K113259

V. 510(K) SUMMARY

FEB 1 0 2012

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

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

Mr. Mihir Shah
CEO
UE LifeSciences, Inc.
4435 Lobella Court
CHESTER SPRINGS PA 19425

FEB 10 2012

Re: K113259
Trade/Device Name: NoTouch BreastScan™ System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: January 17, 2012
Received: January 23, 2012

Dear Mr. Shah:

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

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

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K113259

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113259

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113259

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 30, 2011

UE LIFESCIENCES, INC.
4435 LOBELLA COURT
CHESTER SPRINGS, PENNSYLVANIA 19425
ATTN: MIHIR SHAH

510k Number: K113259
Product: NOTOUCH BREASTSCAN
On Hold As of 12/30/2011

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

Grayson, Giovanna *

om:	Microsoft Outlook
.o:	'mshah@notouchbreastscan.com'
Sent:	Friday, December 30, 2011 3:26 PM
Subject:	Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mshah@notouchbreastscan.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

84

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, December 30, 2011 3:26 PM
To: 'mshah@notouchbreastscan.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 30, 2011
SHAH
MIHIR
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ATTN: MIHIR SHAH

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Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 04, 2011

UE LIFESCIENCES, INC.
4435 LOBELLA COURT
CHESTER SPRINGS, PENNSYLVANIA 19425
ATTN: MIHIR SHAH

510k Number: K113259

Received: 11/4/2011

Product: NOTOUCH BREASTSCAN

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

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

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Exchange
To: 'MIHIR@NOTOUCHBREASTSCAN.COM'
Sent: Friday, November 04, 2011 1:14 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'MIHIR@NOTOUCHBREASTSCAN.COM'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

107

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, November 04, 2011 1:14 PM
To: 'MIHIR@NOTOUCHBREASTSCAN.COM'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
November 04, 2
SHAH
MIHIR
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ATTN: MIHIR SHAH

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Sincerely,

510(k) Staff

III 510(K) COVER LETTER

K 25

November 2, 2011

UE LifeSciences Inc.
C/o Mihir B. Shah
4435 Lobella Ct
Chester Springs PA 19425

Phone: 631-980-8340

E-Mail: MShah@NoTouchBreastScan.com

FDA CDRH DMC
NOV 04 2011
Received

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
10903 New Hampshire Avenue,WO66-5429
Silver Spring, MD 20993

Attn: Mary Pastel, Sc.D.

Subject: Cover Letter for 510(k) submission

Dear Dr. Pastel,

UE LifeSciences Inc. (UELS) is filing an original 510(k) premarket notification submission for the following medical device:

Product Trade Name	NoTouch BreastScan™
Product Code	LHQ
Regulation	21CFR884.2980
Classification	Class I
Indications For Use	NoTouch BreastScan™ device is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ device is intended to be used as an adjunctive screening procedure only and does not replace mammography as primary

UE LifeSciences Inc.

NoTouch BreastScan™

510(k) Premarket Notification

UE LifeSciences Inc.
4435 Lobella Court
Chester Springs, PA 19425

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The following information is provided as required by 21 C.F.R. § 807.87 for UE LifeSciences Inc.'s NoTouch BreastScan 510(k) premarket notification:

I. MEDICAL DEVICE USER FEE

The Company has remitted the Medical Device User Fee for a small business concurrent with this submission. A copy of the Medical Device User Fee Cover Page is provided below.

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) Trade [redacted] 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) UE LIFESCIENCES INC 3111 W. Thompson St 3111 W. Thompson St 3111 W. Thompson St Philadelphia PA 19121 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret [redacted] Process Product Specs	2. CONTACT NAME Matthew Campisi 2.1 E-MAIL ADDRESS mcampisi@notouchbreastscan.com 2.2 TELEPHONE NUMBER (include Area code) 631-988-5334 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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: SBD120107

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR

COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

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) Trade Secret Process

01-Nov-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

II. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
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)*
November 3, 2011	(b)(4) Trade Secret Process	

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	x 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 UE LifeSciences Inc	Establishment Registration Number *(if known)*		
Division Name *(if applicable)*	Phone Number *(including area code)* 267-342-3303		
Street Address *4435 Lobella Court*	FAX Number *(including area code)* 918-516-3303		
City Chester Springs	State / Province PA	ZIP/Postal Code 19425	Country USA
Contact Name Mihir Shah			
Contact Title CEO	Contact E-mail Address mihir@notouchbreastscan.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

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

- ☐ Response to FDA correspondence:

- ☐ 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
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
- ☐ 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	K032350	1	BREASTSCAN IR	1	INFRARED SCIENCES CORP
2		2		2	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

TELETHERMOGRAPHIC SYSTEM

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

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

1 K091311	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
LHQ	884.2984	☒ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel		

Indications *(from labeling)*

NoTouch BreastScan™ device is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ device is intended to be used as an adjunctive screening procedure only and does not replace mammography as primary screening tool for the detection of breast cancer.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name UE LifeSciences Inc.		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* 631-988-5334		
Street Address *26 Evelyn Drive*		FAX Number *(including area code)*		
City Commack		State / Province NY	ZIP Code 11725	Country USA
Contact Name Matthew Campisi	Contact Title VP of Technology		Contact E-mail Address mcampisi@notouchbreastscan.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	

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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. IEC 62304	Standards Organization IEC	Standards Title IEC 62304 Ed 1.0 Medical Device Software – Software life cycle process	Version Ed1	Date 9/9/2008
2	Standards No. IEC 60601-1	Standards Organization IEC	Standards Title IEC 60601-1, Medical Electrical Equipment - Part 1	Version	Date 10/31/2005
3	Standards No. IEC 60601-1-2	Standards Organization AAMI/ANSI/IEC	Standards Title AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)	Version	Date 9/9/2008
4	Standards No. ISO 14971	Standards Organization ISO	Standards Title ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General)	Version Ed 2	Date 9/12/2007
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
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

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III 510(K) COVER LETTER

By Fedex

November 1, 2011

FDA CDRH DMC
NOV 04 2011
Received

K-25

UE LifeSciences Inc.
C/o Mihir B. Shah
4435 Lobella Ct
Chester Springs PA 19425

Phone: 631-980-8340

E-Mail: MShah@NoTouchBreastScan.com

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
10903 New Hampshire Avenue,WO66-5429
Silver Spring, MD 20993

Attn: Mary Pastel, Sc.D.

Subject: Cover Letter for 510(k) submission

Dear Dr. Pastel,

UE LifeSciences Inc. (UELS) is filing an original 510(k) premarket notification submission for the following medical device:

Product Trade Name	NoTouch BreastScan™
Product Code	LHQ
Regulation	21CFR884.2980
Classification	Class I
Indications For Use	NoTouch BreastScan™ device is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ device is intended to be used as an adjunctive screening procedure only and does not replace mammography as primary

	screening tool for the detection of breast cancer.

(b)(4) Trade Secret Process [redacted]. As detailed in this submission, NoTouch BreastScan is substantially equivalent to BreastScan IR in all aspects including safety and effectiveness, technological characteristics, output parameters, indications for use and intended use.

Regulatory History:

(b)(4) Trade Secret Process [redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

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?		x

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

Sincerely,

Mihir Shah
CEO, UE LifeSciences Inc.

APPENDIX A

(b)(4) Trade Secret Process - Product Specs

[redacted]

use.

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):_____

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: November 1, 2011

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

VI. TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. § 807.87(k))

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

M.M

(Signature)

Mihir Shah, CEO
(Typed Name and Title)

11/01/2011
(Date)

(Premarket Notification [510(k)] Number)

VII. FINANCIAL DISCLOSURES

UE LifeSciences Inc. is submitting clinical data to support this 510(k) notice. The Company is providing a certification to the absence of any financial arrangements with the clinical investigators as detailed below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b) (6) [redacted]	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Mihir Shah	TITLE President
FIRM / ORGANIZATION UE LifeSciences	
SIGNATURE M. M	DATE *11/01/2011*

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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
   UE LIFESCIENCES

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   10/30/2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   4435 LOBELLA CT.
   CHESTER SPRINGS, PA 19425

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 267-342-3303
   (Fax) 918-516-3303

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)

   NOTOUCH BREASTSCAN

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)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) MIHIR SHAH
    (Title) CEO

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    4435 LOBELLA CT.
    CHESTER SPRINGS, PA 19425

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 267-342-3303
    (Fax) 918-516-3303

15. DATE OF CERTIFICATION
    10/30/2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

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VIII. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

Consistent with FDA's guidance documents entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), UE LifeSciences Inc. is including this statement that the NoTouch BreastScan complies with the following recognized consensus standards:

ISO 14971:2007 Medical Devices—Application of Risk Management

IEC-60601-1 Medical Electrical Equipment –Part 1

IEC -60601-1-2 Electromagnetic Compatibility

IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes

Data Standards Form (FDA Form 3654) is provided on the pages that follow for each standard listed above.

In addition the test results for the following standards are referenced in the accompanying UELS folder.

Section 35 - DES/0100-15a, Hazard Analysis

Section 36 - DES/0100-15b, Medical Risk Assessment

Section 21 – Standards and Data Reports FDA Form 3654. Also included are Declarations of Conformity from each device manufacturer

Section 31- DES/0100 for Software Life Cycle

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	# 018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

\\DC - 037389/000001 - 3319800 v1

1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
5 The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (9/07) PSC Graphics: (301) 443- 1090 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 14971;2007 MEDICAL DEVICES – APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES (GENERAL)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE Conformance with ISO 14971;2007	CONFORMANCE? ☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

IEC 62304 Ed 1.0 Medical Device Software – Software life cycle process

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	# 020	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
5 The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 62304 ED. 1.0 MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESS		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE Conformance with IEC 62304 ED. 1.0	CONFORMANCE? ☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
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TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]
60601-1 Medical Electrical Equipment – Part 1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3] # 013		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT – PART 1		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE Complete conformance with UL 60601	CONFORMANCE? ☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED* National Differences USA, UL 60601-1 (formally UL2601-1)		
DESCRIPTION • UL requirements for Recognized Components dealing with fire, shock, and safety hazards. These differences address components that do not have a harmonized IEC component standard. The deviations are identified in UL 60601-1 as DC national differences. • National Electrical Code (NEC) requirements per NFPA 70, requirements for healthcare facilities and medical installations per NFPA 99, and other regulatory requirements. These deviations are identified in UL 60601-1 as DR national differences. • Requirements for safety practices. These differences relate to IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the part of the manufacturer. These deviations are identified in UL 60601-1 as D2 national differences. • Requirements for basic safety principles and requirements, the elimination of which would compromise safety for U.S. consumers and users of products. A deviation based on this criterion is identified in UL 60601-1 as a D1 national difference. • National differences that are based on editorial comments or corrections. These deviations are identified in UL 60601-1 as DE national differences.		
JUSTIFICATION National deviation for USA		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]
AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3] # 020		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI / ANSI / IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2	☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐Yes ☐No ☐N/A
PE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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IX. EXECUTIVE SUMMARY

Description of the Device

(b)(4) Trade Secret Process - Product Specs

[redacted]

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as the primary screening tool.

Device Comparison

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

- **Performance Testing**

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

X. DEVICE DESCRIPTION (REFERENCE SECTION 11)

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters on the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as the primary screening tool.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- Air conditioner
- Specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers

Complete and comprehensive descriptions of the device components are included in Section 23 – Software Design Specification and Section 26 - Software Description.

Principles of Operation

(b)(4) Trade Secret Process - Product Specs

[redacted]

NoTouch BreastScan Report with indicated measurements

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

XI SUBSTANTIAL EQUIVALENCE (REFERENCE SECTION 12)

As explained below, NoTouch BreastScan is substantially equivalent to other legally marketed Thermal imaging devices. Specifically, the NoTouch BreastScan is substantially equivalent to BreastScan IR. This is explained in explicate detail in the document named "Analysis of Significant Equivalence with BreastScan IR Predicate Device" SRS-SE located in section 12.

NoTouch BreastScan has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate BreastScan IR. A substantial equivalence chart comparing the similarities and differences between the NoTouch BreastScan and its predicate device is provided in Section 12 and in the Executive Summary contained in this document. Any minor differences in the technological characteristics do not raise new questions of safety or efficacy.

a) Intended Use/ Indications for Use

Intended use/indications for use of NoTouch BreastScan

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters on the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as the primary screening tool.

Intended use/indications for use of BreastScan IR

The intended use is stated as viewing and recording heat patterns generate by the human body in the hospital, acute care settings, outpatient surgery, health care practitioner facilities or in an environment where patient care is provided by qualified personnel. The patient population includes adult. The device is for adjunctive diagnostic screening for detection of breast cancer and disease affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

In other words, the NoTouch BreastScan has the same intended use and indications for use its predicate device. Thus, the NoTouch BreastScan satisfies the first criterion for a finding of substantial equivalence.

b) Technological Characteristics

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

c) **Principles of Operation**

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Predicate Device (BreastScan IR) Report with indicated measurements

(b)(4) Trade Secret Process - Product Specs

[redacted]

NoTouch BreastScan Report with indicated measurements

(b)(4) Trade Secret Process - Product Specs

[redacted]

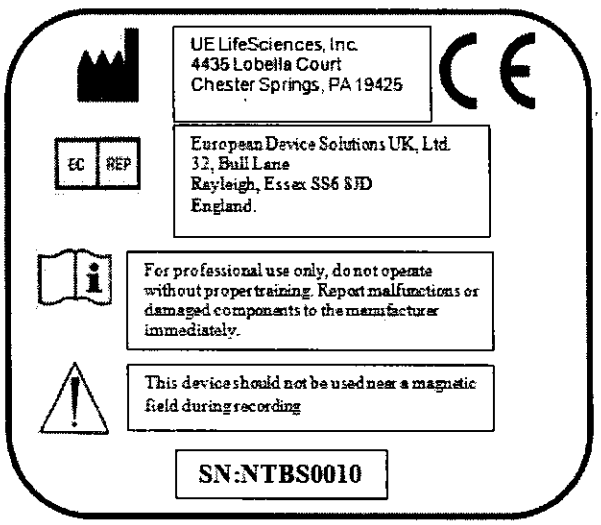
UE LIFESCIENCES INC.'S NOTOUCH BREASTSCAN
SUBSTANTIAL EQUIVALENCE CHART

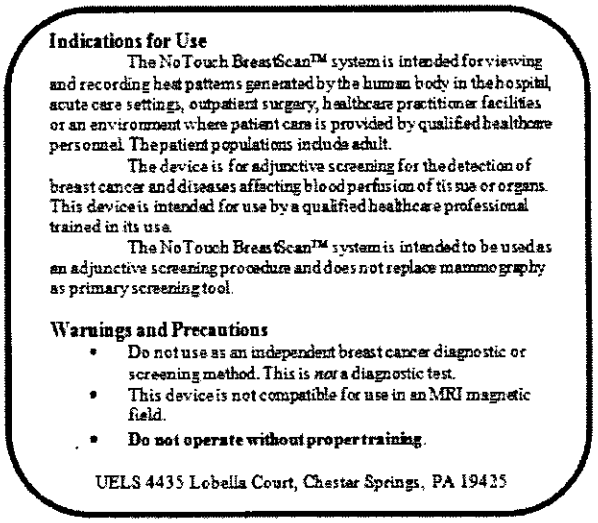
Feature	UE LifeSciences NoTouch BreastScan™ System	Predicate 510(k) premarket notification K032350 BreastScan IR™ System
Intended Use	Visualization/Documentation of temperature patterns and changes –Adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs.	Visualization/Documentation of temperature patterns and changes –Adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs.
Intended User	For use by qualified healthcare personnel trained in its use.	For use by qualified healthcare personnel trained in its use.
Method of Data Collection	(b)(4) Trade Secret Process - Product Specs [redacted]	
Collection Instrument	Infrared camera	Infrared camera
Data processing	CPU with custom algorithms	CPU with custom algorithms
Measurement parameters	Allows for static and dynamic measurement of thermal patterns	Allows for static and dynamic measurement of thermal patterns
Data storage	Hard Drive	Hard Drive
Detector type	Focal Plane Array	Focal Plane Array
Detector Resolution	(b)(4) Trade Secret Process - Product Specs [redacted]	
Thermal Sensitivity	[redacted]	
Camera Output	[redacted]	
Display	Monitor, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-system controls	Keyboard, Mouse, On-system controls

XII. LABELING (REFERENCE SECTION 13)

Proposed Labeling for NoTouch BreastScan

Labels on individually packaged NoTouch BreastScan System





Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. This is *not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

For Instructions for Use Operator's manual and Draft promotional materials

Please see Section 13 of the UELS folder.

XIII. STERILIZATION AND SHELF LIFE (REFERENCE SECTION 14)

The NoTouch BreastScan is not sold sterile, nor is it intended to be sterilized by the user. In the Operator's Manual it states on page 9 that the NoTouch BreastScan system requires basic periodic maintenance. A damp cloth or antibacterial wipe can be used to clean off cart, keyboard mouse and chair. The Operator's Manual is provided in Section 13 in the UELS folder.

The device does not have a labeled shelf life.

XIV. BIOCOMPATIBILITY

The NoTouch BreastScan does not come into contact with the patient. For this reason, the device's biocompatibility is not an issue. Thus, the Company has not provided biocompatibility information for the device.

XV. SOFTWARE (REFERENCE SECTION 16)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Determining Level of Concern

Tables to Determine Level of Concern:

Table 1 Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	**IF Yes, Explain**
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	No
2. Is the Software Device intended to be used in combination with a drug or biologic?	No
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	No
a. Does the Software Device control a life supporting or life sustaining function?	No
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
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?	No
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy,	No

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	IF Yes, Explain
such that if misapplied it could result in serious injury or death?	
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No

Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.	If Yes, explain
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No (The intended device used as an adjunctive screening tool and is not a replacement to primary screening procedures, such as mammography)

Conclusion and Level of Concern Statement:

Based on the prior discussions with the FDA, the NoTouch BreastScan device level of concern is moderate, and therefore UELS has submitted all required documentation for moderate level of concern. Each document is referenced in the table below.

Table 3. Documentation Based on Level of Concern

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	Based on the prior discussions with the FDA, the NoTouch BreastScan device level of concern is MODERATE, and therefore UELS has submitted all required documentation for moderate level of concern. Each document is referenced in the table below. *Section 16 – Level of Concern Analysis*		
Software Description	A summary overview of the features and software operating environment. *Section 31 – Software Design DES/0100* *Section 25 – Software Requirements Specification SRS-1001*		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations. *Section 35 - DES/0100-15A Hazard Analysis* *Section 36 - DES/0100-15B Medical Risk Assessment*		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document. *Sections 26-30 (All SRS docs)*	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts. *Section 32 - DES/0100-6 High Level Design Document*	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document. *Section 23 - SDS/0100 Software Design Specification* *Section 24- SDS-DB Database Design Specification*	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing. *Section 27 - SRS/1003 Traceability Analysis*		

Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities. *Section 25 - SRS-1001 Software Requirements Specification* *Section 31 - DES/0100 Software Design, Development, Verification &Validation and Configure Control Procedures*	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results. *Section 31 Validation and Verification*	cription of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date. *Section 40 - DES/0100-18 Software Revision History*		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors. *Section 33 - DES/0100-10 Unresolved Anomalies*	

Description of Software – (b)(4) Trade Secret Process - [redacted].

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Purpose of software

(b)(4) Trade Secret Process - Product Specs

[redacted]

Design Considerations

(b)(4) Trade Secret Process - Product Specs

[redacted]

Hardware requirements

(b)(4) Trade Secret Process - Product Specs

[redacted]

Programming language(s) used

(b)(4) Trade Secret Process - Product Specs

[redacted]

Off-the-shelf software required

(b)(4) Trade Secret Process - Product Specs

[redacted]

Hazard Analysis (Section 35 - 36)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Software Requirements Specifications (SRS) (Reference Section 25-30)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Traceability Analysis

(b)(4) Trade Secret Process - Product Specs

[redacted]

Software Requirement	V&V Test	Hazard

(b)(4) Trade Secret Process - Product Specs

[redacted]

Verification and Validation Documentation

(b)(4) Trade Secret Process - Product Specs

[redacted]

All SOFTWARE DESIGN, DEVELOPMENT VERIFICATION & VALIDATION AND CONFIGUATION CONTROL PROCEDURES are located in Section 31-41.

Revision Level History

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVI. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (IF APPLICABLE)

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVII. PERFORMANCE TESTING - BENCH

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

XVIII. PERFORMANCE TESTING - CLINICAL

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

Table of Contents

Section	Document Title	Electronic Doc Title
1	MDUFMA Cover Sheet	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
2	CDRH Premarket Review Submission Cover Sheet	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
3	510(k) Cover Letter	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
4	Indications for Use Statement	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
5	510(k) Summary or 510(k) Statement	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
6	Truthful and Accuracy Statement	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
7	Class III Summary and Certification	NA
8	Financial Certification or Disclosure Statement	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
9	Declarations of Conformity and Summary Reports	9_17_21_Declar of Conform_EMC Certificates_FDA Forms
10	Executive Summary	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
11	Device Description	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
12	Substantial Equivalence Discussion	12_SRS_SE_v2
13	Proposed Labeling	13_Labeling
14	Sterilization/Shelf Life	NA
15	Biocompatibility	NA
16	Software	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
17	Electromagnetic Compatibility/Electrical Safety	9_17_21_Declar of Conform_EMC Certificates_FDA Forms

Section	Document Title	Electronic Doc Title
18	Performance Testing – Bench	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
19	Performance Testing – Animal	NA
20	Performance Testing – Clinical	UE LifeSciences 510(k)_11_1_11 Final Signed_rev
21	FORM FDA 3654 Standards Data Reports	9_17_21_Declar of Conform_EMC Certificates_FDA Forms
22	Kit Certification	NA
23	Software Design Specification	23_SDS_0100_Software Design Spec_NTBS
24	Database Design Specification	24_SDS_DB
25	Software Requirement Specification for NoTouch BreastScan	25_SRS_1001 Software Requirements Specification
26	Software Description	26_SRS_1002_Software_Descripti on
27	Traceability Analysis	27_SRS_1003_SoftwareTraceabilit yAnalysisMatrix
28	User Interface Description	28_SRS_1004_User Interface Description
29	Chronological Order of Function of Software Function	29_SRS_1005_Order of Function
30	Thermal Parameters Measured	30_SRS_Parameters
31	Software Design, Development, V&V and Configuration Control Procedure	31_DES_0100_NTBS
32	High Level Design Document	32_DES_0100_6_HLDD_ Component Description_Final
33	Unresolved Anomalies	33_DES_0100_10_Unresolved Anomalies

Section	**Document Title**	**Electronic Doc Title**
34	Software System Testing Check Sheet	34_DES_0100_11_Software & System Testing_QA_Final
35	Hazard Analysis	35_DES_0100_15_A_ Hazard Analysis
36	Medical Risk Assessment	36_DES_0100_15_B_Medical-Risk Assessment
37	System Integration Level Test Plan	37_DES_0100_16_System IntegrationTest Plan
38	Air Cooling Test Plan 1	38_DES_0100_17A_AC test plan1_FinalV2
39	Air Cooling Test Plan 2	39_DES_0100_17B_AC test plan2V2_Final
40	Software Version History	40_DES_0100_18_Software Revision History
41	End User Software Test Plan	41_DES_0100_19.End User Sofware test plan

The following information is provided as required by 21 C.F.R. § 807.87 for UE LifeSciences Inc.'s NoTouch BreastScan 510(k) premarket notification:

I. MEDICAL DEVICE USER FEE

The Company has remitted the Medical Device User Fee for a small business concurrent with this submission. A copy of the Medical Device User Fee Cover Page is provided below.

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**	(b)(4) Trade Secret Process - Product Specs [redacted] 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) UE LIFESCIENCES INC 3111 W. Thompson St 3111 W. Thompson St 3111 W. Thompson St Philadelphia PA 19121 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret Process - Product	2. CONTACT NAME Matthew Campisi 2.1 E-MAIL ADDRESS mcampisi@notouchbreastscan.com 2.2 TELEPHONE NUMBER (include Area code) 631-988-5334 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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: SBD120107

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR

COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a *pediatric population*

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

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) Trade Secret Process - 01-Nov-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

II. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
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)*
November 3, 2011	(b)(4) Trade Secret Process - Product Specs	

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	x 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 UE LifeSciences Inc	Establishment Registration Number *(if known)*		
Division Name *(if applicable)*	Phone Number *(including area code)* 267-342-3303		
Street Address *4435 Lobella Court*	FAX Number *(including area code)* 918-516-3303		
City Chester Springs	State / Province PA	ZIP/Postal Code 19425	Country USA
Contact Name Mihir Shah			
Contact Title CEO	Contact E-mail Address mihir@notouchbreastscan.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

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

- ☐ Response to FDA correspondence:

- ☐ 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
- ☐ 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		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☐ 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	K032350	1	BREASTSCAN IR	1	INFRARED SCIENCES CORP
2		2		2	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
TELETHERMOGRAPHIC SYSTEM

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

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

1 K091311	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
LHQ	884.2984	☒ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel		

Indications *(from labeling)*

NoTouch BreastScan™ device is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ device is intended to be used as an adjunctive screening procedure only and does not replace mammography as primary screening tool for the detection of breast cancer.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name UE LifeSciences Inc.		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* 631-988-5334		
Street Address *26 Evelyn Drive*		FAX Number *(including area code)*		
City Commack		State / Province NY	ZIP Code 11725	Country USA
Contact Name Matthew Campisi	Contact Title VP of Technology		Contact E-mail Address mcampisi@notouchbreastscan.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 62304	IEC	IEC 62304 Ed 1.0 Medical Device Software – Software life cycle process	Ed1	9/9/2008
2	IEC 60601-1	IEC	IEC 60601-1, Medical Electrical Equipment - Part 1		10/31/2005
3	IEC 60601-1-2	AAMI/ANSI/IEC	AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)		9/9/2008
4	ISO 14971	ISO	ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General)	Ed 2	9/12/2007
5					
6					
7					

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

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

Department of Health and Human Services
Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

\\DC - 017389/000001 - 1318800 v1

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III 510(K) COVER LETTER

By Fedex

November 1, 2011

UE LifeSciences Inc.
C/o Mihir B. Shah
4435 Lobella Ct
Chester Springs PA 19425

Phone: 631-980-8340

E-Mail: MShah@NoTouchBreastScan.com

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
10903 New Hampshire Avenue,WO66-5429
Silver Spring, MD 20993

Attn: Mary Pastel, Sc.D.

Subject: Cover Letter for 510(k) submission

Dear Dr. Pastel,

UE LifeSciences Inc. (UELS) is filing an original 510(k) premarket notification submission for the following medical device:

Product Trade Name	NoTouch BreastScan™
Product Code	LHQ
Regulation	21CFR884.2980
Classification	Class I
Indications For Use	NoTouch BreastScan™ device is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ device is intended to be used as an adjunctive screening procedure only and does not replace mammography as primary

	screening tool for the detection of breast cancer.

(b)(4) Trade Secret Process - Product Specs

[redacted]

Regulatory History:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

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?		x

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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

Sincerely,

Mihir Shah
CEO, UE LifeSciences Inc.

APPENDIX A

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):_____

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: November 1, 2011

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

VI. TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. § 807.87(k))

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

(Signature)

Mihir Shah, CEO
(Typed Name and Title)

11/01/2011
(Date)

(Premarket Notification [510(k)] Number)

VII. FINANCIAL DISCLOSURES

UE LifeSciences Inc. is submitting clinical data to support this 510(k) notice. The Company is providing a certification to the absence of any financial arrangements with the clinical investigators as detailed below.

VII. FINANCIAL DISCLOSURES

UE LifeSciences Inc. is submitting clinical data to support this 510(k) notice. The Company is providing a certification to the absence of any financial arrangements with the clinical investigators as detailed below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☑ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b) (6) [redacted]	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Mihir Shah	TITLE President
FIRM / ORGANIZATION UE LifeSciences	
SIGNATURE M. M	DATE *11/01/2011*

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

FORM FDA 3454 (10/09)

PSC Graphics: (301) 443-1090 EF

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
   UE LIFESCIENCES

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   10/30/2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   4435 LOBELLA CT.
   CHESTER SPRINGS, PA 19425

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 267-342-3303
   (Fax) 918-516-3303

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)

   NOTOUCH BREASTSCAN

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)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) MIHIR SHAH
    (Title) CEO

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    4435 LOBELLA CT.
    CHESTER SPRINGS, PA 19425

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 267-342-3303
    (Fax) 918-516-3303

15. DATE OF CERTIFICATION
    10/30/2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

\\DC - 037389/000001 - 3318800 v1

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VIII. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

Consistent with FDA's guidance documents entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), UE LifeSciences Inc. is including this statement that the NoTouch BreastScan complies with the following recognized consensus standards:

ISO 14971:2007 Medical Devices—Application of Risk Management

IEC-60601-1 Medical Electrical Equipment –Part 1

IEC -60601-1-2 Electromagnetic Compatibility

IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes

Data Standards Form (FDA Form 3654) is provided on the pages that follow for each standard listed above.

In addition the test results for the following standards are referenced in the accompanying UELS folder.

Section 35 - DES/0100-15a, Hazard Analysis

Section 36 - DES/0100-15b, Medical Risk Assessment

Section 21 – Standards and Data Reports FDA Form 3654. Also included are Declarations of Conformity from each device manufacturer

Section 31- DES/0100 for Software Life Cycle

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	# 018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
5 The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

FORM FDA 3654 (9/07) PSC Graphics: (301) 443- 1090 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971;2007 MEDICAL DEVICES – APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES (GENERAL)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE Conformance with ISO 14971;2007	CONFORMANCE? ☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

IEC 62304 Ed 1.0 Medical Device Software – Software life cycle process

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	# 020	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? *If yes, report options selected in the summary report table.*	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
5 The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 62304 ED. 1.0 MEDICAL DEVICE SOFTWARE – SOFTWARE LIFE CYCLE PROCESS		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE Conformance with IEC 62304 ED. 1.0	CONFORMANCE? ☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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225

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

60601-1 Medical Electrical Equipment -- Part 1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3] # 013		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report *options* selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance:

226

1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
5 The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE
STANDARD TITLE IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT – PART 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Complete conformance with UL 60601	☒Yes ☐No ☐N/A

TYPE OF DEVIATION OR OPTION SELECTED*
National Differences USA, UL 60601-1 (formally UL2601-1)

DESCRIPTION

• UL requirements for Recognized Components dealing with fire, shock, and safety hazards. These differences address components that do not have a harmonized IEC component standard. The deviations are identified in UL 60601-1 as DC national differences.

• National Electrical Code (NEC) requirements per NFPA 70, requirements for healthcare facilities and medical installations per NFPA 99, and other regulatory requirements. These deviations are identified in UL 60601-1 as DR national differences.

• Requirements for safety practices. These differences relate to IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the part of the manufacturer. These deviations are identified in UL 60601-1 as D2 national differences.

• Requirements for basic safety principles and requirements, the elimination of which would compromise safety for U.S. consumers and users of products. A deviation based on this criterion is identified in UL 60601-1 as a D1 national difference.

• National differences that are based on editorial comments or corrections. These deviations are identified in UL 60601-1 as DE national differences.

JUSTIFICATION National deviation for USA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐Yes ☐No ☐N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), *a deviation to adapt the standard to the device*, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)S
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION
☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]
AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3] # 020		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods *are described; deviations from* the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
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6 The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI / IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2	☒Yes ☐No ☐N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐Yes ☐No ☐N/A
PE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Testing

IX. EXECUTIVE SUMMARY

Description of the Device

(b)(4) Trade Secret Process - Product Specs

[redacted]

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as the primary screening tool.

Device Comparison

A substantial equivalence table below compares NoTouch BreastScan and the predicate device, BreastScan IR and outlines the similarities and the differences.

Feature	UE LifeSciences NoTouch BreastScan™ System	Predicate 510(k) premarket notification K032350 BreastScan IR™ System
Intended Use	Visualization/Documentation of temperature patterns and changes – Adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs.	Visualization/Documentation of temperature patterns and changes – Adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs.
Intended User	For use by qualified healthcare personnel trained in its use.	For use by qualified healthcare personnel trained in its use.
Method of Data Collection	Non-contact passive infrared emissions	Non-contact passive infrared emissions
Collection Instrument(s)	Two FLIR A320 Infrared cameras	One FLIR A40 Infrared camera
Data processing	CPU with custom algorithms	CPU with custom algorithms
Measurement parameters	Allows for static and dynamic measurement of thermal patterns	Allows for static and dynamic measurement of thermal patterns
Data storage	Hard Drive	Hard Drive
Detector type	Focal Plane Array	Focal Plane Array
Detector Resolution	(b)(4) Trade Secret Process - Product Specs [redacted]	
Thermal Sensitivity	[redacted]	
Camera Output	[redacted]	

Trolley Cart	24"x22" rolling cart	24"x30" rolling cart
Air Conditioner	Standard off-the-shelf	Standard off-the-shelf
Display	Monitor, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-system controls	Keyboard, Mouse, On-system controls

Performance Testing

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

X. DEVICE DESCRIPTION (REFERENCE SECTION 11)

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters on the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as the primary screening tool.

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- Air conditioner
- Specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers

Complete and comprehensive descriptions of the device components are included in Section 23 – Software Design Specification and Section 26 - Software Description.

Principles of Operation

NoTouch BreastScan is a digital thermal imaging device, often referred to as Digital Thermal Imaging, Clinical Infrared Imaging or Infrared Thermography. The device incorporates infrared cameras (independently cleared under K033967) that detect and measure the self-emanating infrared radiation from the surface of the breast skin and computer software that displays the static and dynamic thermal patterns of the captured infrared data on a display screen. A complete listing of the thermal parameters is provided in Section 30. This procedure does neither involve any physical contact with the human body nor the use of any ionizing radiation.

During the exam, the patient disrobes from waist up and sits in front of the NoTouch BreastScan system (at a distance of approx 30 inches) in a standard chair with her arms atop of her head. The operator enters the patient's demographic information in the NoTouch BreastScan software and begins the exam. Air-conditioner system (within the NoTouch BreastScan system) turns on and the software begins to gather temperature data via the infrared cameras. After 6 minutes of infrared data recordings, the air conditioning system turns off and the infrared cameras stops the recording. At this time, the patient can put their clothes back on and leave the exam room. The operator follows a few steps through the software to produce a report that can be printed and/or saved on the NoTouch BreastScan system computer. See following page for example of report.

NoTouch BreastScan Report with indicated measurements

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

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(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

NoTouch Breastscan™
Device Labeling

Issue 1: Rev.0: Date: 09/01/2011

1.0 Purpose

The purpose of this document is to describe the general labeling requirements for the NoTouch BreastScan system as stated in Device Labeling Guidance #G91-1 (blue book memo). General labeling requirements for medical devices have been established in 21 CFR Part 801.

All definitions and requirements were taken from the FDA web page.

2.0 Definitions

Labeling:

"Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Directions for Use:

The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information.

Indications for Use:

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is "indicated"
or "intended for use"

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Contraindications:

This describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

Warnings

Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Precautions

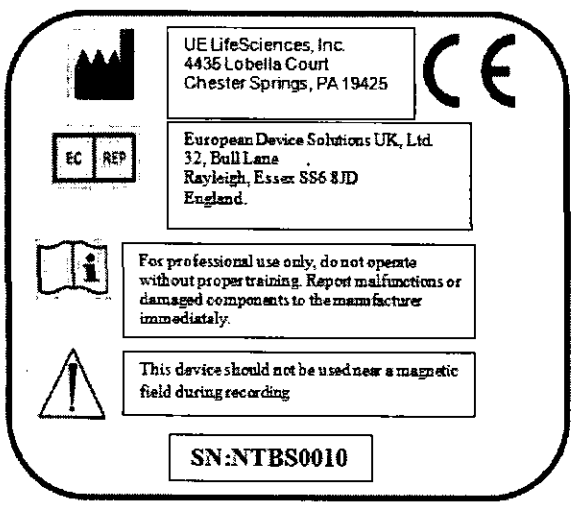
Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

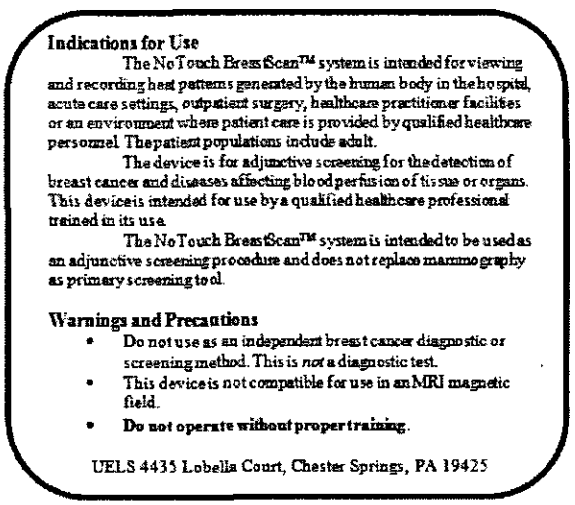
3.0 Label Requirements

a) Name and Place of Business: The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
b) Intended Use: If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
c) Adequate Directions: "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes intended

3.1 Cart labels

These labels should be adhered to the right side of the NoTouch BreastScan cart in clear view.





Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. This is *not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

4.0 Instructions for Use

Instructions for Use are supplied in the Operators Manual in print form. These general instructions are not intended to be used as the only means of training. Users who are not trained are not authorized to use the system.

5.0 Examples of international Symbols as per EN980

ATTENTION SYMBOL;
"See Instructions".
Only *IF* instructions for use are necessary.

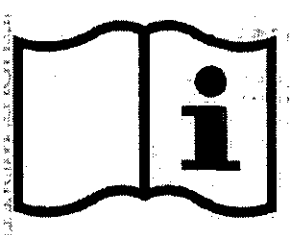
SN:NTBS0001

SERIAL NUMBER;

Alternative symbol to LOT number, the 'SN' prefix must be used.

Manufacture's Details;
The name and address of the manufacturer needs to be "adjacent" to this symbol.

Must be on outer package



Consult Operating Instructions

Self explanatory

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CE

'CE' Logo;

If your products are self-certify devices, ONLY the CE symbol is needed. The number is added for all other devices, as it is the identification number of a 3rd Party Notified Body's intervention.

References:

NTBS Printed Instructions for Use / Operator Manual
Marketing Materials

NoTouch™ BREASTSCAN

Instructions for Use

Operator Manual

Program Version 2.0

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Introduction

Welcome to the NoTouch BreastScan digital thermal imaging system.

NoTouch BreastScan is able to detect very small changes in heat patterns on the breasts and display these findings on a report.

NoTouch BreastScan™ Operators

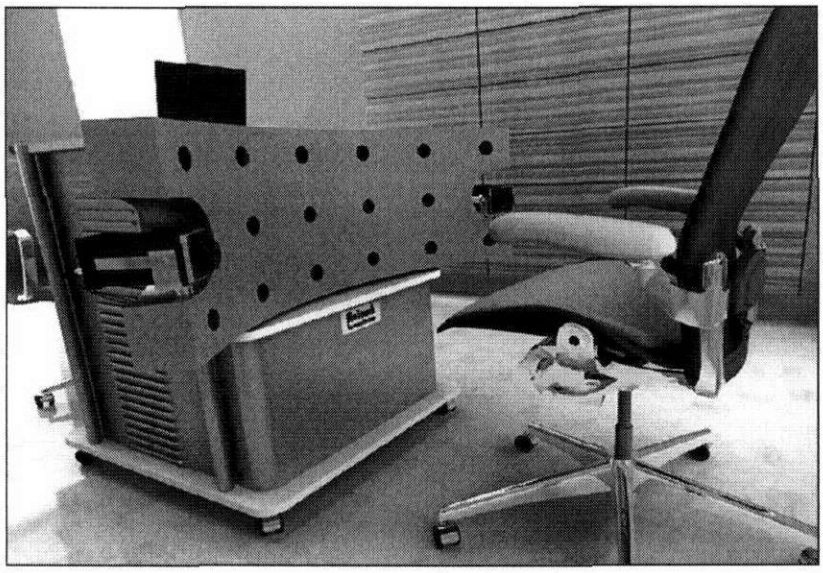
This manual is provided as a general guide and not as a means of training to use the NoTouch BreastScan system.

To properly use the NoTouch BreastScan system a representative of UE LifeSciences Inc. through hands on and/or online workshops in addition to literature will provide training.

Only qualified healthcare personnel who have been trained and certified by a UE LifeSciences Representative should operate the NoTouch BreastScan system.

The NoTouch BreastScan System

NoTouch BreastScan is a digital thermal imaging device, often referred to as Digital Thermal Imaging, Clinical Infrared Imaging or Infrared Thermography. The device incorporates infrared cameras (independently cleared under K033967) that detect and measure the self-emanating infrared radiation from the surface of the breast skin and computer software that displays the static and dynamic thermal patterns of the captured infrared data on a display screen.



This procedure does neither involve any physical contact with the human body nor the use of any ionizing radiation.

During the exam, the patient disrobes from waist up and sits in front of the NoTouch BreastScan system (at a distance of approx 30 inches) in a standard chair with her arms atop of her head. The operator enters the patient's demographic information in the NoTouch BreastScan software and begins the exam. Air-conditioner system (within the NoTouch BreastScan system) turns on and the software begins to gather temperature data via the infrared cameras. After 6 minutes of infrared data recordings, the air conditioning system turns off and the infrared cameras stops the recording. At this time, the patient can put their clothes back on and leave the exam room. The operator follows a few steps through the software to produce a report that can be printed and/or saved on the NoTouch BreastScan system computer. The steps followed by the operator to create the report are provided under the 'Instructions for Use' documentation.

Indications For Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive screening device for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The NoTouch BreastScan™ system is intended to be used as an adjunctive procedure and ***does not replace mammography or ultrasound***.

Contraindications

None Known.

Precautions

Do not operate without proper training. Report any malfunctions or damaged components to the manufacturer immediately.

Warnings

NoTouch BreastScan is ***not*** a diagnostic test. Do not use NoTouch BreastScan as a primary breast cancer diagnostic or screening exam.

This device is not compatible for use in an MRI magnetic field.

Environmental Requirements

NoTouch BreastScan must be operated in a room with proper ventilation and temperature between 68-72 degrees Fahrenheit (20-22.2 degrees Celsius).

If the temperature in the room is higher than 72 F (22.2 C) the patient will not cool properly. If the room is cooler than 68F (20C) the compressor for the Air Conditioner within the NoTouch BreastScan system will not turn on.

Cleaning and Maintenance

The NoTouch BreastScan system requires basic periodic maintenance. A damp cloth or antibacterial wipe can be used to clean the exterior cart, keyboard, mouse and chair.

The camera lens should ***never*** be touched or cleaned. Avoid excess dust by placing the lens caps on the camera when not in use. Report any problems to UE LifeSciences Inc. immediately.

Frequently Asked Questions:

What is Thermography?

Thermography is the most common term used to describe the procedure of thermal (heat) imaging. In simplest terms thermography means "picture of heat".

Certain modern terms are used interchangeably for thermography: electronic thermography, infrared thermography, telethermography, infrared imaging, thermal imaging, infrared thermal imaging, etc.

Is Digital Infrared Imaging Approved by the FDA?

In 1982, Digital Infrared Imaging was first approved by the FDA as an adjunctive breast imaging procedure to be used in conjunction with other imaging tests and/or examination procedures.

Under '21CFR884.2980 Telethermographic system' FDA:

Telethermographic system is intended for adjunctive diagnostic screening for detection of breast cancer or other uses

Identification: A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body.

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This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Classification: Class I (general controls).

[Code of Federal Regulations][Title 21, Volume 8][Revised as of April 1, 2011][CITE: 21CFR884.2980]

Will this test replace a mammogram?

No, NoTouch BreastScan will not replace a mammogram as the primary screening test for the detection of breast cancer.

A physiological imaging procedure (thermography) cannot replace an anatomical imaging procedure (mammography).

Who can take the NoTouch BreastScan Exam?

All adult Men and Women. Men should have chest hair 24hrs before exam.

How often should the test be taken?

The NoTouch BreastScan exam should be taken at a frequency recommended by the patients' physician.

NoTouch BreastScan is entirely radiation free adjunctive breast exam that does not come in physical contact with the human body.

How does NoTouch BreastScan work?

The system is intended to be used as and adjunctive screening device for the detection of breast cancer by measuring various temperature parameters on the surface of the breast.

The NoTouch BreastScan system is composed of a group of components. These components include two digital infrared cameras, a computer system, printer and air conditioner. All the equipment is located on a specially designed cart.

There are two parts to the exam. A: Infrared Recording and B: Data Processing of the recording.

The recording procedure requires the patient to be cooled by the system air-conditioning unit for a short period of time while facing the infrared cameras. The infrared images are Processed by the operator and stored and displayed on a report by the software.

What Takes Place During the Exam?

1)Patient gets disrobed from the waist up.

2)She sits in a chair in front of the NoTouch BreastScan cart with her arms up and her hands placed on top of her head or on her hips.

3)When the test begins, cool air is blown over the breast area for six minutes.

4) IR images will be taken throughout the test and stored in the database.

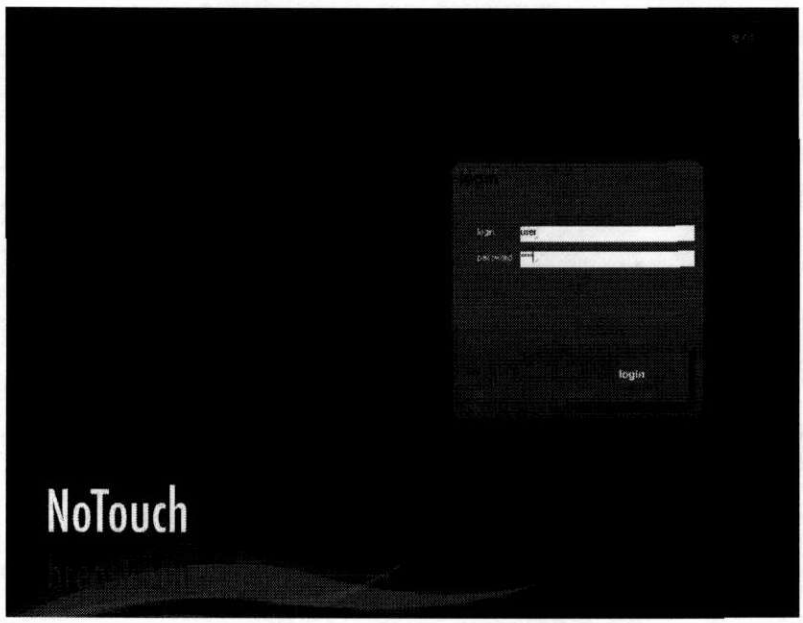
5) The operator will let the patient know when the test is complete.

6) The software will process and store the information and print out a detailed report.

7) The Physician will go over test results with the patient.

Getting Started

Start-up: The system should be plugged into the power outlet in the wall. Turn on the main power switch inside the cart and then start up the computer.



Log-in:

The NoTouch BreastScan login window is launched by double-clicking the icon labeled NTBSOne on the desktop.

To login type "admin" and the default password is "ntbs". The password can be changed at a later time. If the password is changed UELS must be informed of the new password.

Click on the "Login" tab to launch the Main Menu screen.

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Performing the Exam

There are two parts to the NoTouch BreastScan exam. The Recording session and the processing of the recording (also called the scan or sequence file). The Recording session of the NoTouch BreastScan must be completed before the Processing sequence can be performed.

The Recording session requires the patient to be present for the entire session (approximately 6-10 minutes). It also includes entering patient information and positioning the patient prior to starting the recording.

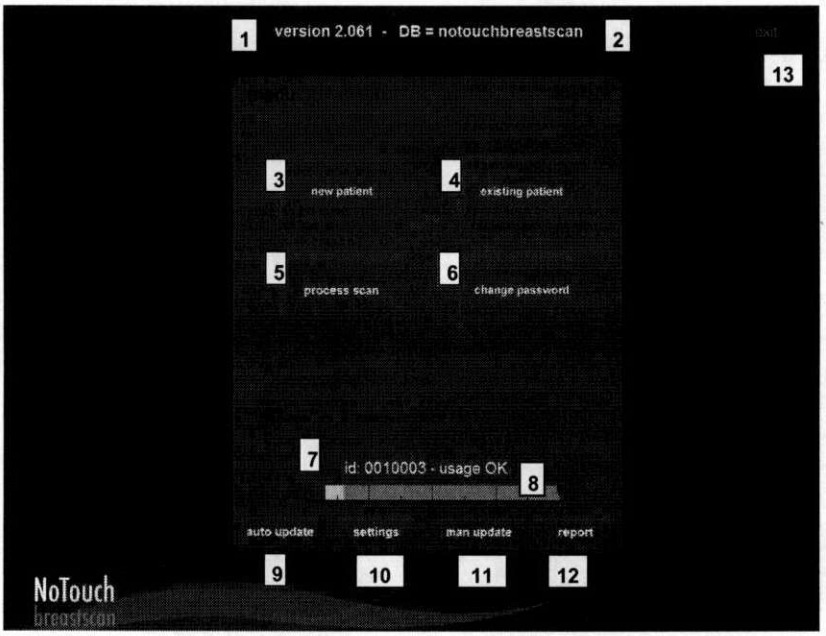
The medical cart has wheels and is movable. The operator should position the cart centered to the patient left to right and approximately 2.5-3 feet away in front of the patient. This will allow even cooling of the breasts and get all of the breast tissue in the camera window. The cart and cameras can be adjusted to get the best view of the breast tissue.

When the "Begin" button is selected in the record window, the software will instruct the infrared cameras to capture thermographic images and will activate and deactivate the cooling device at the appropriate times.

When the software has completed the recording a message will appear informing the operator the recording was successful, this part of the exam is complete. At this time the patient can get dressed and is no longer required.

Before the recording begins the patient should be told to remain still, breath normally and not talk during the recording. As NoTouch BreastScan is taking Infrared images, movement may corrupt the data.

Main Menu



After the operator logs-in the Main Menu will open.

1. Located on the top of the screen is the program version.
2. DB-Name of the database.
3. New Patient– New patient information is entered.
4. Existing Patient-Patient information previously entered in database.
5. Process Scan-All patient recordings are listed in the database and can be processed in this tab.
6. Change Password-Allows operator to change login password.
7. Computer ID-is unique to each system.
8. Usage Meter-Records the number of licenses in system

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and records them on a scale.

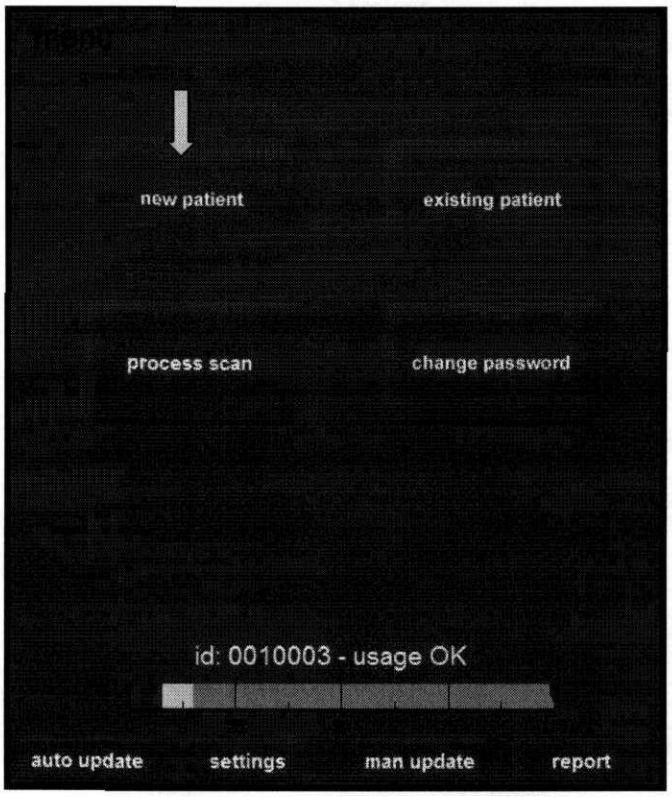
9. Auto Update-When connected to the internet the licenses can be updated automatically.
10. Settings-Changes the setting in the database. Should only be used by UELS.
11. Manual Update-Licenses can be updated by calling on the phone and entering a code manually.
12. Report-Pulls reports by date
13. Exit-Closes the program

Daily Operations

To be discussed in this section are daily operations. Such as performing a scan, entering patient information, patient set-up, performing a recording, processing a recording and printing reports.

It would be useful to run a checklist at the start of the day. Check supply of paper and ink in printer. Run a test scan and make sure everything is running smoothly before a patient comes in for a scan.

Recording a New Patient

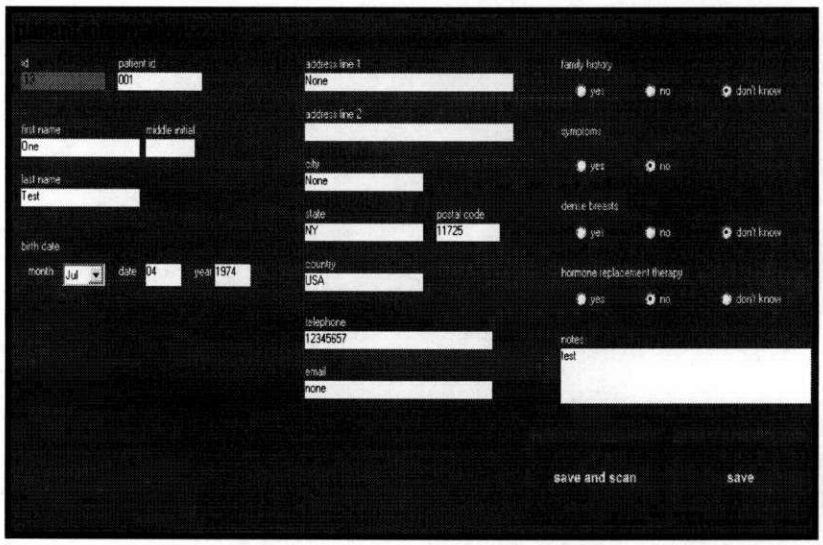


From the Main Menu screen the operator would select the "new patient" tab to add the patient's information into the database.

If the patient were already in the database they would select "existing patient" tab. This will discussed in more detail later in this manual.

When the new patient tab is selected the patient information window will open.

Patient Information Window



In the patient information window all patient information is entered and a patient ID is entered as well. The software gives the individual scan and unique ID number that cannot be changed. There is a note section included to add relevant notes. These notes are stored on the screen and does not print on the report.

From the Patient Information (PID) screen should the "save" tab be selected, the patient information is saved in the database. When "save and scan" is selected the operator is directed to the record window.

It is suggested that the patient get disrobed at this point and the operator would set up the cart and cameras.

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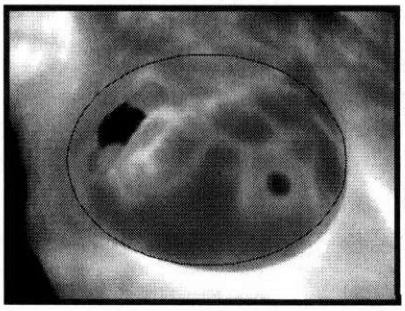
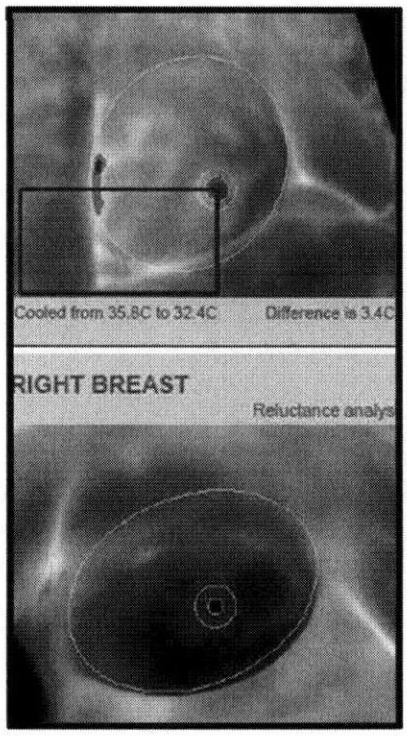
Patient Set-Up:

Before beginning the new recording, the operator must insure the cart and the cameras are set up properly and the patient is correctly positioned.



If there is a bandage, the scan should not be performed or that area should not be selected.

No scarves or Jewelry should be obstructing breast tissue. If so remove it.



The arms need to be placed so no breast tissue is being obscured.

It is preferred that the patient place her hands on her head.

If she cannot hold her arms up for six minutes, she can place her arms on her hips with the elbows facing out as not to obstruct any breast tissue.

To the left is correct positioning of patient and breast image in the camera.

The breast image should fit within the record window. Move cameras and cart to get the best view. Cart should be approximately 30in from the cart to the patient.

Note: there are two different color pallets for processing and printing reports. Gray (uses less ink) or rainbow.

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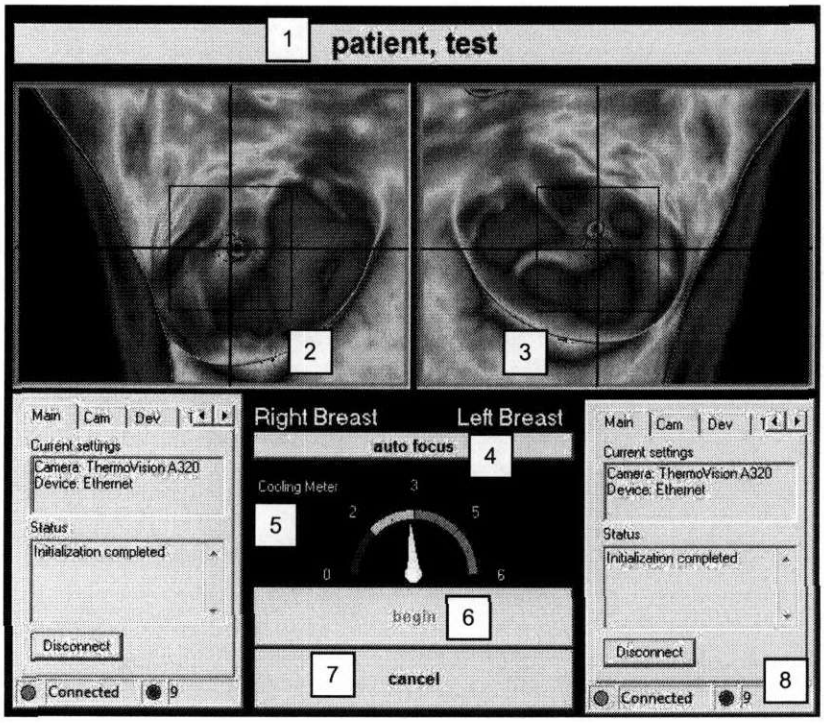
Record Window

Below is an image of proper patient position in the Record window.



Note that the patient is sitting straight in the chair arms are up. Both breasts are centered in the camera view and the image is clear.

After the cameras are auto focused and the image is clear, the patient would be told to breath normally and not to move during the test. When the test begins they will feel cold air blow on them for six minutes. Select the "begin" button to begin the recording.

When begin is selected the program collects images and cool air is blown over the breast for six minutes. There is a cooling meter located under the infrared images to gauge the cooling of the patient. The patient should be cooled at least 2.5 degrees Celsius.

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After the recording has ended the air will stop and the program will stop taking images. There will be a message at the top of the record window stating that the scan was successful.

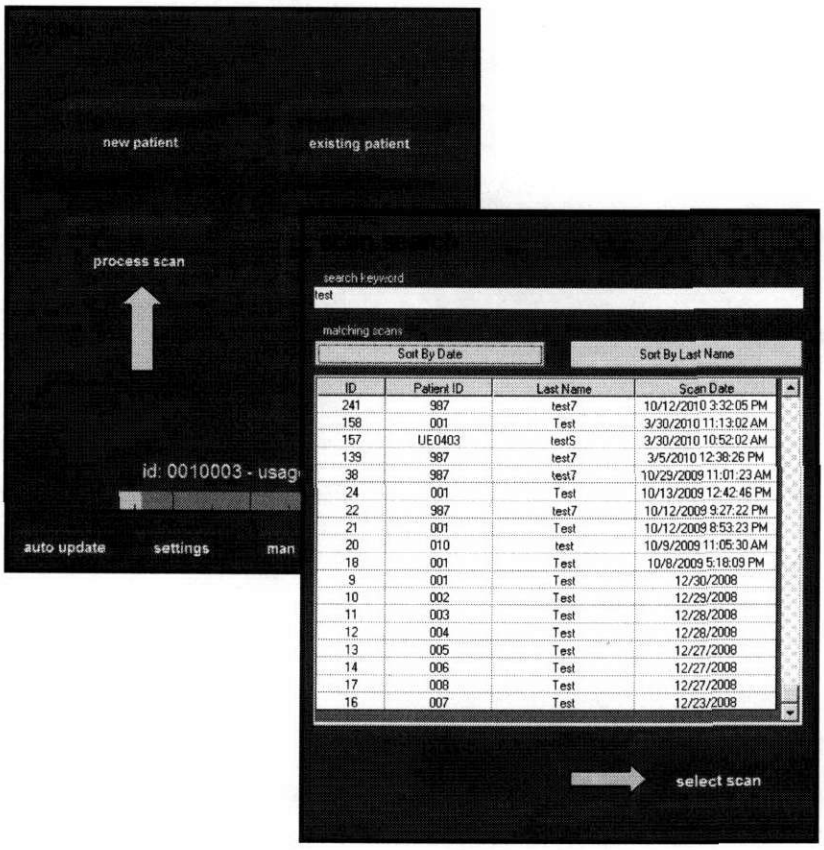
The images will be stored in the database to be processed at a later time. At this point the patient can get dressed and leave the room

Record Window Legend:

1. Name of Patient– will also display a message in this area when recording is completed.
2. Right Breast-Displays IR image of right breast.
3. Left Breast Image-Displays IR image of left breast.
4. Auto Focus-when selected will auto focus cameras.
5. Cooling Meter-displays how patient is cooling during recording.
6. Begin-When selected, program starts to collect images and starts the cool air. Will automatically stop after 6 minutes.
7. Cancel-When selected will cancel the recording and no data will be saved.
8. Frame Rate-the number displays the number of frames during the recording process. (between 11-12 frames).

Process Scan

After the recording is completed the operator will go back to the main menu and select the "process scan" tab.



Scan Search Window

After the Process Scan tab is selected the "Scan Search" window will open.

In the Scan Search window there is a list of names, dates and the Patient ID of all the patients who have been recorded.

These columns can be sorted by date or last name. There is also

a keyword search window provided at the top of the screen.

The operator would select the name of the patient they want to process and the click "select scan" tab.

The purpose of processing a scan is to select areas that are breast tissue.

Then the software will report the temperature measurements in the areas that are selected on a detailed report.

It is very important that the breast tissue be selected properly. The person performing this task must have been trained by a UELS representative or a certified NTBS operator.

Only qualified healthcare personnel who have been trained and certified by a UE LifeSciences Representative are to operate the NoTouch BreastScan system.

Processing A Scan

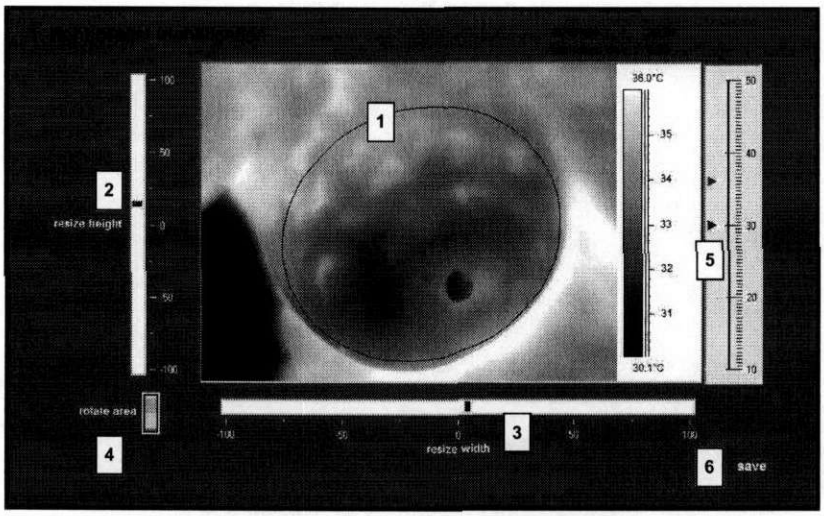
In the breast identification window the first image will be of the right breast pre-cooled for identification. The operator will used the tools provided to select the breast tissue.

After the selection has been made and saved the program will proceed to the next step. The operator will select the right breast post-cooled, the nipple and the areola. After the right breast has been completed the same will be repeated for the left breast.

When all the steps are completed the program will process the data and go on to the review scan window to print out a report.

Breast Identification

In this window the operator will use the tools provided to select the breast tissue.



1. The black outline located over the breast can be moved by clicking and dragging the mouse over the image. The outline can be adjusted in width and height and also rotated.
2. The height slider is located to the left of the image. Click and drag the slider to change size.
3. The width slide is located on the bottom on the image. Click and drag the slider to change size.
4. The rotator tab is located in the lower left portion of the screen. Click on tab to rotate.
5. A color scale is located on the right of the screen. Slide the red and blue markers to adjust contrast. This will help to see the breast tissue more clearly.
6. Save will continue the process for each breast, pre and post cooling and for the nipple and areola.

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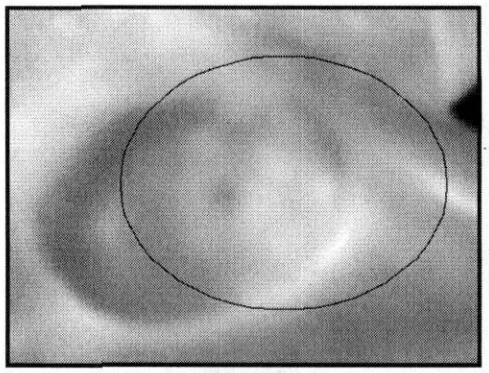
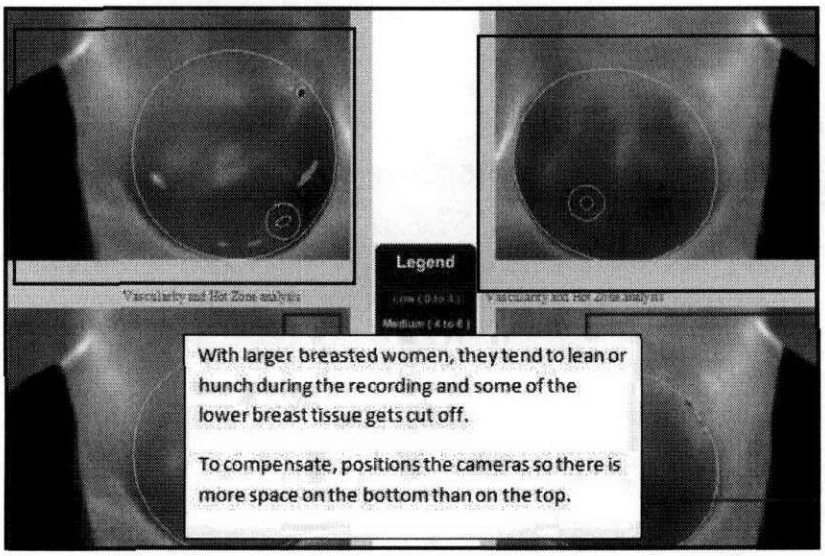
The most important part of the test is to make sure the recording was performed properly. If not there is no need to process the image.

Things to check for:



First make sure the image is clear.

If the image is too blurry do not process it. Have the patient come back and re-take the test.



Patient positioning, all the breast tissue should show in the window and no breast tissue should get cut off.

If all the breast tissue does not fit on the window the cart should be moved away from the patient.

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If the recording was performed properly then continue to process the scan. If an error occurs during the process phase, you can always re-process the scan as many times as needed.

After the processing phase is completed the next screen will be the review scan screen.

Review Scans

1. Exam History-Displays the exam dates (must be highlighted to see image).
2. Reports Processed-Displays the processed dates (if there is no date, it means the patient has been recorded but not processed).
3. Personal Information-Displays name, age, PID and listed information.
4. Right breast image

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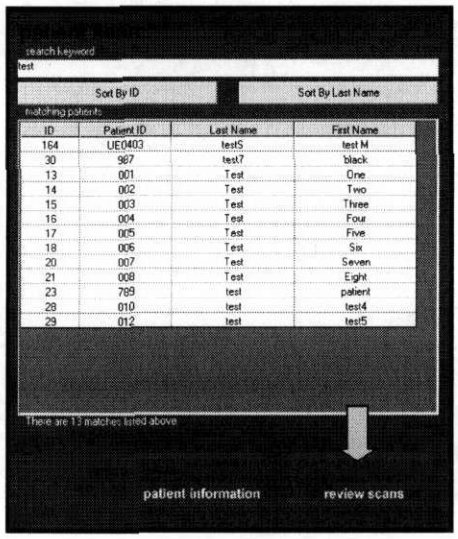
5. Left Breast Image
6. Reluctance, Vascularity and Hot Zone Marker-When Reluctance is selected Markers will be displayed. When Vascularity and Hot Zone Markers is selected Markers will be displayed.
7. Delta-Cooling factor how much the patient has cooled from the beginning of the test to the end (should be 2.5 or higher).
8. Nipple and Full Breast Markers Displays the Temperatures for each breast.
9. Notes-Note that are added will print on report.
10. Suggested Follow up Notes-to print on Written Report.
11. Written Report– Is generated in conjunction with physician recommendations and will be printed out and stored electronically (Ref: NTBS Written Report).
12. Print Report-Print out a graphical report and store a electronic file in the MyImages Folder (Ref: NoTouch BreastScan Graphical Report).

Printing NTBS Reports

Printing graphical and written reports can also be done by going into the existing patient tab and selecting the patient name and then "review scans". Then the "review scan window will open".



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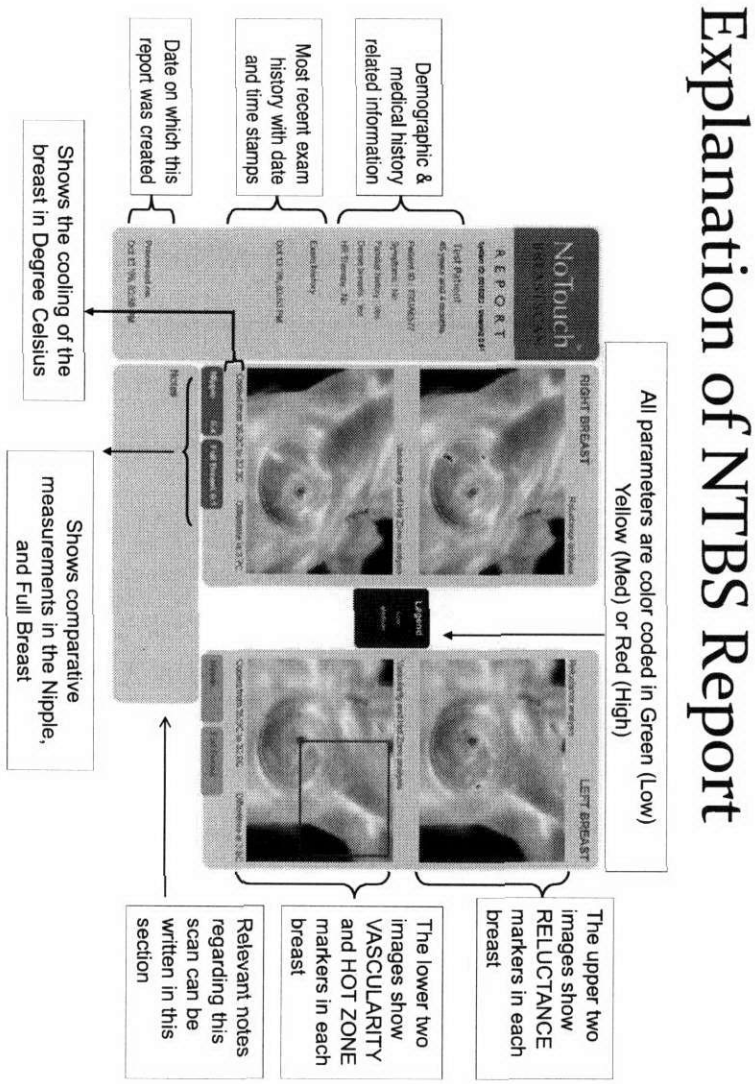
NoTouch BreastScan Graphical Report



See Appendix A for Explanation of Temperature Parameters

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NTBS Written Report

Explanation of Results

Scan Date: Tuesday, October 13, 2009

Patient Name: Test Patient

Patient Age: 43 Years

Patient ID: TRUA6577

Overall Impression: Right Breast No Findings / Left Breast No Findings

This procedure includes 4 distinct measurements and the results for each are indicated below:

Measurement 1: Nipple

No Findings Noted

Measurement 2: Overall Breast

No Findings Noted

Measurement 3: Thermal Reluctance

Right Breast, Findings noted in the following areas

Right Breast-LO

Left Breast, No Findings Noted

Measurement 4: Hot Zone/Asymmetry

Right Breast—No Findings Noted

Left Breast—No Findings Noted

Physician Notes:

Based on the NoTouch BreastScan Results, it is recommended that a follow-up scan be performed in 3 months. In addition, it is also recommended that the patient receive routine monitoring.

Disclaimer: NoTouch BreastScan (NTBS) is strictly an adjunctive breast-screening tool and not a diagnostic exam. NTBS Results do not confirm the presence or absence of breast cancer. This device is intended to be used by a qualified healthcare personnel trained in it's use.

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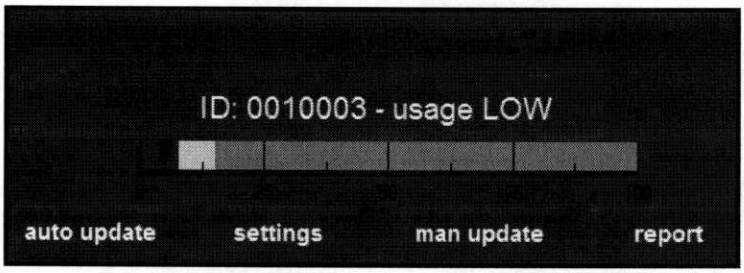
Additional Features

Explanation of License Usage

Located on the lower portion of the Main Menu is the Usage Meter. This feature allows for only a certain number of scans (licenses) to be performed per month. The operator may renew the licenses at any time. It also keeps track of the number of scans performed on a monthly basis and will be used for billing purposes. A license is used every time a recording is performed. When the license usage is getting low there will be a warning message above the scale.

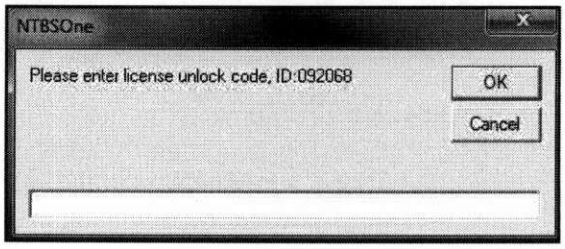


Auto Update

If the computer is connected to the internet and is set up for automatic license updates this tab would be selected and the licenses would update automatically.

Manual Update

When the "man update" tab is selected the following window will open. The operator would call UELS and read the number listed on the screen. The UELS technician would give a unlock code which the operator would enter to update the licenses.



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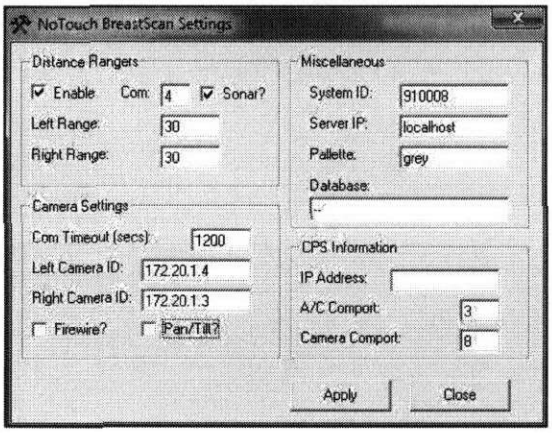
Settings

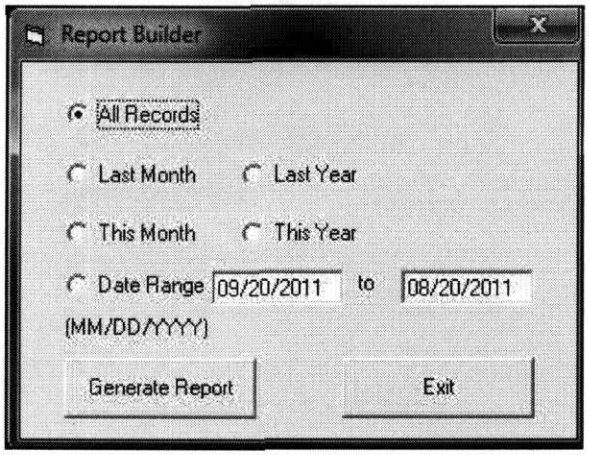
When the setting tab is selected the following window will open.

These setting should not be touched by the operator and used only when directed by a UELS representative.

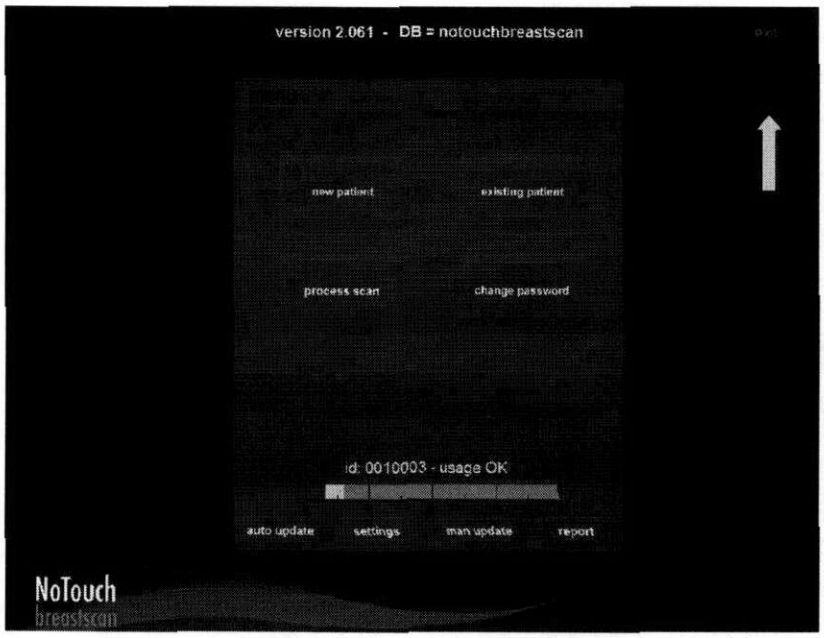


Reports

This tab will print out a list of procedure reports. When the report tab is selected the following window will open. The operator has different date options on which to select. The "generate report" tab would be selected to view and print a list of names that were performed on the selected dates.



Exit Program and Shut Down



From the Main Menu click on the Exit tab at the top right of the screen. This will Close the NoTouch BreastScan program.

From the Windows menu select “shut down” and this will turn off the computer.

Turn off the main power strip inside the cart.

Put the lens caps on the cameras.

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Troubleshooting

Should the program freeze up or not perform properly. It is best to completely shut everything down and restart.

If there is no camera image, check all the wires are plugged in properly.

If there is a power surge you should shut the system down and restart. If there is a power outage, the system should be unplugged until the power comes back on.

There are surge protectors located inside the cart and this should protect the equipment.

Should you have any problems with the system working properly contact your UE LifeSciences Representative right away.

NoTouch BreastScan™

Technical Specifications

Assembled Cart Dimensions: (includes Plenum) L- 26 in x W- 40in x H -37in (66.0 cm x 101.6 cm x 94 cm) Computer: Model: PC Camera Data Interface: Ethernet Office Studio: Windows 7 Display: Flat panel Air Conditioner Specs: Frigidaire: Size: L 16in x W 12in x H 11.75in 5000BTU/h Weight: 40lbs AHAM Certified Electrical Specs: Voltage: 115V Required Voltage: 120 Amperage: 5 to 5.9 amps Frequency: 60 Hz	IR Camera: Model: FLIR ThermoVision A320 Field of view: 25°x 18.8?0.4m (1.3ft.) Focusing: Auto focus, motorized manual Detector Type: Focal Plane Array (FPA) un-cooled microbolometer Pixel resolution: 320 x 240 Temperature Ranges: -20℃ to +120℃ (-4℉ to 248℉) 0℃ to + 350℃ (32℉ to 662℉) Accuracy (% of Reading): ±2℃ or ±2% Spectral Range: 7.5 to 13.0 µm Medical Grade Isolation Transformer: **Domestic:** Input/output 120 v 60 Hz Safety Agency Approvals: UL2601 and CSA 601. Leakage current 100µA

NoTouch BreastScan™

Technical Specifications Continued

International:

Input/output: Selectable, 115 or 230V 50 -60Hz

Safety Agency Approvals: UL2601.1, CSA C22.2 No. 601.1, EN60601-1, EN60742, IEC601-1 CE Marking.

Leakage current 100µA

Thermal Current Limiting Fuse

Air Conditioner Control:

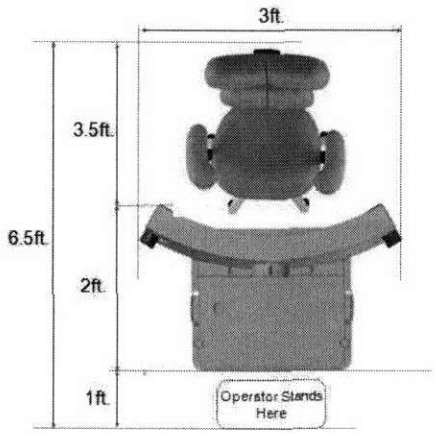
International Power Controller (IPC)

Auto adapts from 100 to 250 volts

NoTouch BreastScan must be operated in a room with proper ventilation and a temperature between 68-72 degrees Fahrenheit (20-22.2 degrees Celsius).

The Air unit does put out some heat. Should the temperature be too high the patient will not cool properly. If the room is too cool, the compressor for the AC will not come on.

The room it is placed in should be no smaller than 8x10 ft.



Total Dimensions: 6.5'x3' = 21 sq. ft.

Top View

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Appendix A: Thermal Parameters Defined.

Description of Reluctance Markers

Description: The reluctance measurement quantifies the difference in cooling between a particular pixel in the breast and the average temperature of its immediate surroundings. The first step in this calculation is to perform an image subtraction between the first frame (before cooling) and last frame (after cooling). A new frame is then created (referred to as the difference frame) with the differences of each pixel. This calculation is performed on every pixel in the difference frame. Each pixel in the difference frame is compared with the surrounding pixels. The surrounding pixels consist of a 7 x 7 matrix of pixels evenly and immediately surrounding and excluding the pixel in question.

Description of Hot Zone Markers

Hot Zone markers indicate any pixel in the last frame that has a temperature that is more than 1.5 standard deviations higher than the average breast temperature. This is performed independently in the left and right breast. The standard deviation is calculated from the temperatures of each pixel on the surface of the each breast. These pixels are marked in yellow. If the temperature of a pixel exceeds 2.0 standard deviations from the average breast temperature, the pixel is marked in red. Note that the pixel temperature is compared only to the average temperature of the breast in which it exists. Any pixels not meeting these criteria remain unchanged. The final results are indicated on the Hot Zone picture on the NoTouch BreastScan Report.

Description of Vascularity Markers

Vascularity markers compare red Hot Zones between contralateral portions of each breast. The breast is divided into 4 quadrants; Lower Inner, Lower Outer, Upper Inner, and Upper Outer. Each quadrant is marked as "Vascular" or "Not Vascular" as indicated by a red box on the Vascularity picture on the NoTouch BreastScan report. A quadrant is marked vascular if there is significant (2 x or more) hot markers as compared to its contralateral quadrant in the other breast.

Description of Full Breast Measurement

The full breast measurement quantifies the difference between the average full breast temperature of the left breast and the average full breast temperature of the right breast. The Avg. Nipple and Avg. Areola temp. are NOT a part of this measurement.

Description of Nipple Measurement

The nipple measurement quantifies the difference between the average nipple temperature of the left breast and the average nipple temperature of the right breast. This measurement is only indicated for the breast with the warmer of the two nipples.

- *In all cases the term "temperature" refers to skin surface temperatures. In degrees Celsius.*
- *Only a trained physician can explain the test results to the patient.*

Appendix B: Suggested Patient Consent Form

Patient ID#_____

Last Name_____First Name_____Middle Initial___

DOB__/__/__ Tel#_____

Street Address_____Apt#_____

City_____State_____Zip_____

Do You Have a History Of Breast Cancer? Yes No

Do you have any primary family members diagnosed with breast cancer? No If Yes who:

Are you on Hormone Therapy?

Do you have any clinical observations about your breasts (lump, pain, discharge, etc.)?

Have you had any surgery on your breasts? If yes, please state when and what procedure was performed.

Do you have dense breasts? Yes No Don't Know

Physician Information

If your primary physician is not the office performing this test, please provide the name of your physician who normally receives mammography, sonogram or yearly clinical breast exam so we can send your doctor a copy of the test results.

Doctor's Name_____Type of Dr_____

Name of Office_____Phone#_____

Address_____Suite_____

City_____State_____Zip_____

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NoTouch BreastScan™ is a dual-IR camera based, fully computerized thermal imaging technology for woman of all ages.

Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.

UE LifeSciences Inc.
4435 Lobella Ct
Chester Springs PA 19425
(+1)631.980.8340
info@NoTouchBreastScan.com

NoTouch

UE LIFESCIENCES INC.

www.notouchbreastscan.com

adjunctive breast cancer screening for women of all ages

NoTouch
BREASTSCAN

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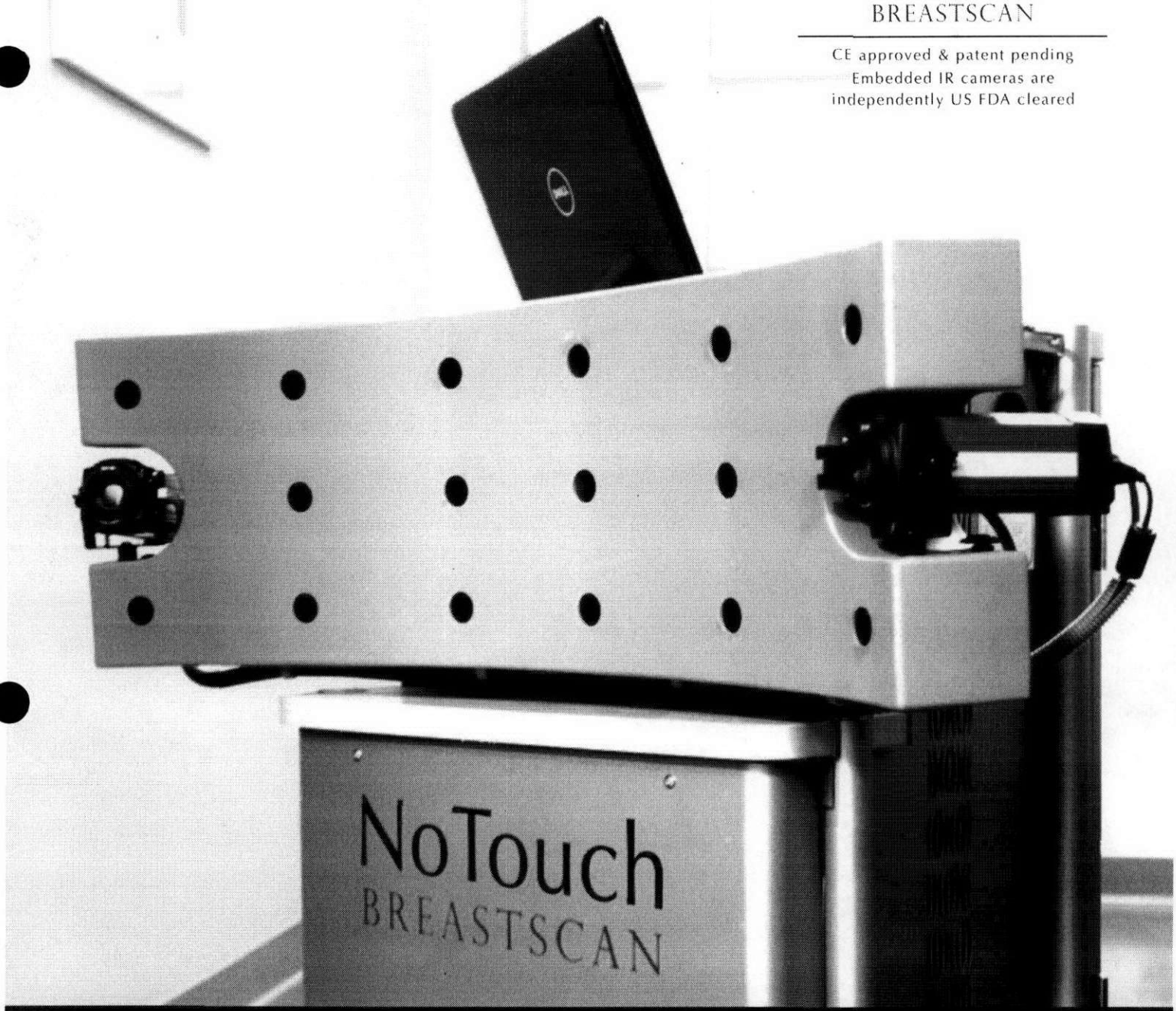
Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.

painless & radiation-free breast evaluation for all women

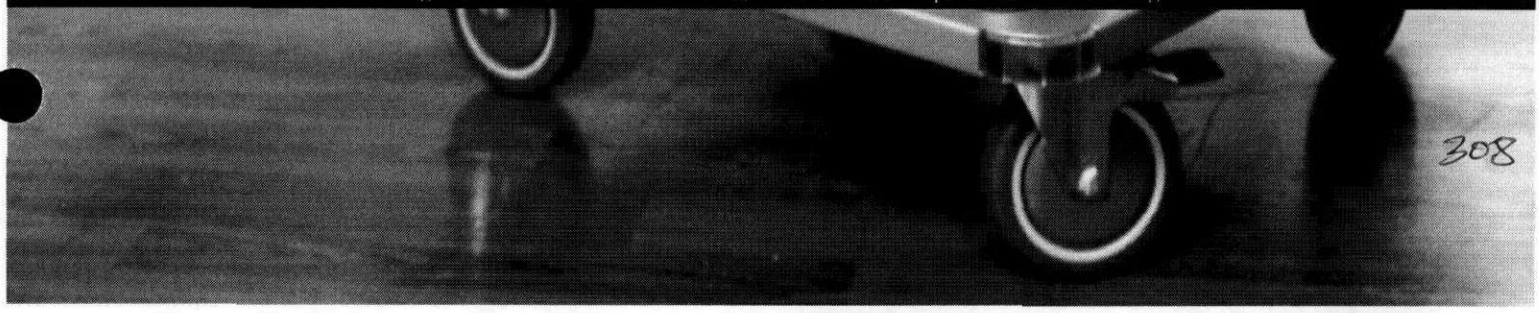
NoTouch
BREASTSCAN

CE approved & patent pending
Embedded IR cameras are
independently US FDA cleared



WORLD'S FIRST, FULLY COMPUTERIZED DUAL IR-DETECTOR BREAST IMAGING

Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.



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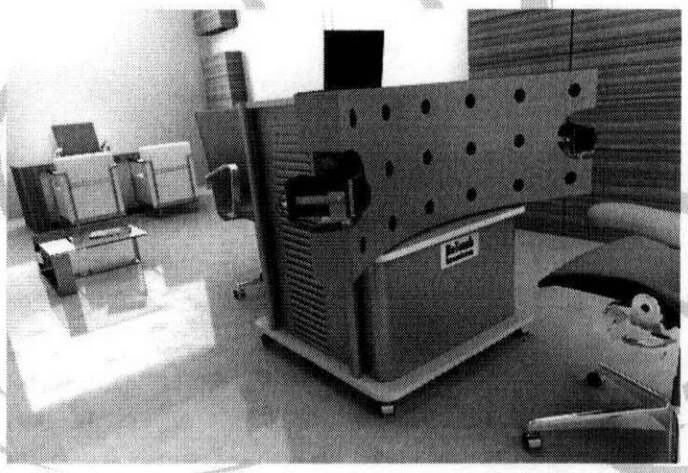
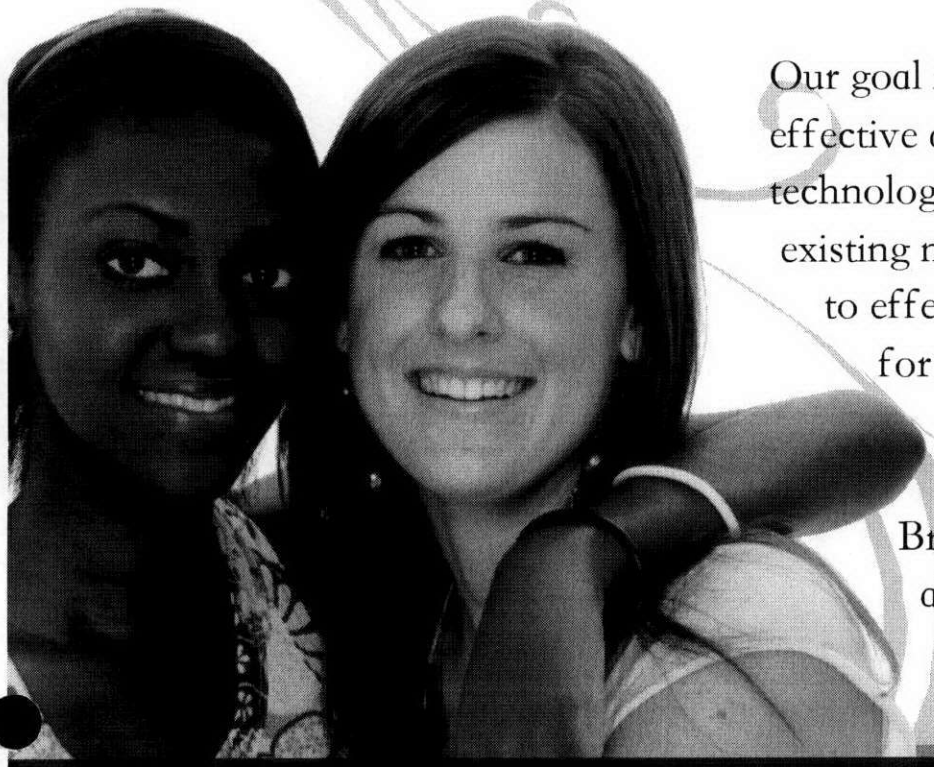
As breast cancer spreads globally to become the most common cancer amongst women and a leading cause of cancer related deaths, younger women under the age of 40, women with dense breasts and high-risk women need effective breast examination tools in addition to the conventional exams.

NoTouch BreastScan™ is a clinically effective, computerized adjunctive breast cancer screening examination incorporated with FDA cleared dual IR imagers that do not require any physical contact with the human body or use of ionizing radiation. This quick, 10 min. exam can be offered to women of any age.



NoTouch BreastScan System

NoTouch BreastScan™ is a CE certified physiological test that provides a simple to understand thermographic map of your breasts.



Our goal is to provide accurate, cost-effective and clinically proven technologies that can compliment all existing modalities, enabling physicians to effectively manage breast health for women of all ages.

Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.

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integrated with FDA cleared infrared imaging cameras

Technical Specifications

NoTouch
BREASTSCAN

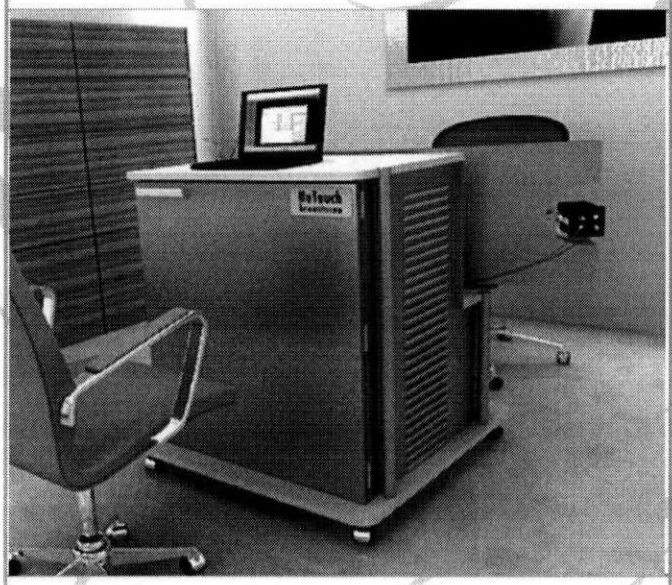
Software Application Suite
- Software based multi-image pixel analysis
- Simultaneous dual-breast evaluation
- Multi-parameter evaluation including Reluctance, Vascularity, Hot-Zone, Nipple, Full Breast & iMeasure assessment for each breast
- Live temp. gauging and target cut-off
- IR assisted range finder
- Auto-PDF creation, printing, email
- Multiple report management per patient
- Exam history management
- Dual IR camera control
- Password protected security

Custom Air Plenum
- Curved 2.5Ft x 1Ft. surface
- Anti-turbulent, even air-flow system
- Accommodates patients of all sizes
- Adjustable lever
- Size: 12″ x 40″

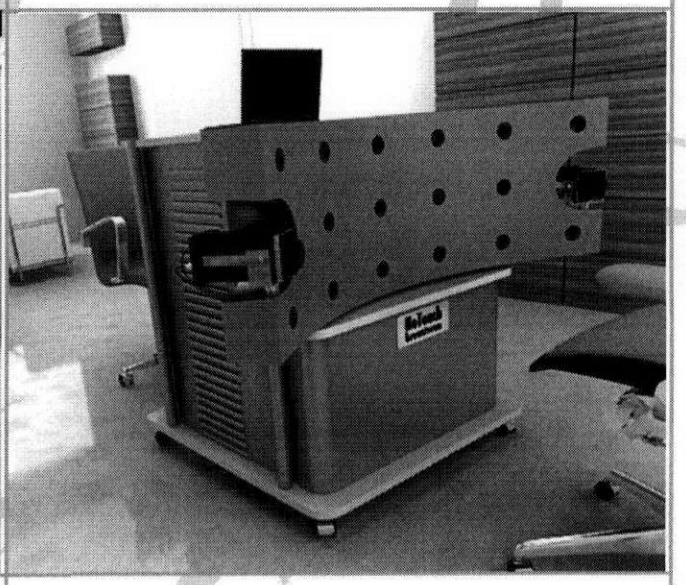
Dynamic Image Series
- Built-in 5000 BTU air cooling
- Software based control system

High Precision, Dual IR Cameras
- Simultaneous & synchronized performance
- US FDA approved
- Focal Plane Array (FPA) Uncooled Micro-bolometer Detector
- Spectral Range: 7.5-13μm, Thermal sensitivity 0.08°C, Spatial Resolution: 1.3 mrad
- Focusing: Auto focus, motorized
- Adaptive Digital Noise Reduction
- Field of View: 25° × 18.8°/0.4m (1.3 ft.)
- Weight: 0.7 kg (per camera)
- Size: 170 x 70 x 70 mm (per camera)
- Frame rate: 7-9 Hz

Miscellaneous
- CE registration# 14020/GB/060209-001MDD
- Computing platform: Windows OS
- Multifunction inkjet printer
- EtherNet Router, USB Hub, FireWire Hub
- Flexible wheel based trolley w/ locking
- Overall Dim: 40″ L x 26″W x 37″ H
- Power: 110V, 5A (single phase)



Rear Angle View



Front Angle View

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Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.

NoTouch BreastScan™ is the world's first, dual-IR camera based fully computerized thermal imaging technology for women of all ages

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Warning: NoTouch BreastScan™ is an adjunct to and not a replacement for mammograms.

UE LifeSciences Inc.
4435 Lobella Ct
Chester Springs PA 19425
(+1)631.980.8340
info@NoTouchBreastScan.com

NoTouch

XIII. STERILIZATION AND SHELF LIFE (REFERENCE SECTION 14)

The NoTouch BreastScan is not sold sterile, nor is it intended to be sterilized by the user. In the Operator's Manual it states on page 9 that the NoTouch BreastScan system requires basic periodic maintenance. A damp cloth or antibacterial wipe can be used to clean off cart, keyboard mouse and chair. The Operator's Manual is provided in Section 13 in the UELS folder.

The device does not have a labeled shelf life.

XIV. BIOCOMPATIBILITY

The NoTouch BreastScan does not come into contact with the patient. For this reason, the device's biocompatibility is not an issue. Thus, the Company has not provided biocompatibility information for the device.

XV. SOFTWARE (REFERENCE SECTION 16)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Determining Level of Concern

Tables to Determine Level of Concern:

Table 1 Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	**IF Yes, Explain**
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	No
2. Is the Software Device intended to be used in combination with a drug or biologic?	No
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	No
a. Does the Software Device control a life supporting or life sustaining function?	No
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
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?	No
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy,	No

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.		IF Yes, Explain
	such that if misapplied it could result in serious injury or death?	
e.	Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No

Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.		If Yes, explain
1.	Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
2.	Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
3.	Could a malfunction of, or a *latent design flaw* in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No (The intended device used as an adjunctive screening tool and is *not* a replacement to primary screening procedures, such as mammography)

Conclusion and Level of Concern Statement:

Based on the prior discussions with the FDA, the NoTouch BreastScan device level of concern is moderate, and therefore UELS has submitted all required documentation for moderate level of concern. Each document is referenced in the table below.

Table 3. Documentation Based on Level of Concern

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	Based on the prior discussions with the FDA, the NoTouch BreastScan device level of concern is MODERATE, and therefore UELS has submitted all required documentation for moderate level of concern. Each document is referenced in the table below. *Section 16 – Level of Concern Analysis*		
Software Description	A summary overview of the features and software operating environment. *Section 31 – Software Design DES/0100* *Section 25 – Software Requirements Specification SRS-1001*		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations. *Section 35 - DES/0100-15A Hazard Analysis* *Section 36 - DES/0100-15B Medical Risk Assessment*		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document. *Sections 26-30 (All SRS docs)*	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts. *Section 32 - DES/0100-6* *High Level Design Document*	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document. *Section 23 - SDS/0100 Software Design Specification* *Section 24- SDS-DB* *Database Design Specification*	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing. *Section 27 - SRS/1003 Traceability Analysis*		

Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities. *Section 25 - SRS-1001 Software Requirements Specification* *Section 31 - DES/0100 Software Design, Development, Verification &Validation and Configure Control Procedures*	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results. *Section 31 Validation and Verification*	cription of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date. *Section 40 - DES/0100-18 Software Revision History*		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors. *Section 33 - DES/0100-10 Unresolved Anomalies*	

Description of Software – (b)(4) Trade Secret Process - Product Specs [redacted].

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Purpose of software

(b)(4) Trade Secret Process - Product Specs

[redacted]

Design Considerations

(b)(4) Trade Secret Process - Product Specs

[redacted]

Hardware requirements

(b)(4) Trade Secret Process - Product Specs

[redacted]

Programming language(s) used

(b)(4) Trade Secret Process - Product Specs

[redacted]

Off-the-shelf software required

(b)(4) Trade Secret Process - Product Specs

[redacted]

Hazard Analysis (Section 36 - 37)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Software Requirements Specifications (SRS) (Reference Section 25-30)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Traceability Analysis

(b)(4) Trade Secret Process - Product Specs

[redacted]

Verification and Validation Documentation

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVI. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY (IF APPLICABLE)

Our device design includes an electronic component, FDA recommends that its electromagnetic compatibility is tested with regard to emissions and immunity. FDA recommends that the testing occur according to IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests (Second Edition, 2001) or some equivalent method.

The Company's Electromagnetic Compatibility and Electrical Safety test methodology and results are provided in Sections 9 and 21 of the UELS folder.

XVII. PERFORMANCE TESTING - BENCH

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

XVIII. PERFORMANCE TESTING - CLINICAL

(b)(4) Trade Secret Process - Testing

[redacted]

(b) (6), (b) (4)

(b) (6), (b) (4)

APPENDIX B

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices (General)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices (general)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Conformance with ISO 14971:2007	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 020	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: IncorporatingHuman Factors Engineering into RiskManagement

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
'EC 62304 ED. 1.0, MEDICAL DEVICE SOFTWARE - SOFTWARE LIFE CYCLE PROCESSES.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	IEC 62304:2006 CLAUSE NUMBER and SOFTWARE SAFETY CONDITIONS POLICIES and PROCEDURES PLANS RECORDS DOCUMENTS AUDITS and REVIEWS 4.0 General requirements 4.1 Quality management system Class A, B, C • ISO 13485 Requirements or Equivalent for Procedures • ISO 13485 Requirements or Equivalent for Plans • ISO 13485 Requirements or Equivalent for Records • ISO 13485 Requirements or Equivalent for Documents • ISO 13485 Requirements or Equivalent for Audits • ISO 13485 Requirements or Equivalent for Reviews 4.2 Risk Management Class A, B, C • ISO 14971 Requirements for Procedures .• ISO 14971 Requirements for Plans • ISO 14971 Requirements for Records • ISO 14971 Requirements for Documents • ISO 14971 Requirements for Audits* • ISO 14971 Requirements for Reviews* 4.3 Software safety classification Class A, B, C • Assignment of Software Safety Class Procedure • Risk Management File Document Procedure* • Software Safety Class Document Procedure* • Software Safety Class Records* • Risk Management File Document • Software Safety Class Docume • Risk Management File Document Review* • Software Safety Class Document Review* • Software Safety Class Records Review* 5.0 Software development process 5.1 Software development planning 5.1.1 I Software development plan Class A, B, C • Software Development Plan Procedure* • System Development Plan Procedure* • Software Development Plan • System Development Plan* • Software Development Plan Review* • System Development Plan Review* 5.1.2 Keep software development plan updated Class A, B, C • Software Development Plan Update Records • Software Plan Update Records Review* 5.1.3 Software development plan reference to system design and development Class A, B, C • Design and Development Validation Procedure • Software Development Coordination Procedure • System Requirements Document Procedure* • System Requirements Document • System Requirements Document Review* 5.1.4 Software development standards, methods and tools planning Class C • Software Development Standards, Methods and Tools Plan Procedure* • Software Development Standards, Methods and Tools Plan • Software Development Standards, Methods and Tools Plan Review* 5.1.5 Software integration and integration testing planning Class B, C• Software Integration (Including SOUP) Plan Procedure* • Software Integration Test Plan Procedure* • Software Integration (Including SOUP) Plan • Software Integration Test Plan • Software Integration (Including SOUP) Plan Review* • Software Integration Test Plan Review* 5.1.6 Software verification planning Class A, B, C • Software Verification Plan Procedure* • Software Verification Plan • Software Verification Plan Review* 5.1.7 Software risk management planning Class A, B, C • Software Risk	☒ Yes ☐ No ☒ N/A

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	Management Plan Procedure* • Software Risk Management Plan • Software Risk Management Plan Review* 5.1.8 Documentation planning Class A, B, C • Software Documentation Plan Procedure* • Software Documentation Plan • Software Documentation Plan Review* 5.1.9 Software configuration management planning Class A, B, C • Software Configuration Management Plan Procedure* • Software Configuration Management Plan • Software Configuration Management Plan Review* 5.1.10 Supporting items to be controlled Class B, C • Support Item Document Procedure* • Support Item Document • Support Item Document Review* 5.1.11 Software configured item control before verification Class B, C • Configuration Items Under Document Control Prior to Verification Records • Configuration Items Under Document Control Prior to Verification Records Review* 5.2 Software requirements analysis 5.2.1 Define and document software requirements from system requirements Class A, B, C • Software Requirements Document Procedure* • Software Requirements Document • Software Requirements Document Review*	

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
IEC 60601-1, Medical Electrical Equipment - Part 1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 013	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1, MEDICAL ELECTRICAL EQUIPMENT - PART 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Complete conformance with UL 60601	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
National Differences USA, UL 60601-1 (formally UL2601-1)

DESCRIPTION
• UL requirements for Recognized Components dealing with fire, shock, and safety hazards. These differences address components that do not have a harmonized IEC component standard. The deviations are identified in UL 60601-1 as DC national differences.
• National Electrical Code (NEC) requirements per NFPA 70, requirements for healthcare facilities and medical installations per NFPA 99, and other regulatory requirements. These deviations are identified in UL 60601-1 as DR national differences.
• Requirements for safety practices. These differences relate to IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the part of the manufacturer. These deviations are identified in UL 60601-1 as D2 national differences.
• Requirements for basic safety principles and requirements, the elimination of which would compromise safety for U.S. consumers and users of products. A deviation based on this criterion is identified in UL 60601-1 as a D1 national difference.
• National differences that are based on editorial comments or corrections. These deviations are identified in UL 60601-1 as DE national differences.

JUSTIFICATION
National deviation for USA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 020	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

device; and the name address of the test laboratory or

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI / IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See attached report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

Section 22: Kit Certification

NA –The NoTouch BreastScan System is not a kit

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

(b)(4) Trade Secret Process - Software Specs

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(b)(4) Trade Secret Process - Testing

NoTouch Breastscan™
User Interface Description
Software Version 2.0
SRS-1004

Issue 1: Rev.0: Date: 09/01/2011

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Purpose

This document describes the user interface for the NoTouch BreastScan software.

Version

NoTouch Software Version 2.0 release date September 2010

About this Document

The remainder of this document is divided into the following sections:

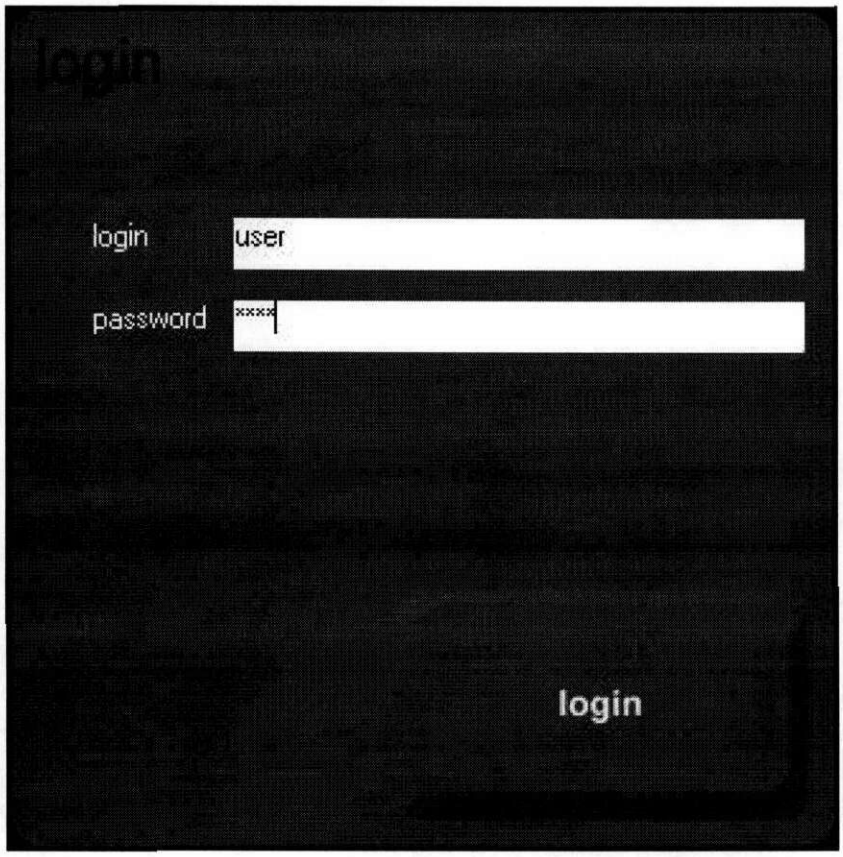
- *Structure and Navigation,* describes the structure of the application and the ways in which users can navigate.
- *Screen Description,* which comprises the main part of the document, contains a detailed description of each screen and its component parts.

References

Refer also to the following documents:

SRS/1001 Software requirements Specification
DES/0100 Software design Specification

Log-In Screen



Description:

The log in screen enables the user to login to the NoTouch program.
After the user starts the NoTouch BreastScan system, the user will enter a log-in name and user password to enter the program.
This insures password protection so only authorized personnel can access the program.

Navigation:

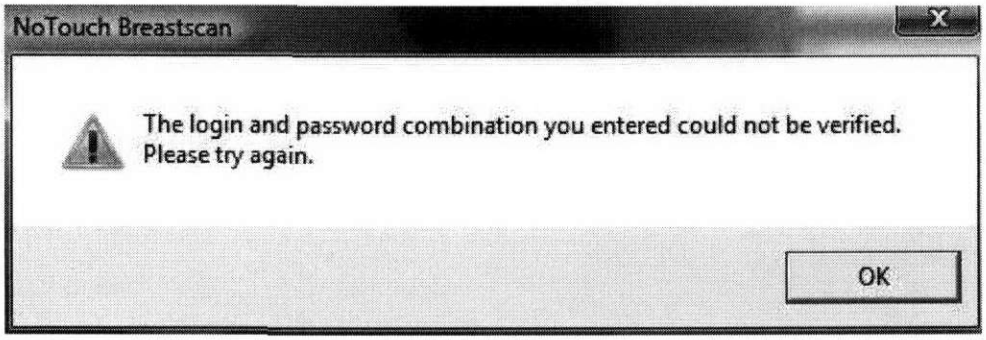
Navigation to this screen is by clicking on the NoTouch BreastScan shortcut located on the desktop. The login window will open after the application has been launched.
After the correct login and password has been entered and the login tab has been selected, the main menu screen will open.
Note that the log in screen is reached only when starting the NoTouch Breastscan software.

Issues:

A login name and password must be issued by a UELS representative first in the MySQL database during installation. The password can be changed by the operator at a later date. The login code has to be changed by a representative of UELS in the MySQL database.

Errors/Alarms:

Should the wrong password be entered the following error message will open and the program will go back to the log in screen.



1. Main Menu

Description:

The Main Menu screen enables the user to perform different procedures within the NoTouch software.
In the main menu window the program number is displayed on the top of the screen as well as the name of the database being used. The user has the option to enter a new patient, pick up an existing patient, process a scan that has been previously recorded or change their password.
The client ID is listed as well as a usage scale.
There is an option to update license usage, control settings and an option to pull reports. Each of these functions will be explained in detail within this document.

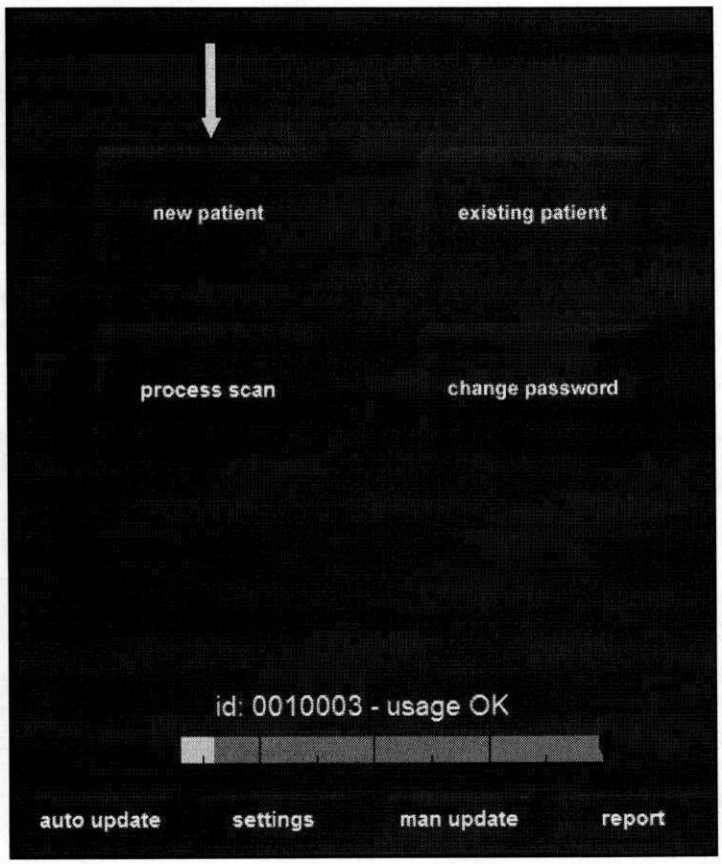
Navigation:

Navigation to this screen is from the login window. The main menu will open after the correct login information has been entered.
In the upper right hand of screen is the exit tab, if selected it closes the program.

Issues: none known

Errors/Alarms: none

2. New Patient Tab



Description:

When the "new patient" tab is selected from the main menu, the patient search window will opened.

Navigation:

When the "new patient" tab is selected from the main menu, the patient information screen will open.
In the upper right hand of screen is the exit tab, if selected closes the program.

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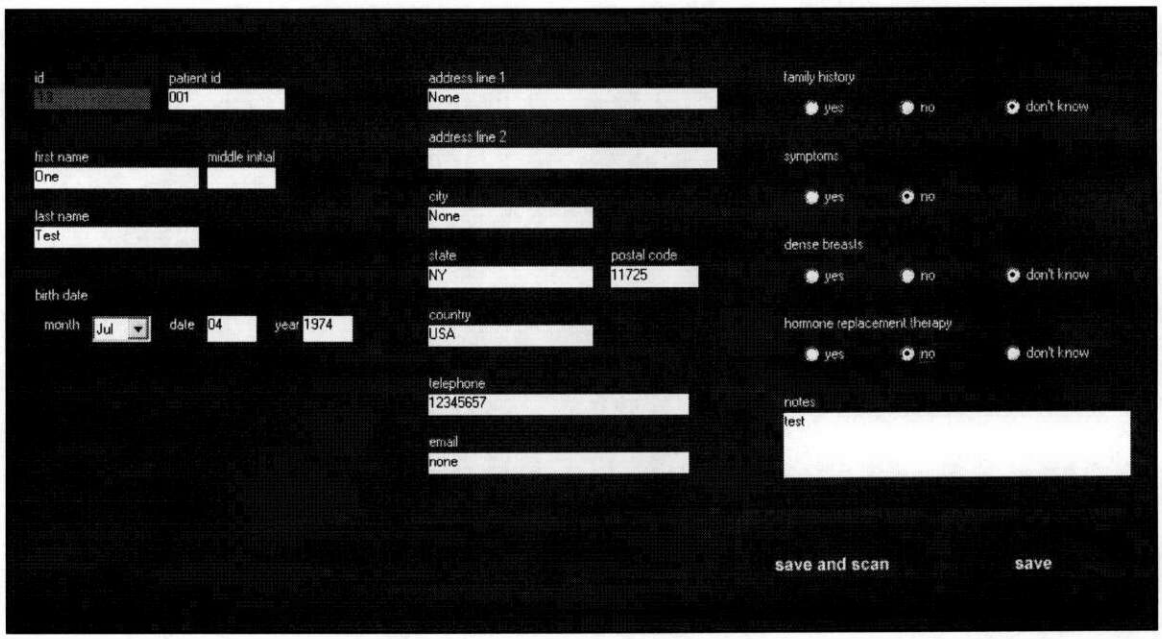
Issues:
None known

Errors/Alarms:
None

3. Patient Information Screen



Description:
When the "new patient" tab is selected from the main menu, the patient information window will open. The Patient information screen enables the user to enter all relevant information such as name, address, Patient ID number and any clinical notes. In this window the user has the option to "save" the patient information in the database or "delete" the patient from the database. Should the user select "save and scan" the program will navigate to the record window.

Navigation:

When the "new patient" tab is selected from the main menu, the patient information screen will open.

In the patient information screen, should the user select "save" the data will be saved in the database and the information will clear the form.

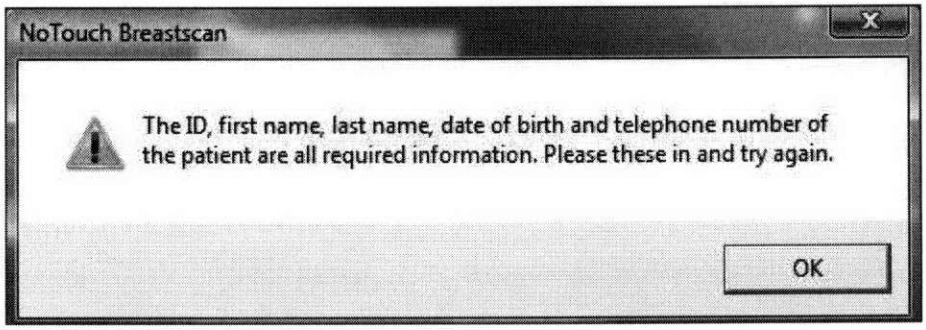
From the patient information window, should the user select "save and scan" the program will navigate to the record window.

In the upper right hand of screen is the menu tab, if selected it takes the user back to the main menu.

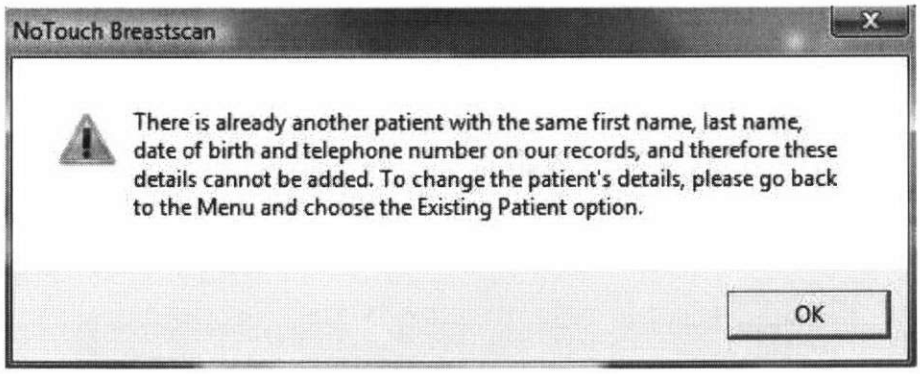
Issues:

The patient information is not deleted until it is saved to the database first. Patient information would have to be deleted from the existing patient tab. Delete tab is ineffective in new patient tab.

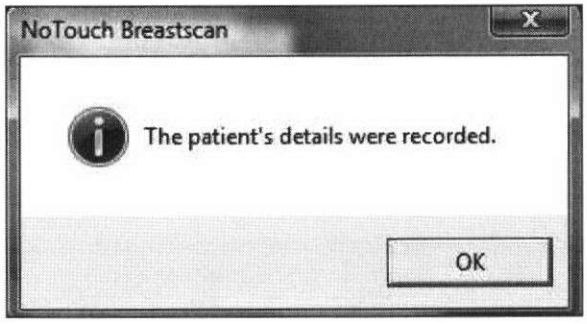
Errors/Alarms: If all required information is not entered and the save or save and scan tabs are selected, the following message window will appear.



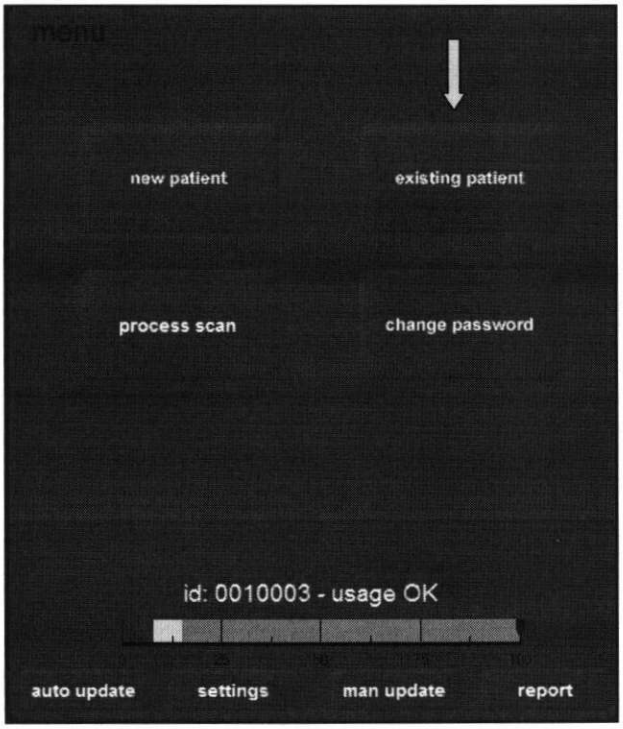
Should a patient have the same name and patient ID number and "save" or "save and scan" is selected, the following message will appear.



When the "save" tab is selected the following window will open stating the details have been recorded to the database. After clicking "OK" the patient information window will be cleared.



4. Existing Patient



Description:

When the "existing patient" tab is selected from the main menu, the patient search window will opened. The Patient search screen enables the user to select an existing patient's name from the database.

Navigation:

When the "existing patient" tab is selected from the main menu, the patient information screen will open.

In the upper right hand of screen is the exit tab, if selected closes the program.

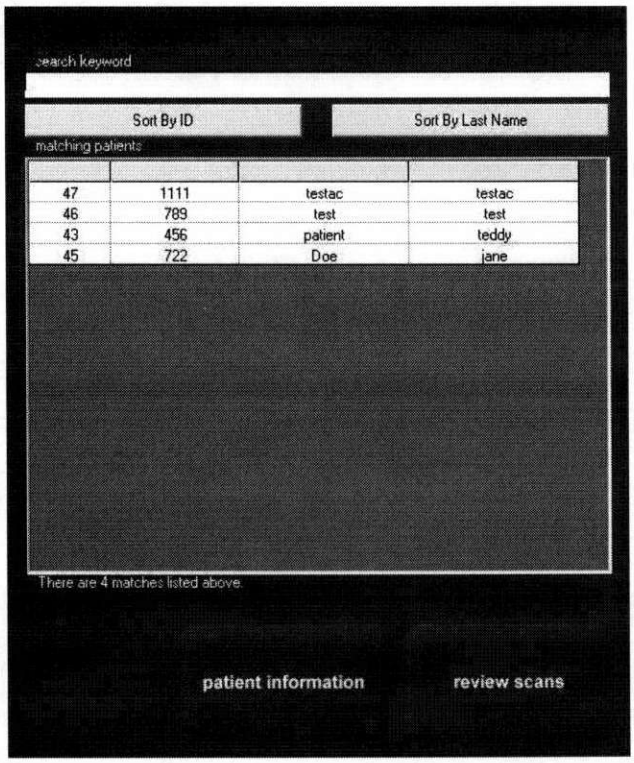
Issues:

None known

Errors/Alarms:

None

5. Patient Search



Description:

In the patient search screen, the user is able to select an existing patient's name from the database. The user has the option to search patient by ID or name. Columns can be sorted by ID or name. User also has the option to select "patient information" to open the patient information window or "review scans" to retrieve previous scans and test results. The search keyword function will filter names in database by entering patient name.

Navigation:

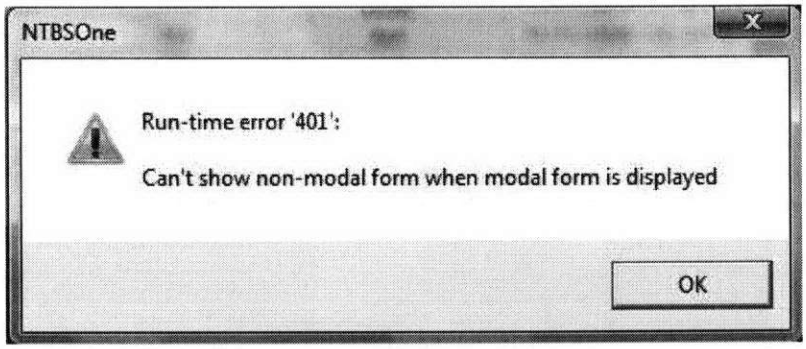
From the "existing patient" tab, the "patient search" screen will open.
In the search screen the user has the option to select patient information and will navigate to the patient information screen
Located in the search screen the user has the option to select review scans to navigate to the review scan window.
In the upper right hand of search screen is the menu tab, if selected it will take the user back to the main menu.

Issues:

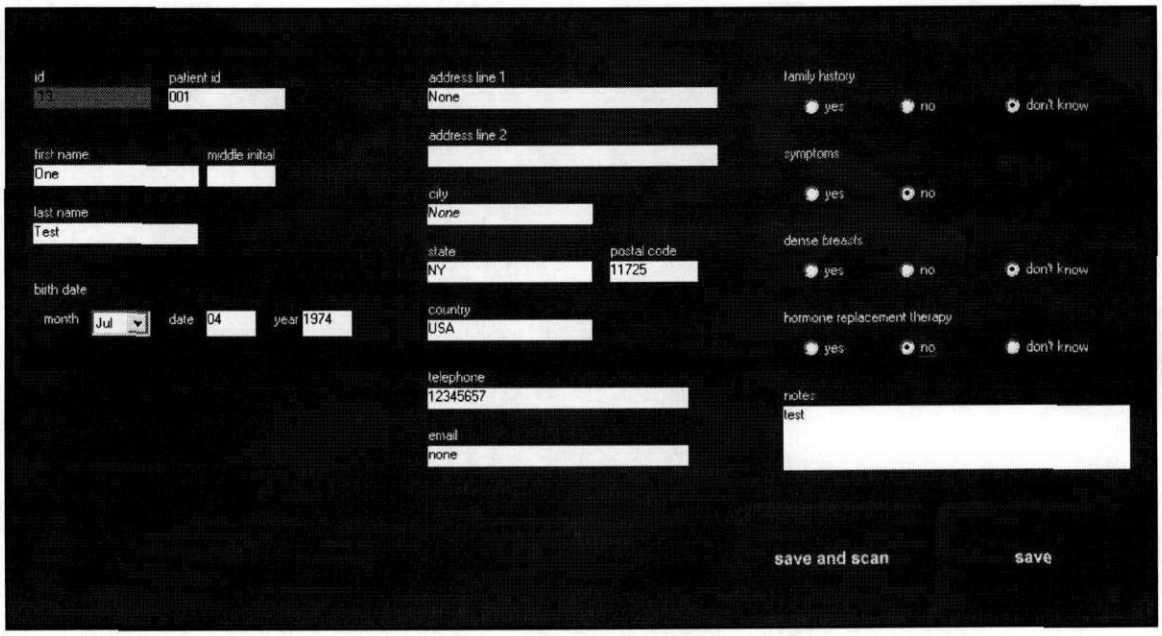
Each column should be labeled

Errors/Alarms:

The following message appears when a name in the database is clicked on twice.



6. Existing Patient Information Screen



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Description:

When the "existing patient" tab is selected from the main menu, the patient information window will open. The patient information window will open with existing patient information from the database.
The Patient information screen enables the user to add or change information and any clinical notes. In this window the user has the option to "save" the patient information in the database or "delete" the patient from the database. Should the user select "save and scan" the program will navigate to the record window.

Navigation:

When the "existing patient" tab is selected from the main menu, the patient information screen will open with the patient information listed in the window.

In the patient information screen, should the user select "save" the data will be saved in the database and the information will clear the form.

From the patient information window, should the user select "save and scan" the program will navigate to the record window.

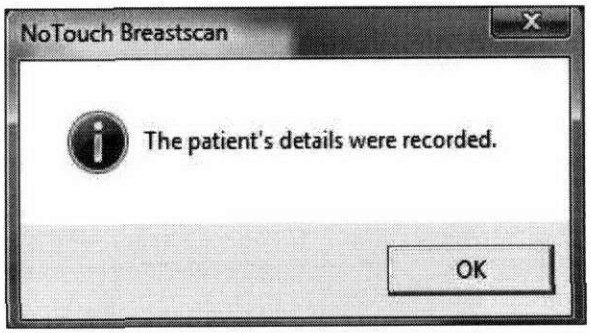
In the upper right hand of screen is the menu tab, if selected it takes the user back to the main menu.

Issues:

The patient notes are stored in the database, but the user does not have access to database. The notes do not print on report. Notes can be changed or deleted by another operator by mistake.

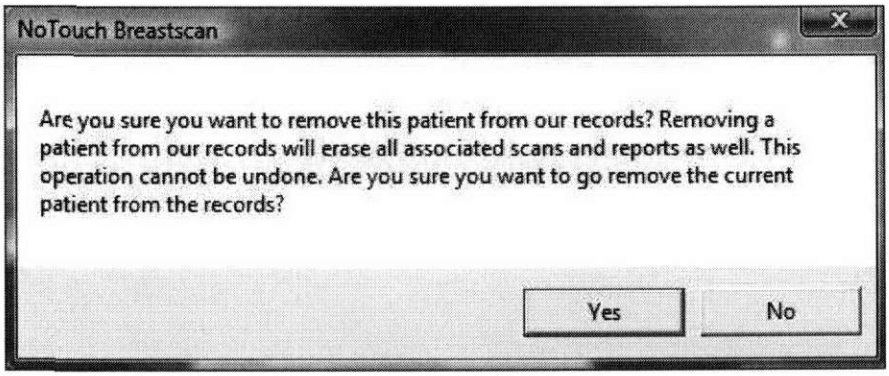
Errors/Alarms:

When the "save" tab is selected the following window will open stating the details have been recorded to the database. After

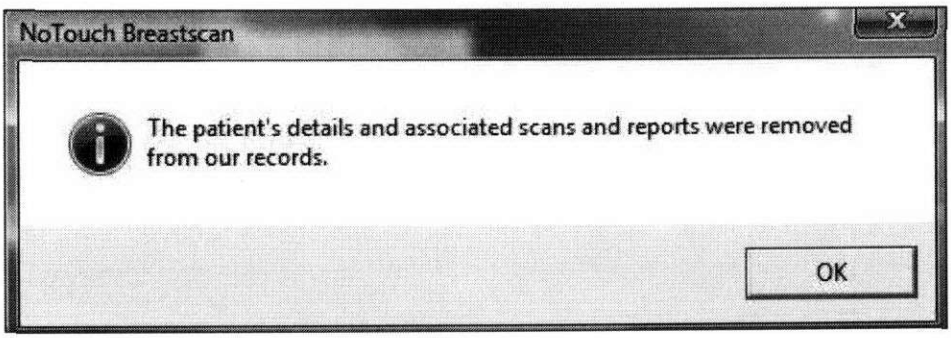


clicking "OK" the patient information window will be cleared.

When the user selects the delete tab in the patient information screen the following message should appear and state the details will be permanently erased. Another message window will appear after "yes" is selected stating the data has been removed. This prevents patient information for accidently being deleted.



After the user confirms they want to delete the patient information the following message confirms all data associated with that patient has been erased.



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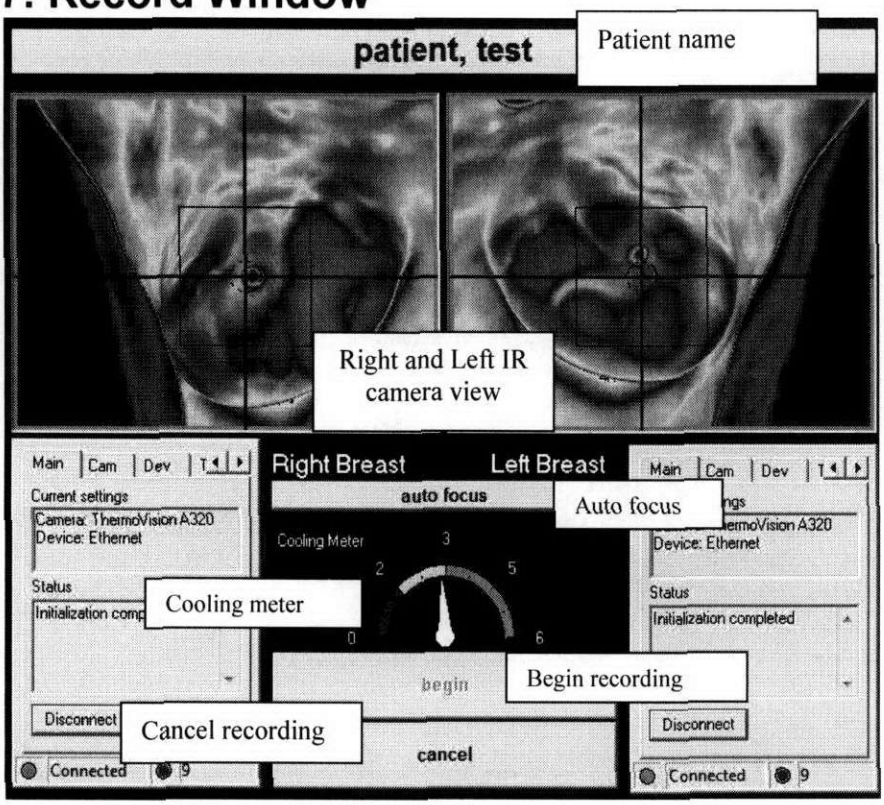
7. Record Window



Description:

The record window enables the user to perform a recording.
The user positions the cart and the cameras so that each breast is centered and clearly seen in the camera view.
After the cameras are focused and the begin tab has been selected the cameras will start to collect data and cool air will come out from the front of the plenum for 6 minutes. After 6 minutes the air will shut off and the recording will end.
After the recording has ended a message will appear stating the recording is complete.
After the recording is complete, a comments window will open and ask if the patient wishes to make a comment about this procedure. Click "Yes" to open the patient comments window, add comments.
After the comments are saved a message will appear that the data was successfully stored to database.

Navigation:

When the "save and scan" tab is selected from the patient information window the record window will open.

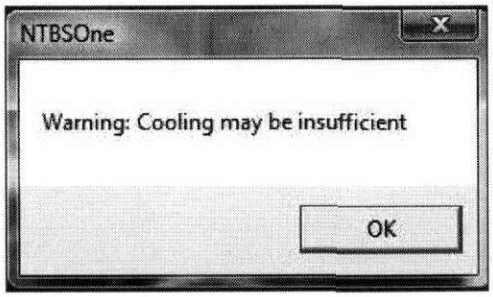
After the recording is complete and data has been stored to the database, the record window will close and navigate back to the *main menu*.

Issues:

- Cameras do not auto focus or only one camera is focused in the record window. User will have to manually focus cameras.
- After selecting Begin – Should the air not come out during the recording- cannot continue with test.

Errors/Alarms:

- No error message for focus. User should be trained to notice the image is blurry. There is a control window for each camera located under the IR image. Should the image continue to be unfocused, the operator can manually focus camera buttons until the image is clear.
- No error message for air not coming on during recording – User should be trained to notice the air is not coming out during the recording.
- If the software detects that the cooling was insufficient, a warning will come up after the recording is complete.



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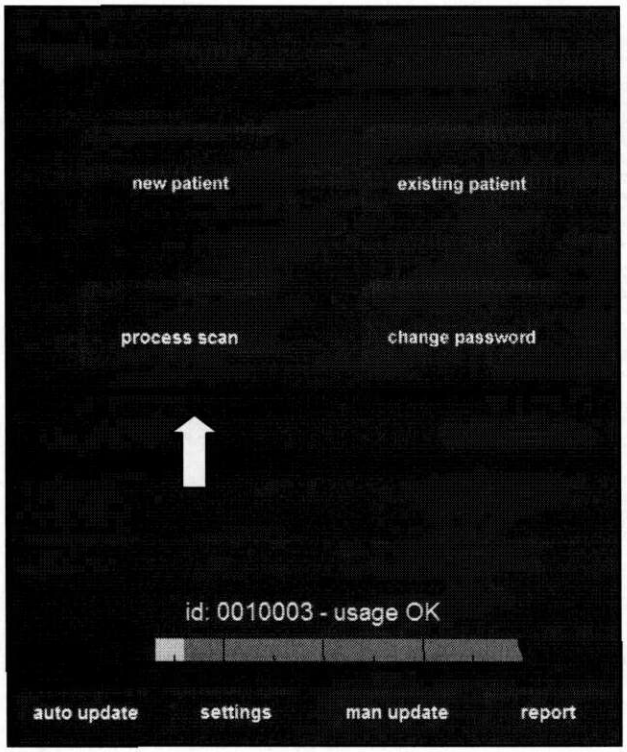
8. Process Scan Tab



Description:

After a recoding is completed, the images can be found in the process scan tab located on the main menu. After "process scan" is selected, the scan search window will open allowing the user to select the patients name from the database and begin the process procedure.

Navigation:

From the main menu the user selects "process scan" tab. After the tab is selected the "scan search" window will open.

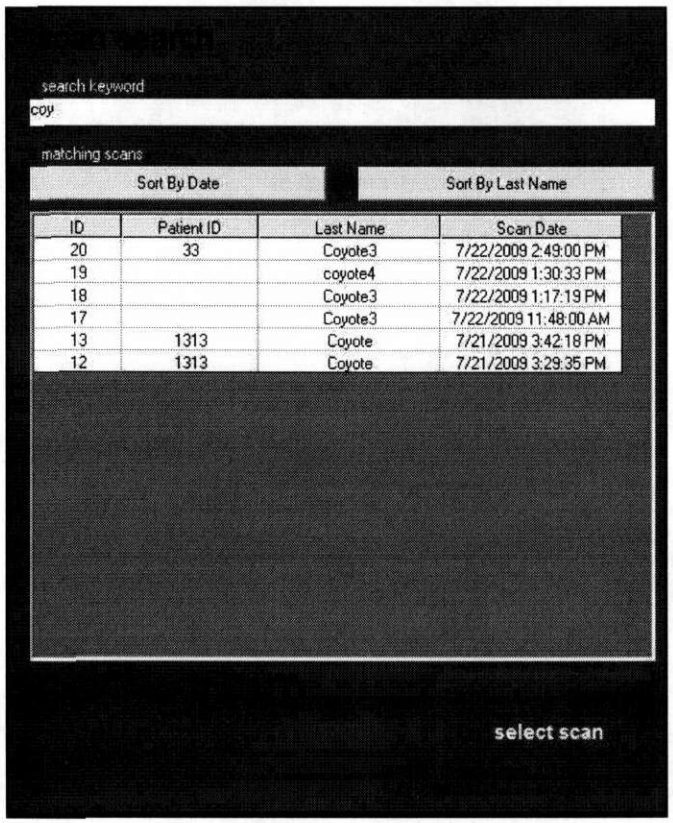
Issues:

None known

Errors/Alarms:

None

9. Scan Search Window



Description:

This window allows the user to select a patient's scan from the database. The user can select the patient's name in the database and click the "select scan button".
The user can sort patient's name alphabetically or sort recordings by date. There is also an option to type a name into the search filed.

Navigation:

The scan search window is opened when the process scan tab is selected from the main menu.

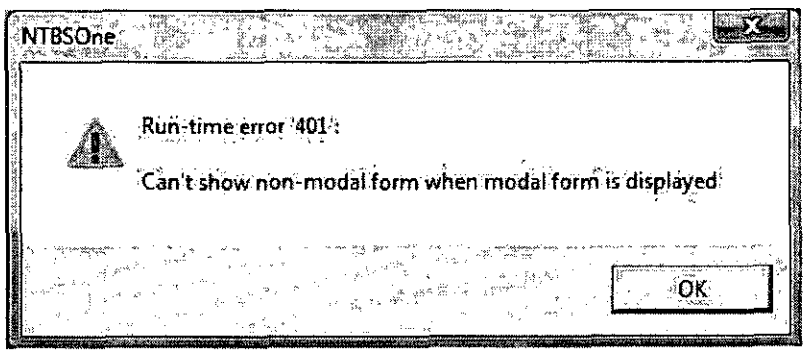
After name is highlighted in the database and the "select scan" tab is selected the program will navigated to the right breast selection window.

Issues:

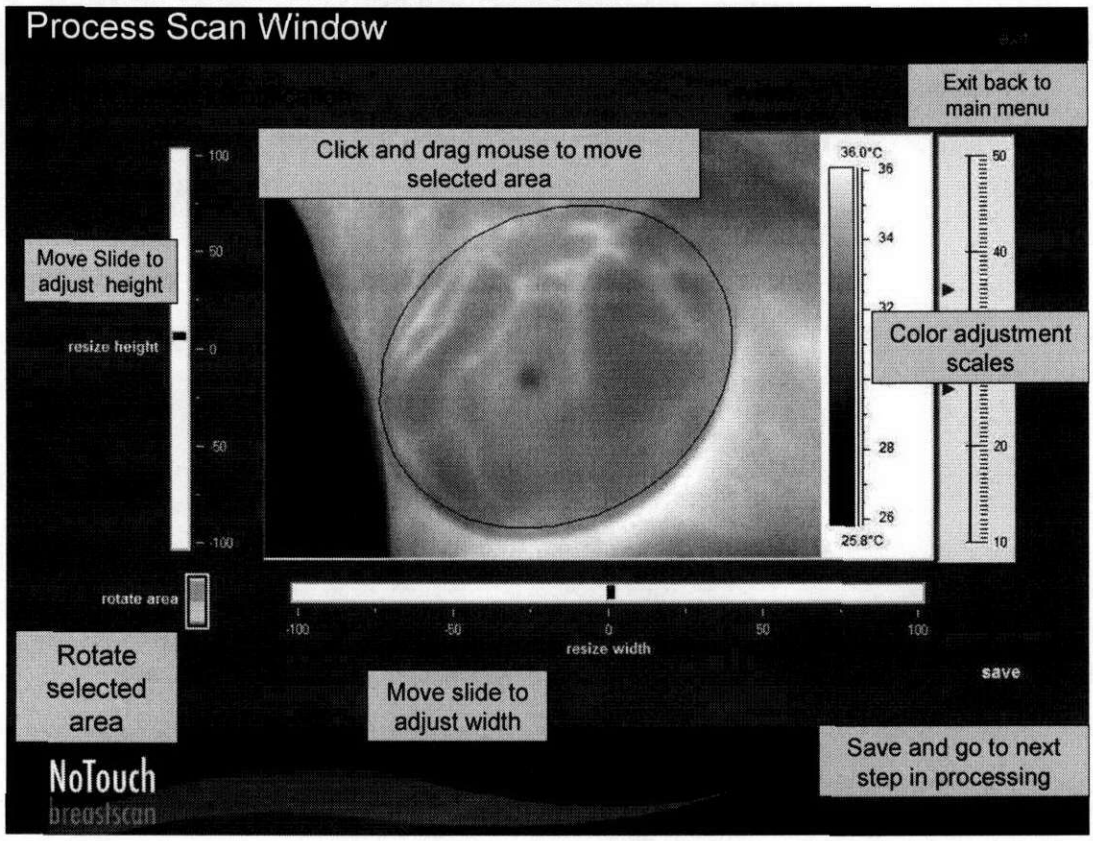
None

Errors/Alarms:

The following message appears when a name in the database is clicked on twice.



10. Breast Identification Screen



Description:

The first window to open will be the recorded image of the right breast. The user has different tools in which to select the breast tissue. The user will outline the breast tissue by using the tools provided by the software. There is a scale for height and one for width to adjust the outlined selection. The user is also able to move the outline by holding and dragging the mouse. There is also a tool for rotating the selected outline. The color adjustment scale will adjust the color of the image.
This window is the same for right and left breast. Right and left nipple and areola.

Navigation:

From this screen the user can save the selection and go on to the next step in the process or exit back to the main menu.

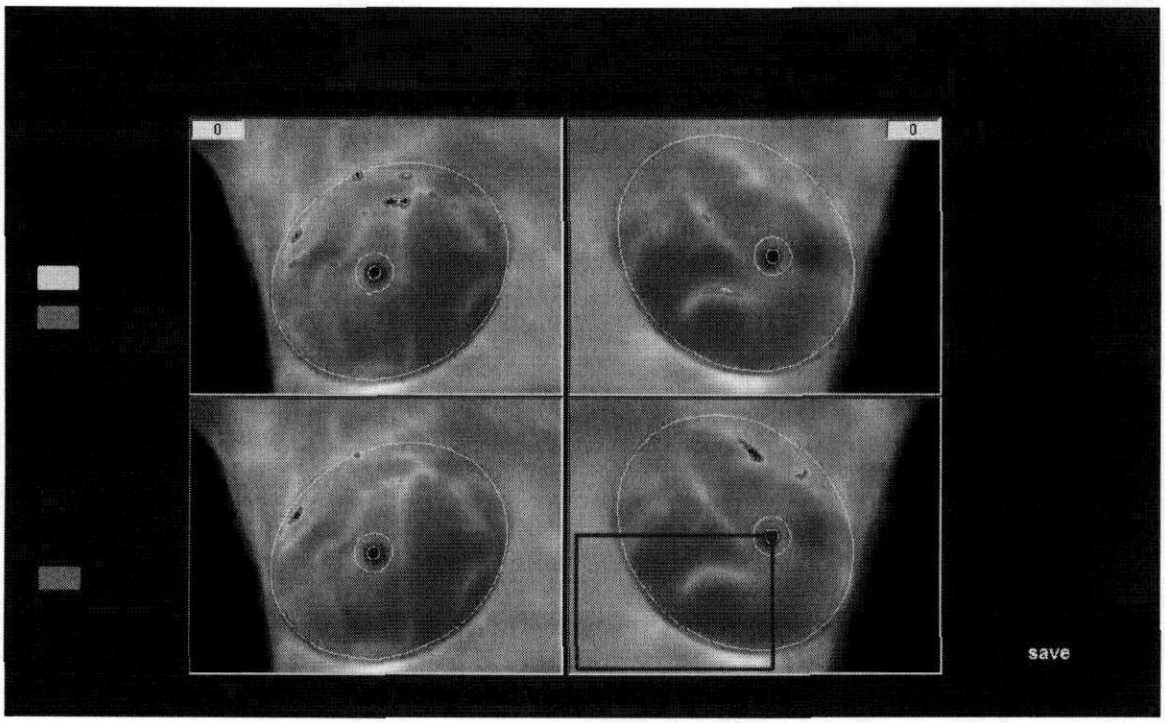
Issues:

Screen flashes when selection is moved.

Errors/Alarms:

None

11. Evaluation Screen



Description:

After the selections have been saved the next step in the process is the evaluation of the collected data. After the data is calculated it is stored in the database.

In the reluctance windows located in the top two frames, the user has the option to move the mouse over areas within the breast and a read a temperature display in degrees Celsius.

In the lower two frames is a visual representation of the hot zone and vascularity analysis.

Navigation:

After the user has selected "save" in the last screen of the process procedure the evaluation window will open.
After the evaluation is complete the user will select save and go on to the review scan window.

The user also has the option to exit this window and return to the main menu.

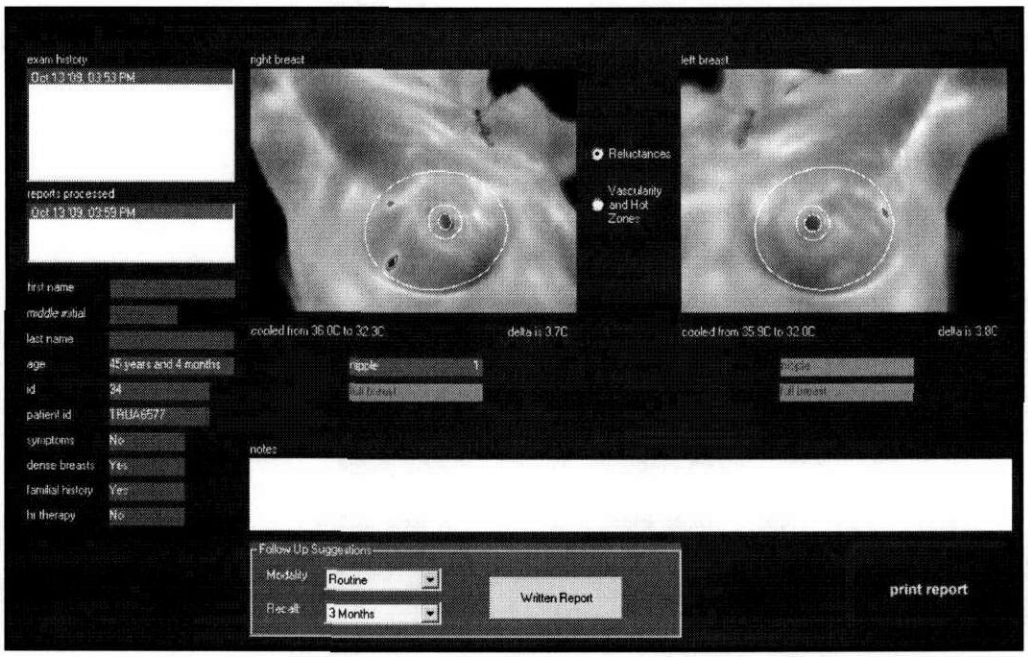
Issues:

Window can be closed before calculation is completed. User exits window during calculation, window closes and goes back to main menu. From the main menu the process scan is selected and the same patient is selected in the search screen. When the breast selection window opens it states to wait process still calculating. When save is selected to go on to next screen the process calculation window is still open. This will continue until the evaluation is allowed to complete.

Errors/Alarms:

None

12. Review Scan Screen



Description:

After the data has been evaluated and saved, a review scan window will open. In the review scan window the user can review all processed recordings and print reports for the selected patient.
The user can view the reluctance and vascularity and hot zone images by highlighting the selection located on the upper right of window.
When the print tab is selected an electronic file is saved as a PDF as well as print out a hard copy.
This completes to process scan function.

Navigation:

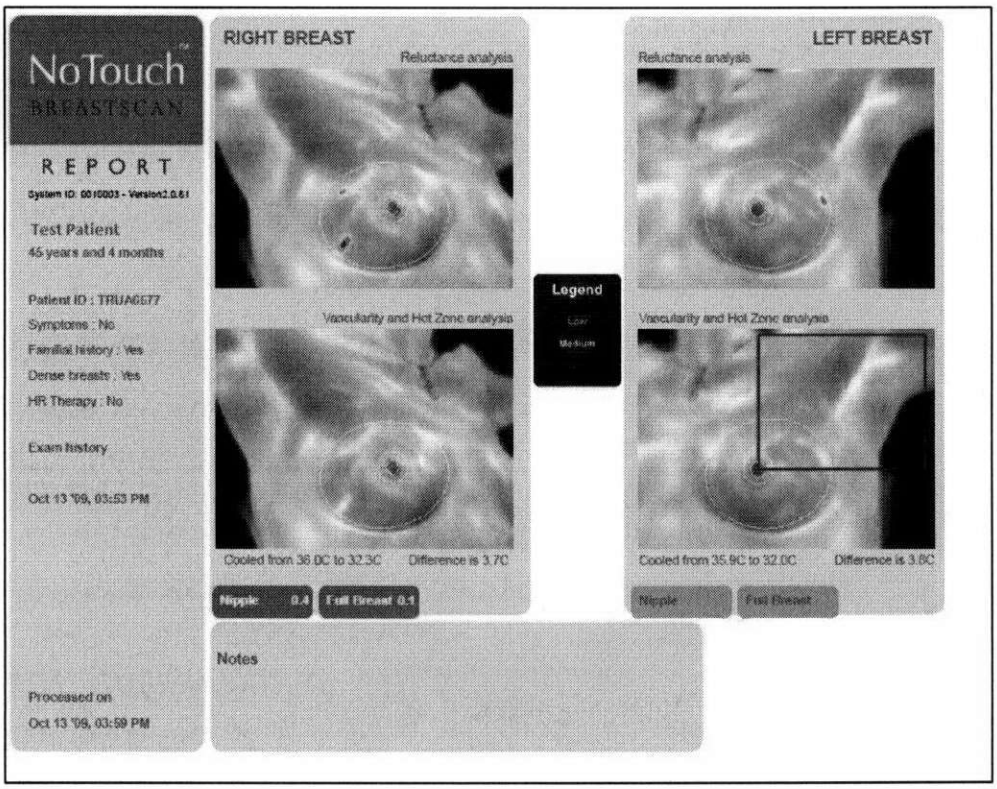
From the evaluation screen the review scan window opens.
The user has the option of closing screen and navigating back to main menu.

Issues:

None known

Errors/Alarms: None

13. Printed Report



Description:

From the review scan screen the user can print reports for the selected patient.
An electronic file is stored on My Images folder with the patient name ID and date.

Navigation:

From the review scan screen the report is printed and the user can go back to main menu and close program.

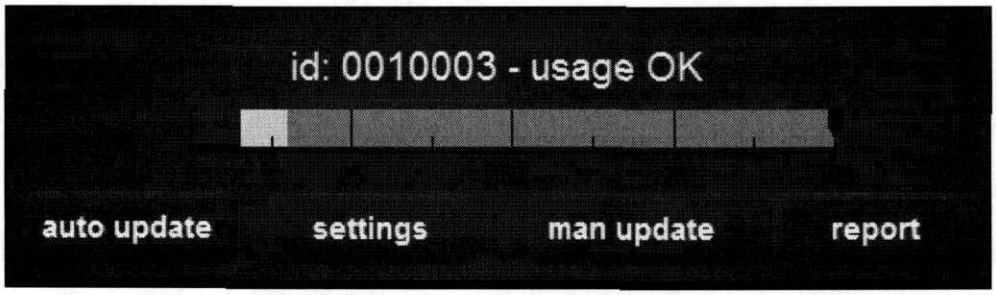
Issues:

The issue of fitting test result on both A4 and letter has been resolved.
New logo and darker type has been added.

Errors/Alarms:

None

14. Usage Display



Description:

Located on the bottom of the main menu screen is the usage display and update tabs. A license is used each time a new recording is performed. The usage scale states the number of licenses the system has to perform recordings. Above the scale are the computer ID number and the usage status. The program will state when the licenses are getting low and the scale will reflect the number of licenses remaining. The program has an option for automatic update tab and manual update tab.

Navigation:

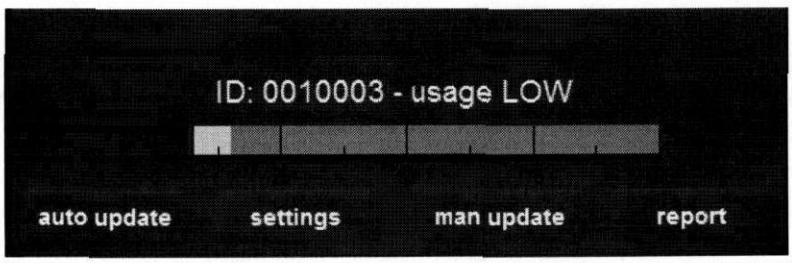
Usage display is located on the main menu.

Issues:

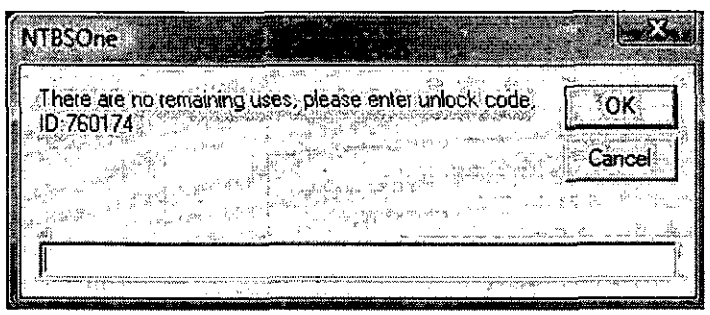
Program will be able to perform automatic licensing once UELS server is online.
User will be able to logon to UELS web page and update licenses automatically. Currently there is a manual option where the user can call in on a phone system to update licenses.

Errors/Alarms:

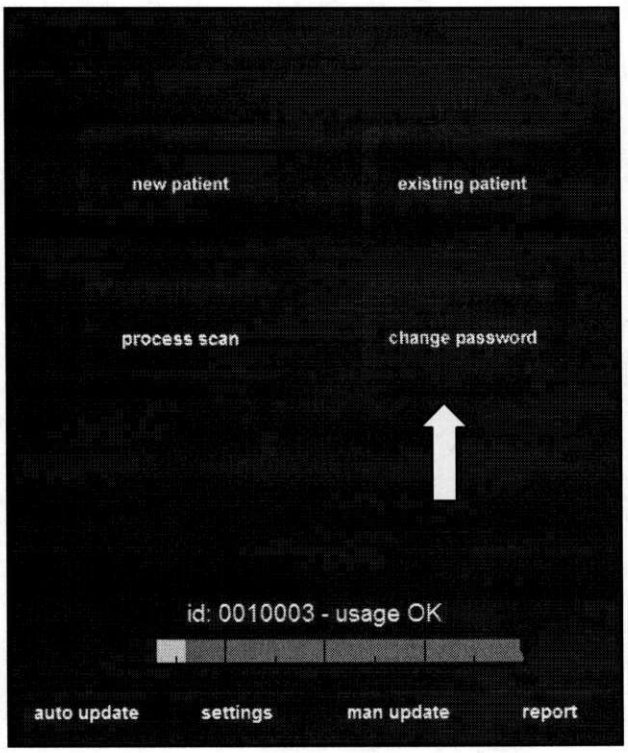
A message will be noted above the scale when licenses are low. The arrow on the scale will move into the yellow and red zone as usage gets low.



When manual update is selected the following window will appear requesting an unlock code. The user will call UELS and read the ID code to the technician. The technician will give the user an unlock code to enter. After the code has been entered and OK selected the window will close and license usage will increase.



15. Change Password Tab



Description:

Located on the main menu screen is the change password tab. When the change password tab is selected the user will have the option to change their login password.

Navigation:

Change password is located on the main menu. When selected a change password window will open. User can also close program from the main menu.

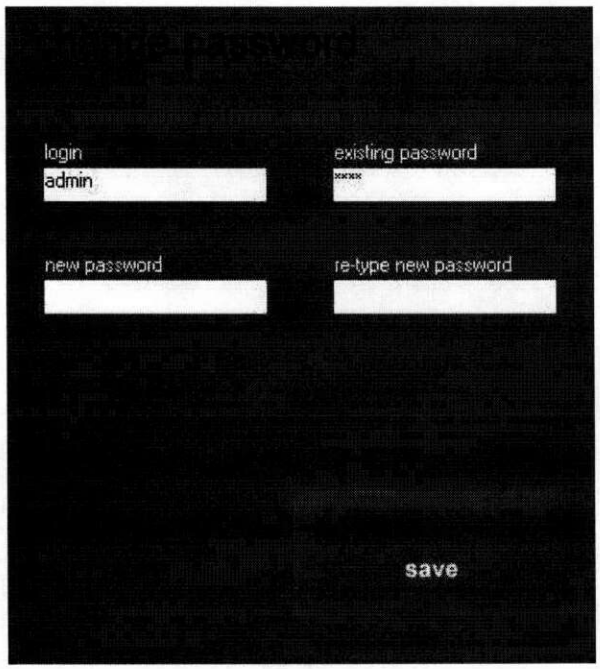
Issues:

None

Errors/Alarms:

None

16. Change Password Window

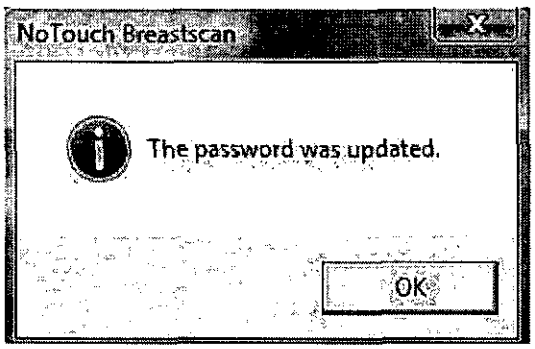


Description:

After the change password tab is selected the change password window will open. When the change password window is open the user will have the ability to change their existing password to a new password and save the new password in the database.

Navigation:

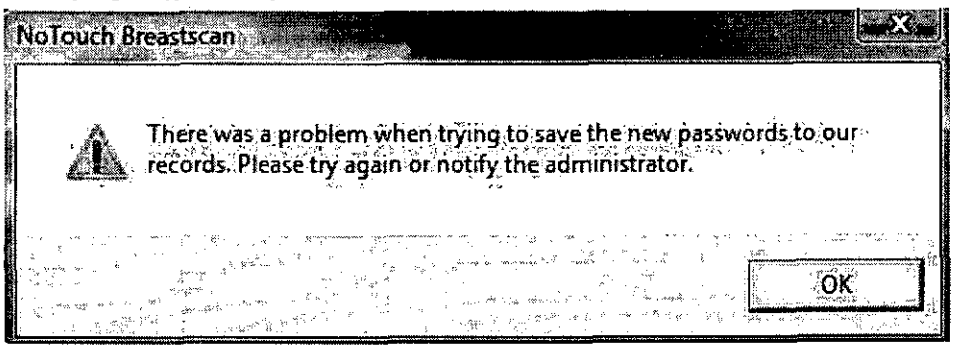
Within the change password window the user has the option to add type and to save their selection. After "save" is selected a message will open stating the password has been updated. After OK has been selected the window should close.



Issues:

After changing the password a message comes up that the password was updated. After user clicks OK an error messages comes up stating there was a problem saving the password (see errors/alarms).
After closing the program and restarting the program, when entering the updated password the user is able to login.

Errors/Alarms:



NoTouch Breastscan™
Chronological Order of Software Function
SRS-1005

Issue 1: Rev.0: Date: 09/01/2011

435

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Purpose

The purpose of this document is to provide the sequence of functions using the NoTouch Breastscan software to perform an exam.

Scope

This procedure encompasses all software functions used in the NoTouch BreastScan software to perform a digital infrared exam.

System Overview

The NoTouch BreastScan software is divided into two distinct parts; the data acquisition (recording) and the data processing. This document will explain the order of operation for both functions.

After the user starts the program and logs in, she will enter the patient information for a new patient. If there is an existing patient, the name will be picked up in the existing patient database.

From either the new patient or existing patient tab there is an option to "save and scan". This will open the recording window and the user will perform the recording from this screen. After the recording is complete the data will be stored in the database.

After the recording is complete, the user will go to into the "process scan" tab. In this window the user will select the patient name from the database and "select scan". During the processing, successive windows will open after each selection and direct the user through the next steps. After the steps have been completed the data is stored in the database.

After the data is stored the "review scan" window will open. This window stores all the recoded history and the reports processed for the selected patient. It also shows a visual representation of the results from each exam. The user has the option to print out a report and create a PDF from this screen.

The following is a detailed description of each function.

Log-In

After the NoTouch BreastScan software has been started the user will enter a log-in name and password to enter the program.
This insures password protection so only authorized personnel can access the program.

Main Menu

In the main menu window the user has the option to enter a new patient, pick up an existing patient, process a scan that has been previously recorded or change their password. There is also an option to add usage licenses. One license is used each time a patient is recorded and processed.

New Patient

When the new patient tab is selected, the patient information window is opened. The user will enter all relevant information such as name, address, Patient ID number and any clinical notes. In this window the user has the option to save the patient information for a later date or delete the patient from the database.
After all patient information is entered and save and scan has been selected, the record window will open. If patient is not already in the room the user will bring the patient in and have the patient sit in a chair in front of the NTBS system. Then user will have the patient disrobe from the waist up and place their arms above their head or on their hips if they cannot place their arms above their head.

Record New Patient

In the record window there is an IR image of both breasts. The user will set up the cart and cameras to get optimal image of each breast. Then the user will focus the cameras and begin the test. Images will be recorded every 30 seconds for 6 minutes for a total of 12 frames. Cool air will be blowing out during this time During the scan the software measures how the surface of the breast tissue has cooled during the test, which is represented on the cooling meter.
After the recording is complete, the data is saved to the database; the window closes and goes back to the main menu.

Existing Patient

When there is an existing patient. The user will open the existing patient tab and select the patient's name and click patient information. The patient information window will open. All relevant information such as name, address, Patient ID number and any clinical notes can be changed in this screen. In this window the user has the option to save the patient information for a later date or delete the patient from the database.
After all patient information is entered and save and scan has been selected, the record window will open. If patient is not already in the room the user will bring the patient in and have the patient sit in a chair in front of the NTBS system. Then user will have the patient disrobe from the waist up and place their arms above their head. If they cannot place their arms above their head, the patient can place their hands on their hips.

Record Existing Patient

In the record window there is an IR image of both breasts. The user will set up the cart and cameras to get optimal image of each breast. Then the user will focus the cameras and begin the test. Images will be recorded every 30 seconds for 6 minutes for a total of 12 frames. Cool air will be blowing out during this time During the scan the software measures how the surface of the breast tissue has cooled during the test, which is represented on the cooling meter.

After the recording is complete, the data is saved to the database; the window closes and goes back to the main menu.

Process Scan

After a recoding is completed, the images can be found in the process scan tab located on the main menu. To process a scan the user will select the "process scan" tab and select the patient's name in the database and click the select scan button. The recorded image for the right breast will appear. The user will outline the breast tissue by using the selection tools provided by the software. There is a scale for height and one for width to adjust the outlined selection. The user is also able to move the whole selection by holding and dragging the mouse.
After each selection is saved another image will appear until all of the images have been selected. The right and left breast selection is performed pre and post cooling. Then the right and left nipple are selected post cooling.
After each of the selections has been saved the data is calculated and stored in the database. After saving, a review scan window will open. In the review scan window the user can review all processed recordings and print reports for the selected patient.
After the report is printed the exam is complete and the report is given to the physician for assessment.

Reference documents:

SRS/1001 Software Requirement Specifications
SRS/1004 User Interface Description

NoTouch BreastScan™
Thermal Parameters Measured
SRS-Parameters

Issue 1: Rev.0: Date: 09/01/2011

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1.0 Purpose

The purpose of this document is to describe the thermal parameters measured by NoTouch BreastScan. In all cases the term "temperatures" refers to surface temperatures.

2.0 Thermal Parameters

2.1 Reluctance Measurement

Data Used:	First and last infrared frame of each breast
Measurement Output:	Visual, not numerical
Type of measurement:	Within a single breast

Description: The reluctance measurement quantifies the difference in cooling between a particular pixel in the breast and the average temperature of its immediate surroundings. The first step in this calculation is to perform an image subtraction between the first frame (before cooling) and last frame (after cooling). A new frame is then created (referred to as the difference frame) with the differences of each pixel. This calculation is performed on every pixel in the difference frame. Each pixel in the difference frame is compared with the surrounding pixels. The surrounding pixels consist of a 7 x 7 matrix of pixels evenly and immediately surrounding and excluding the pixel in question.
X – Pixel being measured
A – Pixels being averaged for comparison with pixel being measured i.e. X

```
A A A A A A A
A A A A A A A
A A A A A A A
A A A X A A A
A A A A A A A
A A A A A A A
A A A A A A A
```

If the pixel in question "Pixel X" cooled less than 1.3C when compared to the average cooling of the surrounding pixels, then that pixel is then indicated in RED on the reluctance image (top image) of the NoTouch report. If the measurement is less than 1.1C, that pixel is indicated in YELLOW. If the measurement is less than 1.0C, that pixel is indicated in GREEN. All other pixels are represented with the original color provided by the FLIR color palette.

2.1	2.0	2.3	1.9	2.1	2.1	2.1
2.3	2.0	2.3	2.3	2.4	2.1	2.5
2.1	2.1	2.1	2.2	2.2	2.2	2.1
2.4	2.4	2.3	**1.9**	2.1	2.3	2.4
2.1	2.2	2.3	2.4	2.5	2.1	2.4
2.3	2.4	2.2	2.2	2.2	2.2	2.1
2.4	2.3	2.5	2.1	2.1	2.1	2.3

Example of a 'difference frame'

Temperature Difference of Pixel X = 1.9
Average Temperature of all 7x7 pixels excluding "X" = 2.225
(Pixel X Difference) – (7x7 Avg. Temp.) = 2.225 - 1.9 = 0.325
Therefore, Pixel X will remain unchanged

2.2 Nipple Measurement

Data Used: Average nipple temperatures (left and right)
Measurement Output: Numerical
Type of measurement: Comparison
Description: The nipple measurement quantifies the difference between the average nipple temperature of the left breast and the average nipple temperature of the right breast. This measurement is only indicated for the breast with the warmer of the two nipples.
Example

Left Nipple Avg: 26.2C

Right Nipple Avg: 25.4C

Difference: 0.8 (Left Warmer)

2.3 Full Breast Measurement

Data Used: Average full breast temperatures (left and right)
Measurement Output: Numerical
Type of measurement: Comparison
Description: The full breast measurement quantifies the difference between the average full breast temperature of the left breast and the average full breast temperature of the right breast. The Avg. Nipple and Avg. Areola temp. are NOT a part of this measurement.
Example:

Left Breast Avg: 24.6C
Right Breast aAvg: 24.4C
Difference: 0.2C (Right Warmer)

2.4 Hot Zone Measurement

Data Used: Last infrared frame of each breast
Average Full Breast Temperatures
Measurement Output: Visual, not numerical
Type of measurement: Within a single breast

Description: Hot Zone markers indicate any pixel in the last frame that has a temperature that is more than 1.5 standard deviations higher than the average breast temperature. This is performed independently in the left and right breast. The standard deviation is calculated from the temperatures of each pixel on the surface of the each breast. These pixels are marked in yellow. If the temperature of a pixel exceeds 2.0 standard deviations from the average breast temperature, the pixel is marked in red. Note that the pixel temperature is compared only to the average temperature of the breast in which it exists. Any pixels not meeting these criteria remain unchanged. The final results are indicated on the Hot Zone picture on the NoTouch Report.
Example:

Right Breast Standard Deviation: 0.6C
Average Right Breast Temperature (post cooling): 31.4C
Pixel X value: 32.9C
32.9 is greater than (31.6 + 2.0 x 0.6 = 32.8) so Pixel X is colored RED

2.5 Vascularity Measurement

Data Used: Last infrared frame of each breast
Average Full Breast Temperatures
Measurement Output: Visual, not numerical
Type of measurement: Within a single breast
Description: Vascularity markers compare red Hot Zones (described above) between contralateral portions of each breast. The breast is divided into 4 quadrants; Lower Inner, Lower Outer, Upper Inner, and Upper Outer. Each quadrant is marked as "Vascular" or "Not Vascular" as indicated by a red box on the Vascularity picture on the NoTouch report. A quadrant is marked vascular if there is significant (2 x or more) hot markers as compared to its contra-lateral quadrant in the other breast.
Example:

Count of RED markers in UO (upper outer) Quadrant of Right Breast: 25
Count of RED markers in UO (upper outer) Quadrant of Left Breast: 64
Therefore 64 > (2 x 25) and the UO quadrant of the left breast is marked as "Vascular" with a red box.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Hefner

Subject: 510(k) Number K113259

To: The Record

Please list CTS decision code **SE**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

X Final Decision (SE).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✠
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✠	
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X

Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
884.2980	1	LHQ

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief) (Branch Code) (Date)

Final Review: 2/10/2012

(Division Director) (Date)

5

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)			X
5. a. Did the firm request expedited review? (See management.)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here: K091311	X	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			✠

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	X		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	X		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			x

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm	X		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	X		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm			X
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm			X
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	X		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	X		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf	X		
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	X		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			X

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K113259

Date: February 9, 2012
To: The Record
From: Lauren Hefner

Office:OIVD
Division: DRAD

510(k) Holder: UE Lifesciences
Device Name: NoTouch Breastscan
Contact: Mihir B. Shah
Phone: 267 342-3303
Fax: 918 516-3303
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce NoTouch Breastscan into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

III. Device Description

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart

Principles of Operation

(b)(4) Trade Secret Process - Product Specs

[redacted]

10

(b)(4) Trade Secret Process - Product Specs

[redacted]

11

Technical Specifications

NoTouch
BREASTSCAN

(b)(4) Trade Secret Process - Product Specs

[redacted]

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	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

IV. <u>Indications for Use</u>

The IFU for the device is identical to that of predicate device, K032350 Infrared Sciences BreastScan IR System. The IFU of the predicate K033967 series A,E,S, and P – IR cameras differs but this is a predicate for the infrared camera technology not for the complete device.

The IFU for this device is:
The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

The IFU for the predicate devices(K032350 Infrared Sciences BreastScan IR System and K033967 series A,E,S, and P – IR cameras follow):

K032350 Infrared Sciences BreastScan IR System
The Infrared Sciences BreastScan IRPTM System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

K033967 series A,E,S, and P – IR cameras
The Flir devices are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes. Environment of use: hospital, sub-acute, public areas, i.e., airports

V. Predicate Device Comparison

(b)(4) Trade Secret Process - Product Specs

[redacted]

VI. Labeling

(b)(4) Trade Secret Process - Product Specs

[redacted]

VII. Sterilization/Shelf Life/Reuse

Not supplied sterile, indefinite shelf life, reusable.

VIII. Biocompatibility

No patient contact.

IX. Software

The sponsor has provided complete software documentation for a moderate level of concern. The documentation appears to adequate.

Version: 2.0		
Level of Concern: Moderate		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor claims compliance with the following standards:
ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General)

IEC 60601-1, Medical Electrical Equipment - Part 1

AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601-1-2:2001 with Amendment 1:2004 is the U.S.. (General)

AAMI / ANSI / IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY – COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004)

XI. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs [redacted]

XII. Performance Testing – Animal

Not applicable

XIII. Performance Testing – Clinical

(b)(4) Trade Secret Process - Product Specs [redacted]

XIV. Substantial Equivalence Discussion

(b)(4) Trade Secret Process - Product Specs [redacted]

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVI. Contact History

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVII. Recommendation SE

Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: Class I
Product Code: LHQ

Lauren Hefner
Reviewer

February 9, 2012
Date

Branch Chief

2/10/2012
Date

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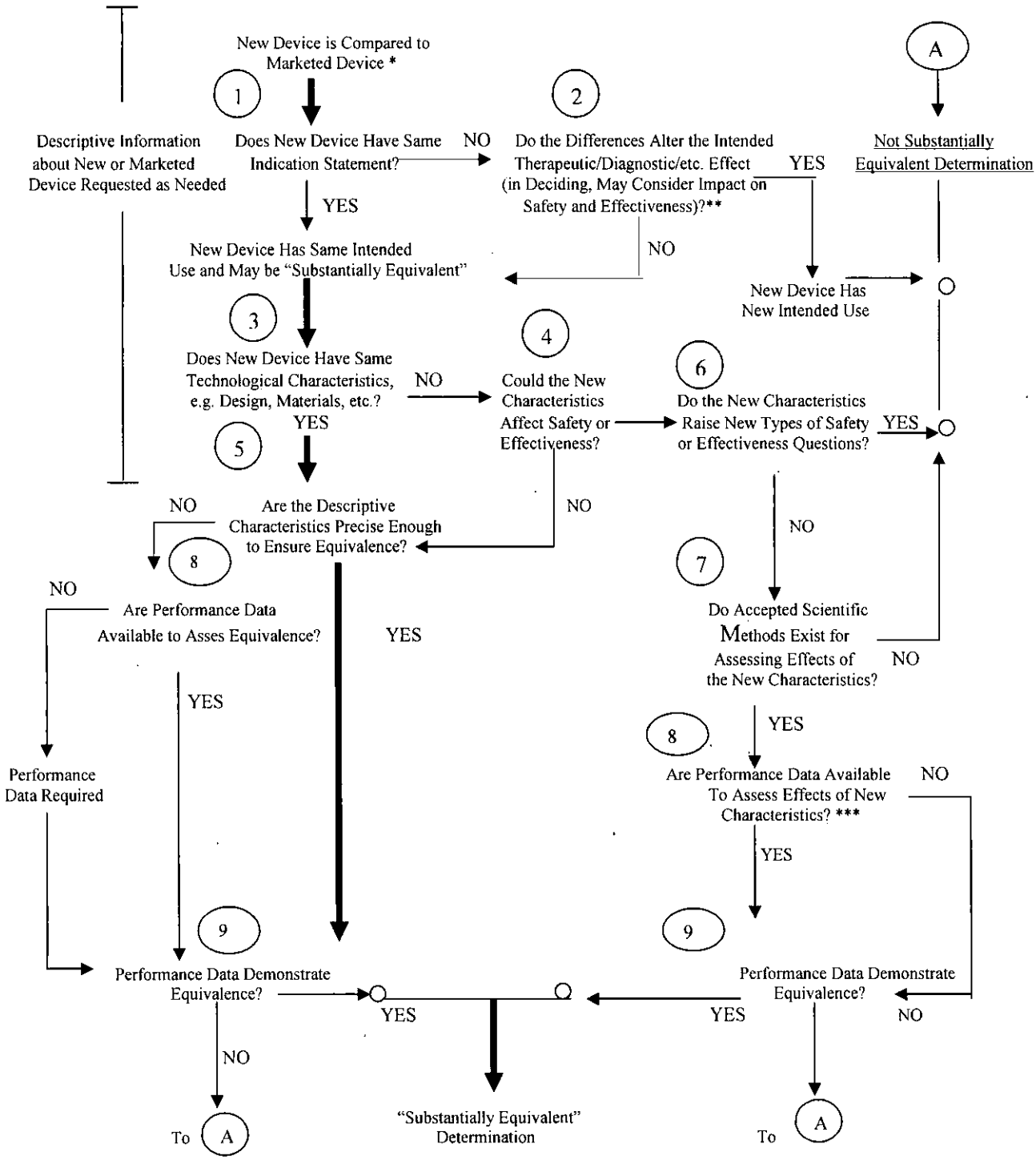
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Hefner, Lauren N

From: Hefner, Lauren N
Sent: Wednesday, February 08, 2012 10:21 AM
To: 'Mihir Shah'
Subject: RE: Concerning K113259 NoTouch BreastScan

Hello Mr. Shah,
Yes, the revised information you provided is acceptable. Thank you for your prompt response.

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Mihir Shah [mailto:mihir@notouchbreastscan.com]
Sent: Wednesday, February 08, 2012 10:18 AM
To: Hefner, Lauren N
Cc: Matthew Campisi
Subject: Re: Concerning K113259 NoTouch BreastScan

Dear Lauren, thanks for your message.

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

Skype ID: NoTouchBreastScan

www.NoTouchBreastScan.com

On Wed, Feb 8, 2012 at 7:13 AM, Hefner, Lauren N <Lauren.Hefner@fda.hhs.gov> wrote:

Thank you Mr. Shah,

(b)(4) [redacted]

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Mihir Shah [mailto:mihir@notouchbreastscan.com]
Sent: Tuesday, February 07, 2012 4:58 PM
To: Hefner, Lauren N
Cc: O'Hara, Michael D; Pastel, Mary; Matthew Campisi
Subject: Re: Concerning K113259 NoTouch BreastScan

Dear Lauren,

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell

+1.918.516.3303 Fax

Skype ID: NoTouchBreastScan

www.NoTouchBreastScan.com

On Tue, Feb 7, 2012 at 2:39 PM, Hefner, Lauren N <Lauren.Hefner@fda.hhs.gov> wrote:

Good afternoon Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thank you,
Lauren Hefner

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

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Hefner, Lauren N

From: Hefner, Lauren N
Sent: Thursday, January 19, 2012 7:53 AM
To: 'Mihir Shah'
Cc: Pastel, Mary; O'Hara, Michael D
Subject: RE: NoTouch BreastScan (K113259) - Indications for use clarification

Good Morning Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Mihir Shah [mailto:mihir@notouchbreastscan.com]
Sent: Wednesday, January 18, 2012 8:48 PM
To: Hefner, Lauren N
Subject: Re: NoTouch BreastScan (K113259) - Indications for use clarification

(b)(4) Trade Secret Process - Product Specs [redacted].

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122

+1.267.342.3303 Cell
+1.918.516.3303 Fax

Skype ID: NoTouchBreastScan

www.NoTouchBreastScan.com

On Tue, Jan 17, 2012 at 6:01 PM, Mihir Shah <mihir@notouchbreastscan.com> wrote:

Dear Lauren, (b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

Skype ID: NoTouchBreastScan

www.NoTouchBreastScan.com

On Tue, Jan 17, 2012 at 9:04 AM, Hefner, Lauren N <Lauren.Hefner@fda.hhs.gov> wrote:

Good Morning Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

Sincerely,

Lauren Hefner

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Mihir Shah [mailto:mihir@notouchbreastscan.com]
Sent: Tuesday, January 17, 2012 12:26 AM
To: Hefner, Lauren N
Cc: Smith, John J.
Subject: NoTouch BreastScan (K113259) - Indications for use clarification

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

Hefner, Lauren N

From: Mihir Shah [mihir@notouchbreastscan.com]
Sent: Thursday, December 29, 2011 2:54 PM
To: Hefner, Lauren N
Cc: O'Hara, Michael D; Pastel, Mary; Matthew Campisi; Smith, John J.
Subject: Re: Concerning K113259 NoTouch Breastscan
Attachments: 003_510(k) Cover Letter.pdf

Dear Lauren,

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

Skype ID: NoTouchBreastScan

www.NoTouchBreastScan.com

On Thu, Dec 29, 2011 at 12:57 PM, Hefner, Lauren N <Lauren.Hefner@fda.hhs.gov> wrote:

> Good Afternoon Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Hefner, Lauren N
Sent: Wednesday, December 14, 2011 10:27 AM
To: 'MShah@NoTouchBreastScan.com'
Cc: O'Hara, Michael D; Pastel, Mary; Boyd, Sean M
Subject:

Good Morning Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[redacted]

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

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January 17, 2012

Privileged And Confidential
Via Federal Express

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Lauren Hefner, M.S., D.A.B.R., Division of Radiological Devices (WO66 Room G312)

RE: (b)(4) Trade Secret Process - Product Specs [redacted]

Dear Ms. Hefner:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

4435 Lobella Ct
Chester Springs, PA 19425

Attachment 1

1. Indications for Use Statement – Red Lined
2. Indications for Use Statement – Clean

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):_____

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):_____

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Attachment 2

1. The 510(k) Summary – Red Lined
2. The 510(k) Summary – Clean

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. ~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

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Attachment 3

1. Labeling – Red Lined
2. Labeling – Clean

XII. LABELING (REFERENCE SECTION 13)

Proposed Labeling for NoTouch BreastScan

Labels on individually packaged NoTouch BreastScan System

For Instructions for Use Operator's manual and Draft promotional materials, please see Section 13 of the UELS folder.

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs, PA 19425

CE

EC REP

European Device Solutions UK, Ltd.
32, Bull Lane
Rayleigh, Essex SS6 8JD
England.

For professional use only, do not operate without proper training. Report malfunctions or damaged components to the manufacturer immediately.

This device should not be used near a magnetic field during recording

SN:NTBS0010

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. This is *not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

NoTouch Breastscan™
Device Labeling

Issue 1: Rev.0: Date: 09/01/2011

1.0 Purpose

The purpose of this document is to describe the general labeling requirements for the NoTouch BreastScan system as stated in Device Labeling Guidance #G91-1 (blue book memo). General labeling requirements for medical devices have been established in 21 CFR Part 801.

All definitions and requirements were taken from the FDA web page.

2.0 Definitions

Labeling:

"Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Directions for Use:

The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information.

Indications for Use:

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is "indicated"
or "intended for use"

411

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Contraindications:

This describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

Warnings

Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Precautions

Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

3.0 Label Requirements

a) Name and Place of Business: The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
b) Intended Use: If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
c) Adequate Directions: "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes intended

3.1 Cart labels

These labels should be adhered to the right side of the NoTouch BreastScan cart in clear view.

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs, PA 19425

EC REP

European Device Solutions UK, Ltd.
32, Bull Lane
Rayleigh, Essex SS6 8JD
England.

For professional use only, do not operate without proper training. Report malfunctions or damaged components to the manufacturer immediately.

This device should not be used near a magnetic field during recording

SN:NTBS0010

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. *This is not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

4.0 Instructions for Use

Instructions for Use are supplied in the Operators Manual in print form. These general instructions are not intended to be used as the only means of training. Users who are not trained are not authorized to use the system.

5.0 Examples of international Symbols as per EN980

ATTENTION SYMBOL;
"See Instructions".
Only IF instructions for use are necessary.

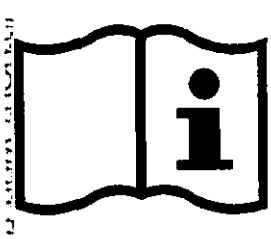
SN:NTBS0001

SERIAL NUMBER;

Alternative symbol to LOT number, the 'SN' prefix must be used.

Manufacture's Details;
The name and address of the manufacturer needs to be "adjacent" to this symbol.

Must be on outer package



Consult Operating Instructions

Self explanatory

c/4

CE

'CE' Logo;

If your products are self-certify devices, ONLY the CE symbol is needed. The number is added for all other devices, as it is the identification number of a 3rd Party Notified Body's intervention.

References:

NTBS Printed Instructions for Use / Operator Manual
Marketing Materials

XII. LABELING (REFERENCE SECTION 13)

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UELS 4435 Lobella Court, Chester Springs, PA 19425

NoTouch Breastscan™
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or "intended for use"

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

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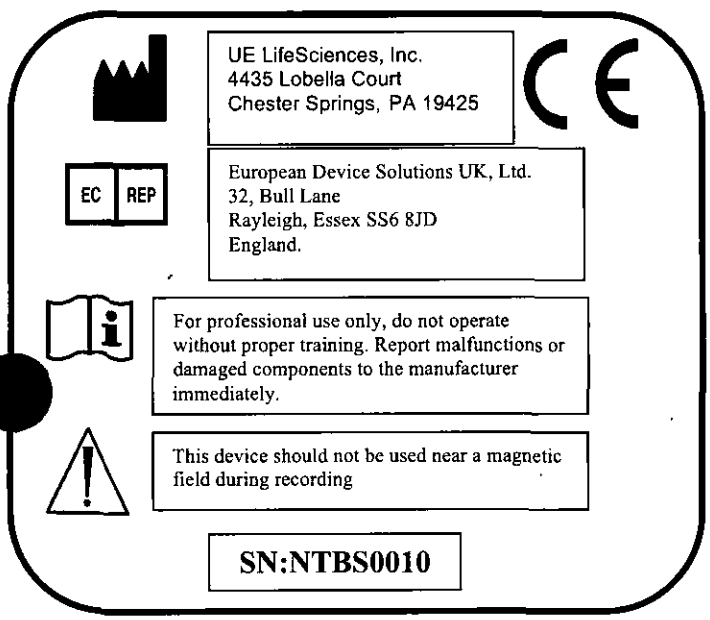

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UELS 4435 Lobella Court, Chester Springs, PA 19425

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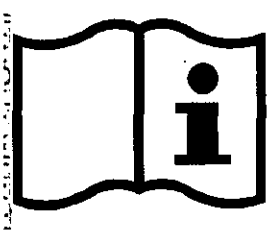

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Self explanatory

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If your products are self-certify devices, ONLY the CE symbol is needed. The number is added for all other devices, as it is the identification number of a 3rd Party Notified Body's intervention.

References:

NTBS Printed Instructions for Use / Operator Manual
Marketing Materials

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Hefner

Subject: 510(k) Number K113259

To: The Record

Please list CTS decision code **TH**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

X Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✠
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✠	
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X

Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
884.2980	1	~~IYM~~ LHQ

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ 12/30/11

(Branch Chief) (Branch Code) (Date)

Final Review: _____

(Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)			X
5. a. Did the firm request expedited review? (See management.)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here: K091311	X	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	X		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	X		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			x

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm	X		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	X		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm			X
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm			X
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	X		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	X		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf		X	
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	X		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			X

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K113259

Date: December 29, 2011
To: The Record
From: Lauren Hefner

Office:OIVD
Division: DRAD

510(k) Holder: UE Lifesciences
Device Name: NoTouch Breastscan
Contact: Mihir B. Shah
Phone: 267 342-3303
Fax: 918 516-3303
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce NoTouch Breastscan into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	

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	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

IV. Indications for Use

The IFU for this device is:
The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.
The device is for adjunctive screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.
The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.

The IFU for the predicate device(k033967 series A,E,S, and P – IR cameras):
The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.
(b)(4) Trade Secret Process - Product Specs [redacted]

V. Predicate Device Comparison

(b)(4) Trade Secret Process - Product Specs [redacted]

VI. Labeling

(b)(4) Trade Secret Process - Product Specs [redacted]

VII. Sterilization/Shelf Life/Reuse

(b)(4) Trade Secret Process - Product Specs [redacted]

VIII. Biocompatibility

(b)(4) Trade [redacted]
S t P

IX. Software

(b)(4) Trade Secret Process - Product Specs [redacted]

Version:		
Level of Concern:		
	Yes	No

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Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b)(4) Trade Secret Process - Product Specs [redacted]

XI. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs [redacted]

XII. Performance Testing – Animal

Not applicable

XIII. Performance Testing – Clinical

requested

XIV. Substantial Equivalence Discussion

(b)(4) Trade Secret Process - Product Specs [redacted]

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?	?		If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

(b)(4) Trade Secret Process - Product Specs [redacted]

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

(b)(4) Trade Secret Process - Product Specs [redacted]

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade [redacted]
S t P

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(b)(4) Trade Secret Process - Product Specs

[redacted]

XVI. Contact History

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVII. Recommendation TH

Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: Class I
Product Code: ~~IYM~~ LHQ

Lauren Hefner
Reviewer

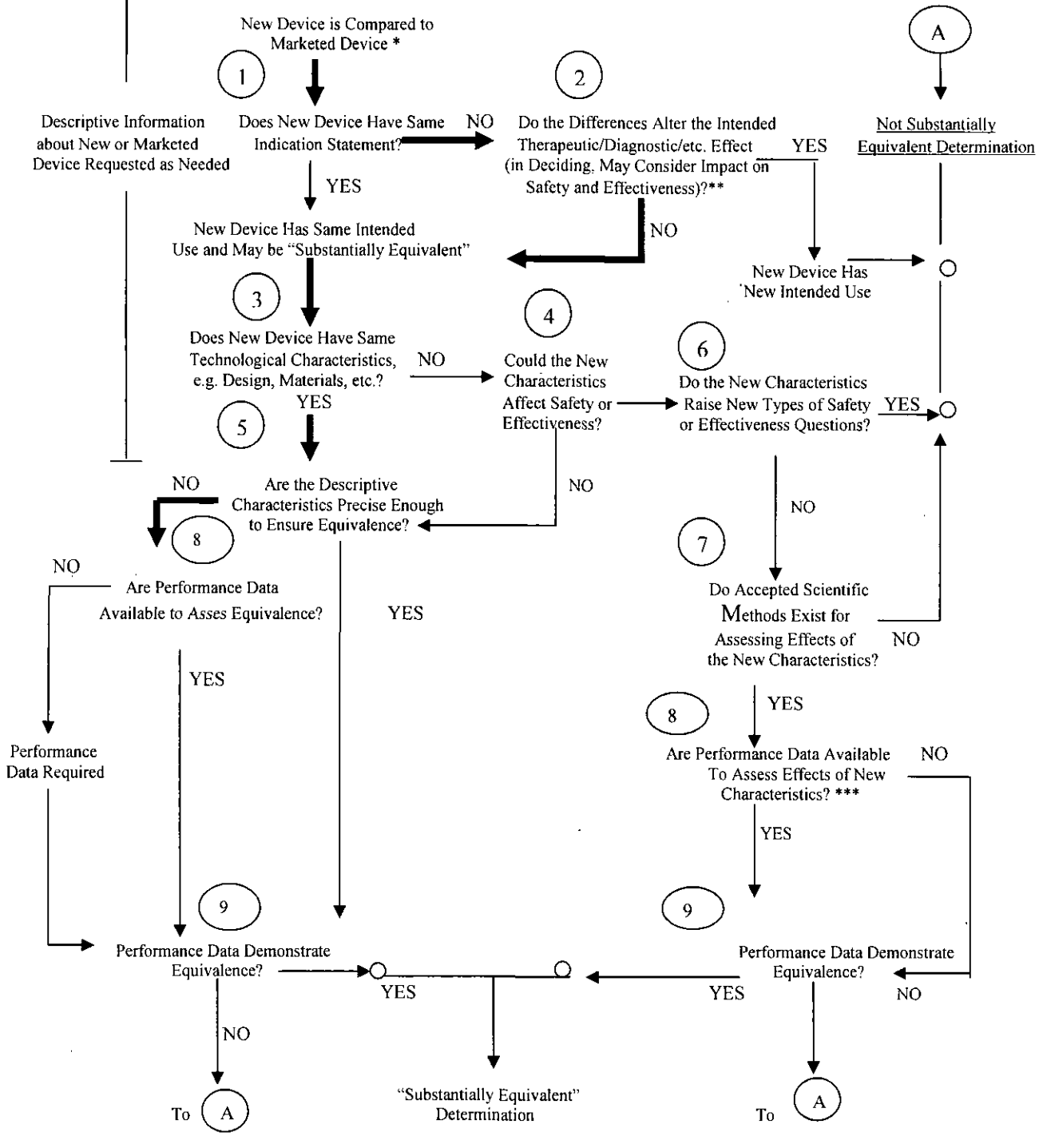
December 29, 2011
Date

Branch Chief

12/30/11
Date

97

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Hefner, Lauren N

From: Hefner, Lauren N
Sent: Thursday, December 29, 2011 12:58 PM
To: 'MShah@NoTouchBreastScan.com'
Cc: O'Hara, Michael D; Pastel, Mary
Subject: Concerning K113259 NoTouch Breastscan

Good Afternoon Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Lauren

Lauren Hefner, M.S., D.A.B.R.
[redacted]ision of Radiological Devices
[redacted]Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
Silver Spring, MD 20993-0002
email: lauren.hefner@fda.hhs.gov
Phone: (301) 796-6881

From: Hefner, Lauren N
Sent: Wednesday, December 14, 2011 10:27 AM
To: 'MShah@NoTouchBreastScan.com'
Cc: O'Hara, Michael D; Pastel, Mary; Boyd, Sean M
Subject:

Good Morning Mr. Shah,

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Lauren

Lauren Hefner, M.S., D.A.B.R.
Division of Radiological Devices
US Food and Drug Administration

Bldg 66 Room G312
10903 New Hampshire Av,
[redacted]er Spring, MD 20993-0002
[redacted]il: lauren.hefner@fda.hhs.gov

Phone: (301) 796-6881

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____

Subject: 510(k) Number K113259

To: The Record

Please list CTS decision code _____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

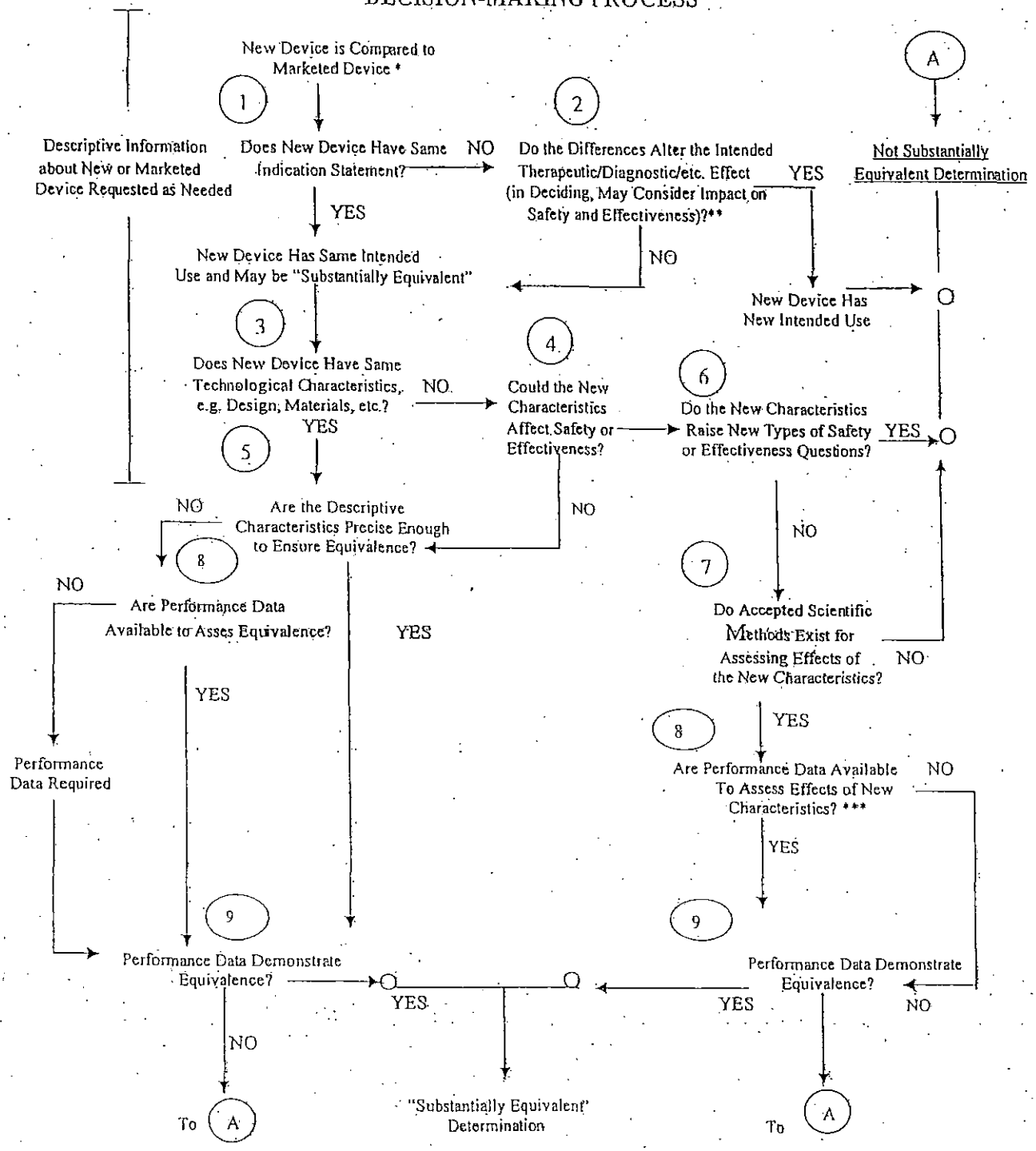
Review:_____

(Branch Chief) (Branch Code) (Date)

Final Review:_____

(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2012

UE LIFESCIENCES, INC.
4435 LOBELLA COURT
CHESTER SPRINGS, PENNSYLVANIA 19425
ATTN: MIHIR SHAH

510k Number: K113259

Product: NOTOUCH BREASTSCAN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'm.shah@notouchbreastscan.com'
Sent: Monday, January 23, 2012 2:51 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'm.shah@notouchbreastscan.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

54

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, January 23, 2012 2:51 PM
To: 'm.shah@notouchbreastscan.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 23, 2012
SHAH
MIHIR
UE LIFESCIENCES, INC.
4435 LOBELLA COURT
CHESTER SPRINGS, PENNSYLVANIA 19425
ATTN: MIHIR SHAH

510k Number: K113259

Product: NOTOUCH BREASTSCAN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

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Sincerely,

55

510(k) Staff

K113259 | S1

January 17, 2012

Privileged And Confidential
Via Federal Express

FDA CDRH DMC
JAN 23 2012
Received

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Lauren Hefner, M.S., D.A.B.R., Division of Radiological Devices (WO66 Room G312)

RE: (b)(4) Trade Secret Process - Product Specs [redacted]

Dear Ms. Hefner:

(b)(4) Trade Secret Process - Product Specs

[redacted]

K-66 57

(b)(4) Trade Secret Process - Product Specs

[redacted]

With best regards,

Mihir Shah
CEO, UE LifeSciences Inc.

M.Shah@NoTouchBreastScan.com
+1.631.980.8340, Ext122
+1.267.342.3303 Cell
+1.918.516.3303 Fax

4435 Lobella Ct
Chester Springs, PA 19425

Attachment 1

1. Indications for Use Statement – Red Lined
2. Indications for Use Statement – Clean

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):_____

Device Name: NoTouch BreastScan™ System

Indications for Use:

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

IV. INDICATIONS FOR USE STATEMENT

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510(k) Number (if known):_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

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Attachment 2

1. The 510(k) Summary – Red Lined (2 pages)
2. The 510(k) Summary – Clean (2 pages)

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

The NoTouch BreastScan system is intended to be used as an adjunctive screening device for the detection of breast cancer by measuring various temperature parameters from the surface of the breast.

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use. ~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Technological Characteristics

The NoTouch BreastScan consists of a group of hardware and software components. The hardware components consist of:

- Two digital infrared cameras
- A computer system, with printer
- An air conditioner unit
- A specially designed mobile cart.

Software Components include:

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- NoTouch BreastScan Software
- PDF Viewer
- Drivers for Infrared imagers
- ThermaCam Researcher Software

Performance Data

Testing of NoTouch BreastScan was performed as per the requirements. In all instances, the NoTouch BreastScan functioned as intended and the software and hardware performed as expected. Complete validation and verification was performed on all software and hardware subsystems.

Substantial Equivalence

The NoTouch BreastScan is as safe and effective as BreastScan IR. The NoTouch BreastScan has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NoTouch BreastScan and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the NoTouch BreastScan is as safe and effective as BreastScan IR. Thus, the NoTouch BreastScan is substantially equivalent.

V. 510(K) SUMMARY

510(k) SUMMARY

UE LifeSciences Inc.'s NoTouch BreastScan

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs PA 19425

Tel: 631-980-8340

Contact Person: Mihir Shah
Tel: 267-342-3303
Email: MShah@notouchbreastscan.com

Date Prepared: January 17, 2012

Common or Usual Name: NoTouch BreastScan

Classification Name: Class 1 per 21 CFR 884.2980 Telethermographic system.

Predicate Devices

BREASTSCAN IR

Intended Use / Indications for Use

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Attachment 3

1. Labeling – Red Lined (7 pages)
2. Labeling – Clean (7 pages)

XII. LABELING (REFERENCE SECTION 13)

Proposed Labeling for NoTouch BreastScan

Labels on individually packaged NoTouch BreastScan System

For Instructions for Use Operator's manual and Draft promotional materials, please see Section 13 of the UELS folder.

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs, PA 19425

EC REP

European Device Solutions UK, Ltd.
32, Bull Lane
Rayleigh, Essex SS6 8JD
England.

For professional use only, do not operate without proper training. Report malfunctions or damaged components to the manufacturer immediately.

This device should not be used near a magnetic field during recording

SN:NTBS0010

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. This is *not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

NoTouch Breastscan™
Device Labeling

Issue 1: Rev.0: Date: 09/01/2011

1.0 Purpose

The purpose of this document is to describe the general labeling requirements for the NoTouch BreastScan system as stated in Device Labeling Guidance #G91-1 (blue book memo). General labeling requirements for medical devices have been established in 21 CFR Part 801.

All definitions and requirements were taken from the FDA web page.

2.0 Definitions

Labeling:

"Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Directions for Use:

The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information.

Indications for Use:

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is "indicated"
or "intended for use"

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Contraindications:

This describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

Warnings

Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Precautions

Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

3.0 Label Requirements

a) Name and Place of Business: The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
b) Intended Use: If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
c) Adequate Directions: "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes intended

3.1 Cart labels

These labels should be adhered to the right side of the NoTouch BreastScan cart in clear view.

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs, PA 19425

CE

EC REP

European Device Solutions UK, Ltd.
32, Bull Lane
Rayleigh, Essex SS6 8JD
England.

For professional use only, do not operate without proper training. Report malfunctions or damaged components to the manufacturer immediately.

This device should not be used near a magnetic field during recording

SN:NTBS0010

Indications for Use

The NoTouch BreastScan™ system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult.

The device is for adjunctive diagnostic screening for the detection of breast cancer and diseases affecting blood perfusion of tissue or organs. This device is intended for use by a qualified healthcare professional trained in its use.

~~The NoTouch BreastScan™ system is intended to be used as an adjunctive screening procedure and does not replace mammography as primary screening tool.~~

Warnings and Precautions

- Do not use as an independent breast cancer diagnostic or screening method. This is *not* a diagnostic test.
- This device is not compatible for use in an MRI magnetic field.
- **Do not operate without proper training.**

UELS 4435 Lobella Court, Chester Springs, PA 19425

4.0 Instructions for Use

Instructions for Use are supplied in the Operators Manual in print form. These general instructions are not intended to be used as the only means of training. Users who are not trained are not authorized to use the system.

5.0 Examples of international Symbols as per EN980

ATTENTION SYMBOL;
"See Instructions".
Only IF instructions for use are necessary.

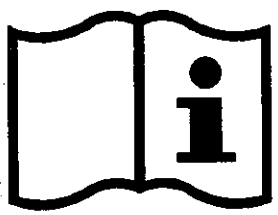
SN:NTBS0001

SERIAL NUMBER;

Alternative symbol to LOT number, the 'SN' prefix must be used.

Manufacture's Details;
The name and address of the manufacturer needs to be "adjacent" to this symbol.

Must be on outer package



Consult Operating Instructions

Self explanatory

CE

'CE' Logo;

If your products are self-certify devices, ONLY the CE symbol is needed. The number is added for all other devices, as it is the identification number of a 3rd Party Notified Body's intervention.

References:

NTBS Printed Instructions for Use / Operator Manual
Marketing Materials

XII. LABELING (REFERENCE SECTION 13)

Proposed Labeling for NoTouch BreastScan

Labels on individually packaged NoTouch BreastScan System

For Instructions for Use Operator's manual and Draft promotional materials, please see Section 13 of the UELS folder.

UE LifeSciences, Inc.
4435 Lobella Court
Chester Springs, PA 19425

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NoTouch Breastscan™
Device Labeling

Issue 1: Rev.0: Date: 09/01/2011

1.0 Purpose

The purpose of this document is to describe the general labeling requirements for the NoTouch BreastScan system as stated in Device Labeling Guidance #G91-1 (blue book memo). General labeling requirements for medical devices have been established in 21 CFR Part 801.

All definitions and requirements were taken from the FDA web page.

2.0 Definitions

Labeling:

"Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Directions for Use:

The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information.

Indications for Use:

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is "indicated"
or "intended for use"

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Contraindications:

This describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

Warnings

Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Precautions

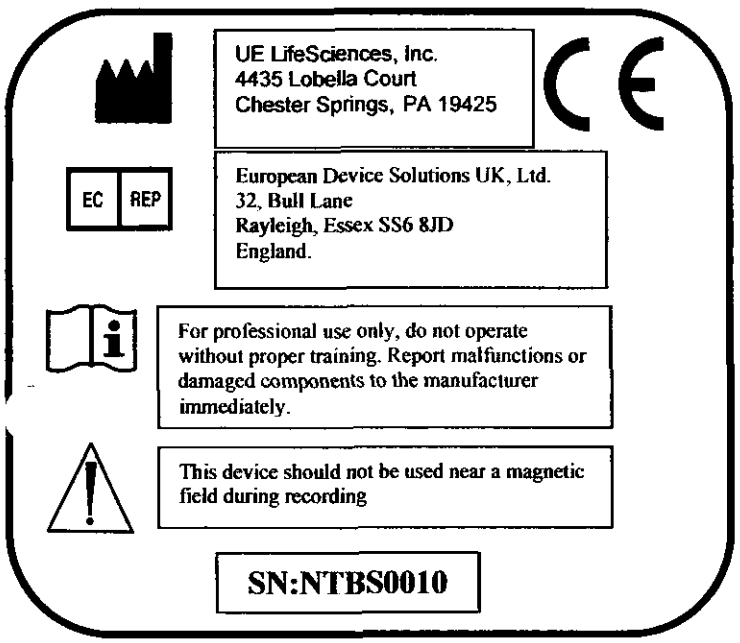
Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device.

3.0 Label Requirements

a) Name and Place of Business: The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the street address, city, state, and zip code.
b) Intended Use: If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
c) Adequate Directions: "Adequate directions for use" means directions under which the layman can use a device safely and for the purposes intended

3.1 Cart labels

These labels should be adhered to the right side of the NoTouch BreastScan cart in clear view.



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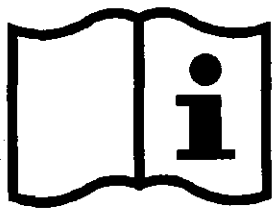

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