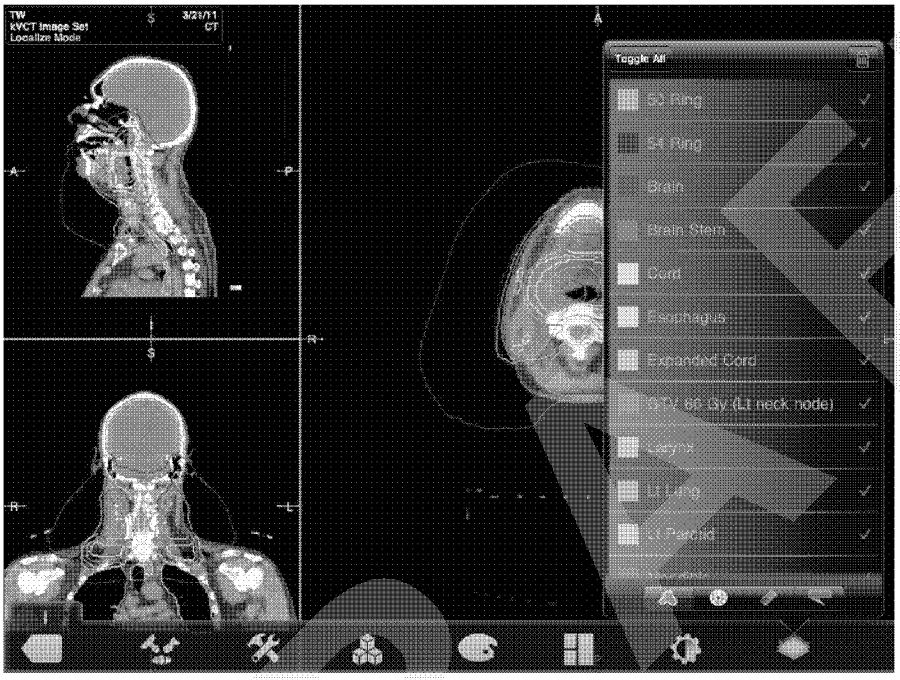
To delete annotations, tap the gear at the top right. Turn on Shake to Delete in the Options tab, or delete with the usual swipe gesture in the Overlays tab.

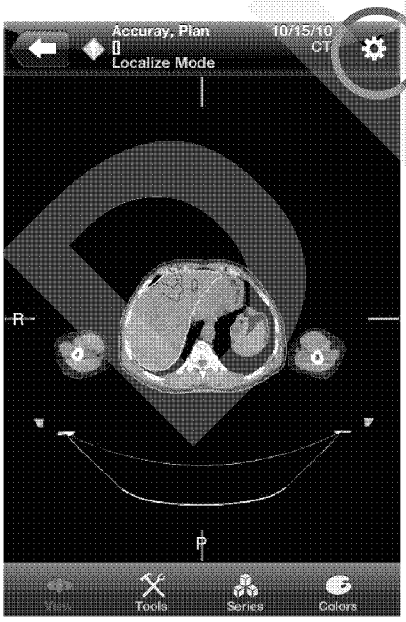
Radiation Therapy Data Sets

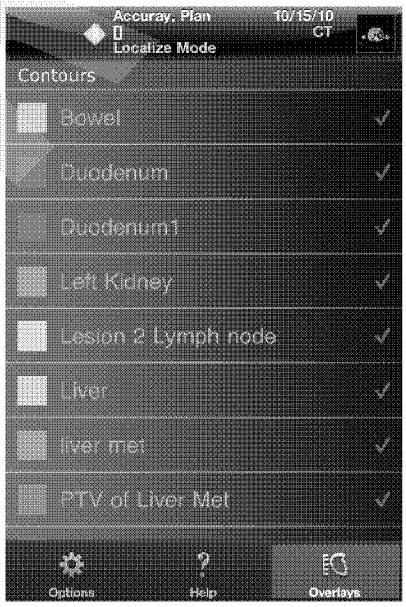
Radiation Therapy data sets that contain the RTdose, the RTstruct, and the image data can be displayed for the purpose of radiation therapy plan review and approval. DVH display requires both the contours and the dose information. If the prescription dose is not available from the RT data files, a prompt will appear when the scan is loaded for the user to specify the value. Isodose curves are created relative to this dose value..

Overlays

Overlays include contours, measurement lines, isodose curves, and annotations. They can be accessed from the overlay button on the iPad (far right of the lower toolbar) or from the Overlays button at the bottom of the gear flip view.



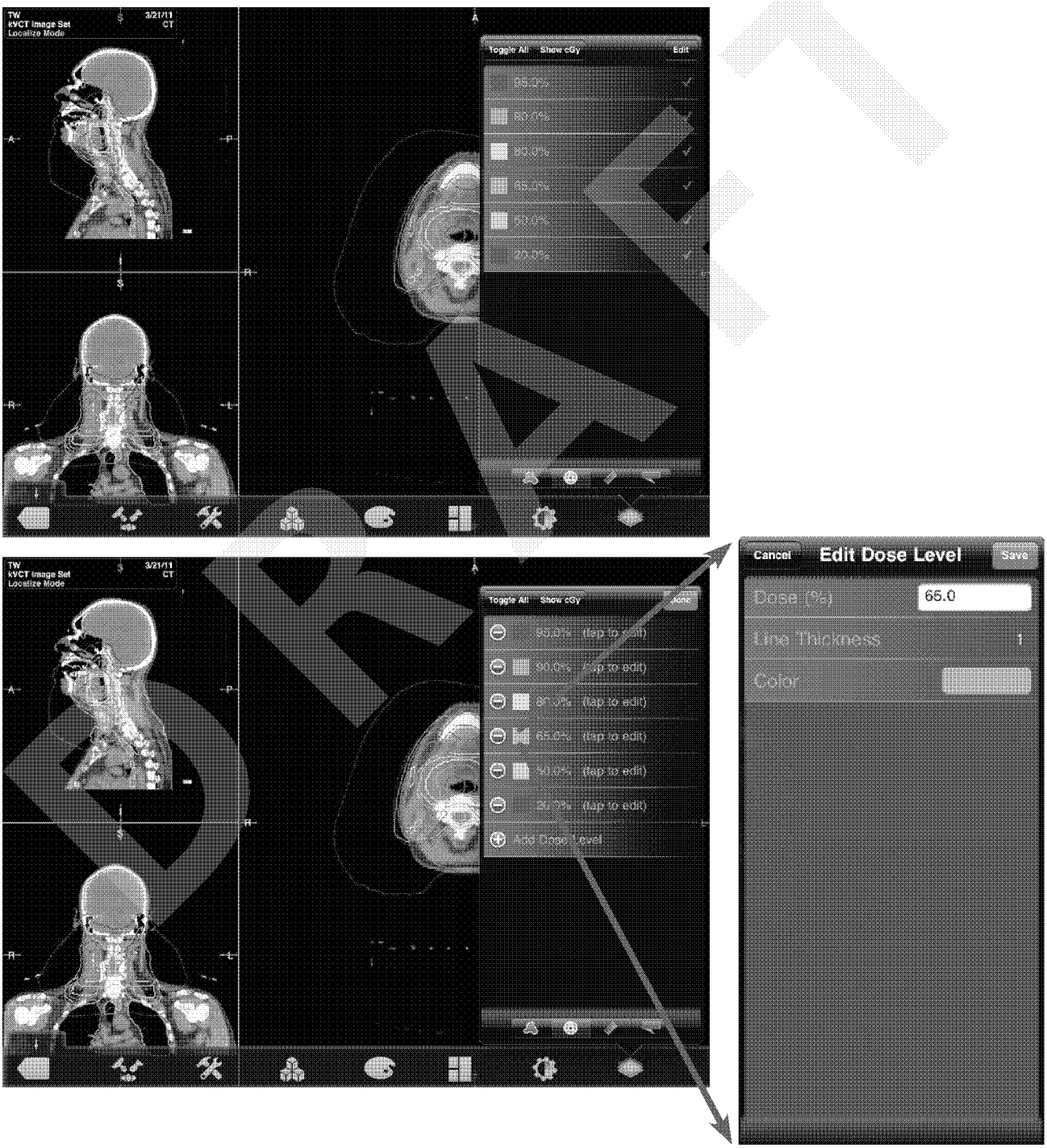




iPad Menu

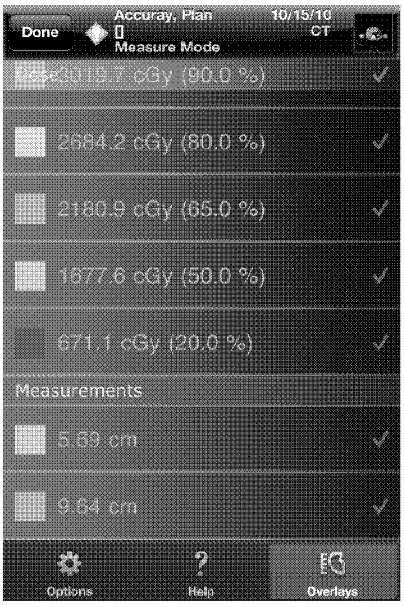
Overlays are grouped by type using icons along the bottom of the Overlay menu. Tap each icon to view the respective overlays. At the top of the same menu is a Toggle All button which will toggle the visibility of all the items on the list at the same time. Tap an overlay's row to toggle its visibility; a checkmark appears next to items that are visible.

Isodose overlays include options at the top of the menu to toggle between viewing percentages and cGy, as well as to edit the individual settings of the isodose curves. When the edit mode is activated, tap "Add Dose Level" at the bottom of the list to create more, or use the red delete icon to remove levels.



iPhone Menu

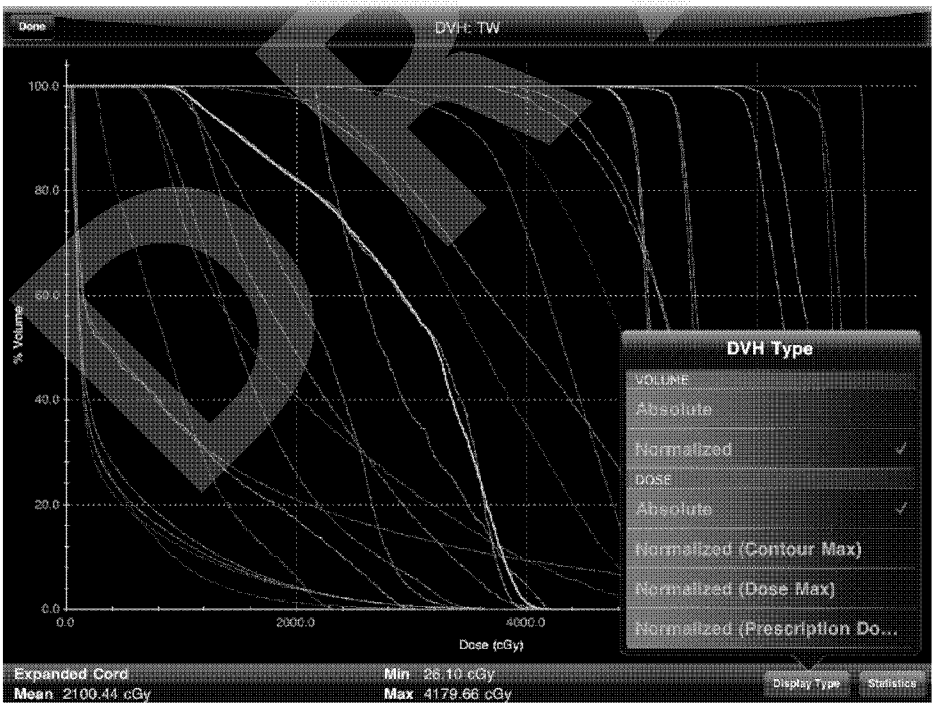
Overlays are stacked one type on top of another. Scroll through the list to find overlays of each type. Tap an overlay's row to toggle its visibility; a checkmark appears next to items that are visible.



DVH

To access the DVH display, select "Show DVH" from the Tools menu.

The DVH display will appear and be viewable with the device in landscape orientation. DVH curves will display based on the current DVH type, accessible using the Display Type button. Tap that button to select between the Volume types of Absolute or Normalized, and the Dose types of Absolute, Normalized (Contour Max), Normalized (Dose Max), and Normalized (Prescription Dose).



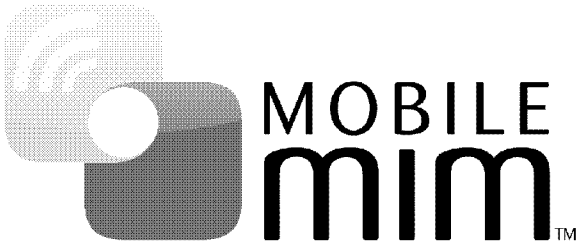
Touching the graph displays an interactive positional indicator to the currently active contour. The indicator localizes to a point on that contour based on the location of the touch. Sliding the finger left and right will move the indicator. The indicator includes a label which identifies the corresponding Volume, and dose at that point.

To change active contour and view more details about each contour, tap the Statistics button. A table appears listing each contour by name, its color, and several statistical details about the dose for that contour. Tap a contour row to make it the active contour (for the interactive positional DVH display). Tap the eye icon at the right edge of the table to toggle the visibility of DVH curves, or the Toggle All button at the top of the table to show or hide all at once.

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.



USER GUIDE

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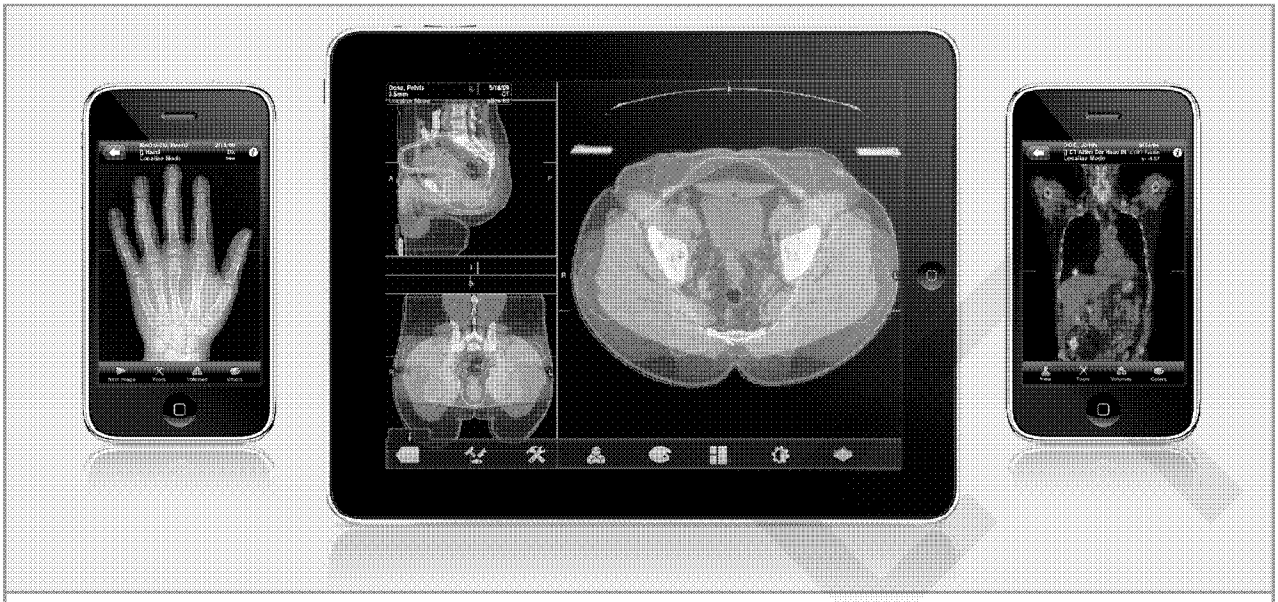
VOL 013 – PROPOSED LABELING

002_MOBILE MIM MARKETING BROCHURE (draft)



Remote Medical Imaging for the iPad & iPhone

- ✓ Multi-planar reconstruction of data sets (CT, MRI, PET, SPECT)
- ✓ Multi-touch interface – zoom, pan, window/level
- ✓ X-rays & Ultrasound at full resolution without downsampling
- ✓ Radiation Therapy display of isodose curves, DVH, & contours
- ✓ Available on the iPad, iPhone, and iPod touch
- ✓ Free download from the Apple App Store
- ✓ Image access through MIMcloud™ or a MIM™ Workstation

Apple, the Apple logo, iPad, iPhone, and iPod touch, are trademarks of Apple Inc., registered in the U.S. and other countries.

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

 Rev. Date TBD

VOL 016 - SOFTWARE

001_LEVEL OF CONCERN

LEVEL OF CONCERN

MIM Software has determined the level of concern of this device to be major. 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 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: *Yes. Mobile MIM can be used to issue approval of radiation treatment plans that can be used to in the decision process for treatment or therapy.*

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.*

Conclusion: Major Level of Concern due to 3(d).

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002_PRODUCT SPECIFICATION

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003_DEVICE HAZARD ANALYSIS

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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 (RT) is accurate and its design, development and testing was done in accordance to the following procedures. In addition, all subsequent revisions to Mobile MIM (RT) will abide by the same guidelines.

Lynn Hanigan
(Signature)

9/30/2011
(Date)

Lynn Hanigan
Quality Manager
MIM Software Inc

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006_Verification and Validation Testing

SOFTWARE VERIFICATION AND VALIDATION PLAN

PROJECT NAME: MOBILE MIM (RT)

SVVP NUMBER: SVVP-0009

SOFTWARE VERSION: 3.x

REVISION:	DESCRIPTION:	DATE:
A	Preliminary – Implementation Phase	9/8/11
B	Alpha - Added 4.2.3	9/29/11

Prepared By: Mark Cain **Date:** 9/8/2011

Approved By: Mark Cain **Date:** 9-27-11

Approved By: Lynn Hanigan **Date:** 9/27/11

Form Number: FM03-005B *Form Revision Date: 9/1/10*

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007_Revision Level History

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008_Unresolved Anomalies and ECOs

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