Records Processed under FOI request 2016-10204; Released by CDRH on 08/23/2016

K082380

SEP 16 2008

510(k) Summary

superDimension, Ltd.
Special 510(k)
Proposed Minor Modifications to inReach™ Planning Laptop

Date Prepared:

08/18/2008

510(k) Applicant:

superDimension, Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Ph: +972-(0)9-971-3700
Fax: +972-(0)9-971-3701

FDA CDRH DMC
AUG 19 2008
Received

510(k) Application Correspondent:

Margaret DePuydt, P.E., RAC
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441
Phone: 763-210-4052
Cell : 612-845-7771
Fax : 763-210-4098
Email : mdepuydt@superdimension.com

Name of Device :

Trade Name :	- superDimension®/ inReach™ Planning Laptop - inReach™ Planning Laptop
Common Name:	inReach™ Planning Laptop - Bronchoscopy Planning/CT-Viewing
Classification Name:	Picture Archiving and Communications System 21 CFR 892.2050 Product code LLZ

Equivalent Legally-Marketed Device:
inReach System, K081379

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

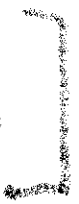
Description:

superDimension is proposing that the inReach™ Planning Laptop, with its current software be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components in places outside of the endoscopy room.

There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved.

Intended Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.



Summary of Characteristics Compared to Predicate Device:

Minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the proposal that the Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing, or with the other system components.

No changes are being made to the hardware or intended use, or technological characteristics of the current marketed device.

Performance Data:

The planned modifications were subjected to the superDimension design control process. There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved (K081379, June 11, 2008). The inReach System and software design input/output requirements are not changing and will continue to meet the user needs and intended uses, performing to design specifications. Therefore software and design validations/verifications are not required to be performed.

There are no new, increased, altered, or eliminated risks associated with this minor modification. A risk analysis is not required to be performed. The risk analysis documents presented in K081379 have not changed, and still apply to the Planing Laptop.

Appropriate labeling changes are identified in the User Manual and summarized in the User Manual Change Revision Table.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Clinical Data:

Clinical tests were not required to validate the changes to the inReach System to incude the Planning Laptop.

Conclusion:

The inReach System is safe and effective for its intended use.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2008

superDimension, Ltd.
% Ms. Margaret DePuydt
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPLOIS MN 55441

Re: K082386
Trade/Device Name: inReach Planning Laptop
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 15, 2008
Received: August 19, 2008

Dear Ms. DePuydt:

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

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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

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

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

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Indications for Use

510(k) Number (if known): K082386

Device Name: inReach Planning Laptop

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082386

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2008

superDimension, Ltd.
% Ms. Margaret DePuydt
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
MINNEAPLOIS MN 55441

Re: K082386
Trade/Device Name: inReach Planning Laptop
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 15, 2008
Received: August 19, 2008

Dear Ms. DePuydt:

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

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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

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

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

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Indications for Use

510(k) Number (if known): K082386

Device Name: inReach Planning Laptop

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082386

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 19, 2008

SUPERDIMENSION, LTD.
C/O SUPERDIMENSION, INC.
161 CHESHIRE LANE NORTH,
SUITE 100
MINNEAPOLIS, MN 55441
ATTN: MARGARET DEPUYDT

510(k) Number: K082386
Received: 19-AUG-2008
Product: INREACH PLANNING LAPTOP

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

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

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

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

Sincerely yours,

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
SUPERDIMENSION LTD 16193 84th Place North Maple Grove MN 55311 US	Jonathan Kovach 2.1 E-MAIL ADDRESS jkovach@superdimension.com 2.2 TELEPHONE NUMBER (include Area code) 7632104015
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA	2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-7632104098

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/dc/mdufma

Select an application type:

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

3.1 Select one of the types below

[X] Original Application

Supplement Types:

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

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

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

5. 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, parents, and partner firms

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

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

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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

07-Aug-2008

"Close Window" Print Cover sheet

RA

II

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/15/2008	(b) (4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
superDimension, Ltd.	3004659744		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(763) 210-4052		
Street Address	**FAX Number *(including area code)***		
8 Hamenofim St. POB 2045	(763) 210-4098		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Herzliya		46120	Israel
Contact Name			
Margaret DePuydt			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Manager	mdepuydt@superdimension.com		

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

Company / Institution Name			
superDimension, Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(763) 210-4052		
Street Address	**FAX Number *(including area code)***		
161 Cheshire Lane, Suite 100	(763) 210-4098		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Minneapolis	MN	55441	U.S.A.
Contact Name			
Margaret DePuydt			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Manager	mdepuydt@superdimension.com		

PSC Graphics (301) 443-1090 EF

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1)

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose 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):*

Proposing that the inReach™ Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing or with the other system components. Also to incorporate the necessary respective changes into the Instructions For Use (inReach User Manual).

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 JAK	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K081379	superDimension/Bronchus Brand Name: inReach System	superDimension, Ltd.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Bronchoscope

	Trade or Proprietary or Model Name for This Device	Model Number
1	the inReach™ Planning Laptop	AED00047-01
2		
3		
4		
5		

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

1 K042438	2 K052260	3 K052852	4 K062315	5 K071473	6 K080271
7 K081379	8	9	10	11	12

Data Included in Submission

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

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*
LLZ	892.2050

Classification Panel

Radiology

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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 Identifer (FEI) Number: 3004659744	☑ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: superDimension, Ltd.		Establishment Registration Number: 3004659744	
Division Name *(if applicable)*		Phone Number *(including area code)*: (763) 210-4052	
Street Address: 8 Hamenofim St. POB 2045		FAX Number *(including area code)*: (763) 210-4098	
City: Herzliya	State / Province	ZIP/Postal Code: 46120	Country: Israel
Contact Name: Margaret DePuydt	Contact Title: Regulatory Affairs Manager	Contact E-mail Address: mdepuydt@superdimension.com	

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

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

IS

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616. Expiration Date: 06-30-2008

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
Margaret DePuydt

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
08/19/2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 763-210-4052
(Fax) 763-210-4098

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)
superDimension Bronchus / inReach System - Remote Planning Station

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 PERON WHO SIGNED IN NO. 11
(Name) Margaret DePuydt
(Title) Regulatory Affairs Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 763-210-4052
(Fax) 763-210-4098

15. DATE OF CERTIFICATION
08/19/2008

FDA-3674 (1/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j)) Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date** - This is the date of the application/submission which the certification accompanies.

3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification** - This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14.** - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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

FDA-3674 (1/08) (BACK)

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

superDimension

superDimension, Inc. 161 Cheshire Lane, Suite 100, Minneapolis, MN 55441-5433
p 800.387.9016 (toll free), 763.210.4000 f 763.210.4098 www.superdimension.com

08/15/2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ 401)
9200 Corporate Boulevard
Rockville, MD 20850

Re : Special 510(k)
Proposed Minor Modifications to inReach™ Planning Laptop

Attention : Document Mail Clerk

This Special 510(k) is being submitted to notify you of the intention of superDimension Ltd., the 510(k) Applicant, to make minor modifications to the device description and the labeling of the inReach™ System, currently cleared under 510(k) K081379. The indications for use of the device, as described in its labeling, are the same as the indications for use of the 510(k) Applicant's unmodified predicate device. The hardware, software, and disposables for the predicate device are not changing.

superDimension is proposing that the inReach™ Planning Laptop be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components.

Additionally, minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the aforementioned proposal.

Device Undergoing Change:

Trade names:	- superDimension®/inReach™ Planning Laptop - inReach™ Planning Laptop
Common name:	inReach™ Planning Laptop- Bronchoscopy Planning/CT-Viewing
Classification name:	Picture Archiving and Communications System
Classification:	Class II 21 CFR Part 829.2050
Product Code:	LLZ
Panel:	Radiology
Performance Standard:	None established under Section 514

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

superDimension

superDimension, Inc. 161 Cheshire Lane, Suite 100, Minneapolis, MN 55441-5433
p 800.387.9016 (toll free), 763.210.4000 f 763.210.4098 www.superdimension.com

510(k) Applicant:
superDimension, Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Establishment Registration Number: 3004659744

510(k) Application Correspondent:
Margaret DePuydt, P.E., RAC
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441

Phone: 763-210-4052
Cell: 612-845-7771
Fax: 763-210-4098
Email: mdepuydt@superdimension.com
Establishment Registration Number: 3004962788

Based on our review of the published guidance for Special 510(k) Notification submittals, we believe the information provided in this submittal to be appropriate to support the modifications to the inReach System.

Should the need arise to discuss the contents of this 510(k) or request further information, please feel free to contact me at the phone number, fax, or email address listed above.

Sincerely,

Margaret DePuydt, P.E., RAC
superDimension, Inc.
Regulatory Affairs Manager

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Section 1
Table of Contents

superDimension Ltd.
Special 510(k)
Proposed Minor Modifications to inReach™ Planning Laptop

Title	Section
MDUFMA Coversheet	Section 1
CDRH Coversheet	Section 1
Certification of Compliance with Clinical Trials	Section 1
Cover Letter	Section 1
Table of Contents	Section 1
Screening Checklist	Section 1
Indications for Use Statement	Section 2
Truthful and Accurate Statement	Section 3
Declaration of Conformity with Design Controls	Section 4
510(k) Summary	Section 5
Device Description and Comparison	Section 6
Substantial Equivalence Discussion	Section 7
Proposed Labeling	Section 8
Summary of Design Control Activities	Section 9

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☒ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	**Missing or Inadequate**
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	Section 1	
Table of Contents.	Section 1	
Truthful and Accurate Statement.	Section 1	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Section 6	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Section 6	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Section 8	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 2	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	Section 7	
510(k) Summary or 510(k) Statement.	Section 5	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Section 6	
Identification of legally marketed predicate device. *	Section 6	

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	No mandatory performance standards for this device
Class III Certification and Summary. **	NA	Not a Class III device
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	No clinical study for changes to device
510(k) Kit Certification ***	NA	Not a kit

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	**Inadequate or Missing**
Name and 510(k) number of the submitter's own, unmodified predicate device.	Section 6	
A description of the modified device and a comparison to the sponsor's predicate device.	Sections 6 & 7	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	Section 6	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	Section 9	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	Section 9	

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

c. A Declaration of Conformity with design controls that includes the following statements:	Section 4	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	See above	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	See above	

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Indications for Use

510(k) Number (if known): _____

Device Name: inReach Planning Laptop

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric 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)

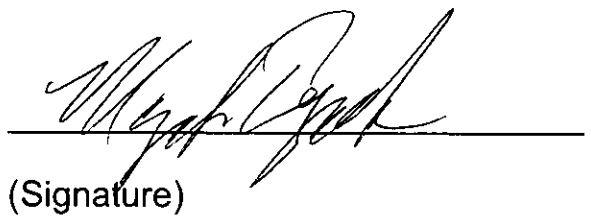
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(k)]

superDimension, Ltd.
Traditional 510(k)
Indication Expansion

I certify that, in my capacity as Regulatory Affairs Manager of Regulatory Affairs of superDimension, Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Margaret DePuydt

(Typed Name)

8/18/08

(Date)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Declaration of Conformity with Design Controls

superDimension, Ltd.
Special 510(k)
Changes to inReach System

Verification Activities

To the best of my knowledge, the validation and verification activities, as required by the risk analysis, for the modifications were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

Jay Johnson, 15/August/2008
Jay Johnson, Date
WW VP Research and Development

Manufacturing Facility

The manufacturing facility of superDimension, Ltd. is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Ronen Raz, 14/August/2008
Ronen Raz, Date
VP Operations

[Note: The above two statements should be signed by the designated individual(s) responsible for those activities].

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

510(k) Summary

superDimension, Ltd.
Special 510(k)
Proposed Minor Modifications to inReach™ Planning Laptop

Date Prepared:

08/18/2008

510(k) Applicant:

superDimension, Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Ph: +972-(0)9-971-3700
Fax: +972-(0)9-971-3701

FDA CDRH DMC
AUG 19 2008
Received

510(k) Application Correspondent:

Margaret DePuydt, P.E., RAC
Regulatory Affairs Manager
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441
Phone: 763-210-4052
Cell : 612-845-7771
Fax : 763-210-4098
Email : mdepuydt@superdimension.com

Name of Device :

Trade Name :	- superDimension®/ inReach™ Planning Laptop
	- inReach™ Planning Laptop
Common Name:	inReach™ Planning Laptop - Bronchoscopy Planning/CT-Viewing
Classification Name:	Picture Archiving and Communications System
	21 CFR 892.2050
	Product code LLZ

Equivalent Legally-Marketed Device:
inReach System, K081379

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Description:

superDimension is proposing that the inReach™ Planning Laptop, with its current software be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components in places outside of the endoscopy room.

There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved.

Intended Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of Characteristics Compared to Predicate Device:

Minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the proposal that the Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing, or with the other system components.

No changes are being made to the hardware or intended use, or technological characteristics of the current marketed device.

Performance Data:

The planned modifications were subjected to the superDimension design control process. There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved (K081379, June 11, 2008). The inReach System and software design input/output requirements are not changing and will continue to meet the user needs and intended uses, performing to design specifications. Therefore software and design validations/verifications are not required to be performed.

There are no new, increased, altered, or eliminated risks associated with this minor modification. A risk analysis is not required to be performed. The risk analysis documents presented in K081379 have not changed, and still apply to the Planing Laptop.

Appropriate labeling changes are identified in the User Manual and summarized in the User Manual Change Revision Table.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Clinical Data:

Clinical tests were not required to validate the changes to the inReach System to incude the Planning Laptop.

Conclusion:

The inReach System is safe and effective for its intended use.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Product Description and Product Changes

superDimension, Ltd.
Special 510(k) Submission
Proposed Minor Modifications to inReach™ Planning Laptop

Introduction:

superDimension is proposing that the inReach™ Planning Laptop be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components.

Additionally, minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the aforementioned proposal.

Rationale for use of Special 510(k)

Changes are being made to the Applicant's own legally marketed device. The intended use and indications for use of the modified device, as described in its labeling, are the same as the intended use and indications for use of the Applicant's unmodified predicate device. The modified device has the same technological characteristics as the unmodified predicate device.

Identification of Applicant's Own Legally-Marketed Predicate Device

Trade names:	- superDimension®/ inReach™ Planning Laptop - inReach™ Planning Laptop
510(k) for predicate:	K081379

Information Applicable to Both Modified and Predicate Devices

Trade names:	- superDimension®/ inReach™ Planning Laptop - inReach™ Planning Laptop
Common name:	inReach™ Planning Laptop - Bronchoscopy Planning/CT-Viewing
Classification name:	Picture Archiving and Communications System
Classification:	Class II 21 CFR Part 892.2050
Product Code:	LLZ
Panel:	Radiology
Performance Standard:	None established under Section 514
510(k) for predicate:	K081379
Registration Number:	3004659744

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Contents of Remainder of This Section

- Detailed Description of Changes
- Description of Similarities
- Specifications for inReach System, applicable to both unmodified and modified devices

Detailed Description of Changes:

Proposed Minor Modifications to inReach™ Planning Laptop

superDimension is proposing that the inReach™ Planning Laptop, with its current software be approved to be used either as a stand-alone for performing bronchoscopy planning, as currently approved (K081379, June 11, 2008) or for CT-Viewing, or with the other system components in places outside of the endoscopy room.

There are no modifications proposed to the technology, software, hardware, firmware, product design or specifications, mode of operation, or manufacturing processes as currently approved.

Minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the proposal that the inReach™ Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing, or with the other system components.

Description of Similarities:

Indications for Use

Both modified and unmodified devices have the same indications for use. The indications for use are as follows:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Specifications for inReach™ Planning Laptop:

This proposed modification will not incur any changes to the currently approved superDimension/inReach™ Planning Laptop specifications (K081379, June 11, 2008).

(b)(4) Specifications



Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Substantial Equivalence

superDimension, Ltd.
Special 510(k) Submission
Proposed Minor Modifications to inReach™ Planning Laptop

Below is a comparison of the major characteristics of the superDimension inReach System devices, to include the inReach™ Planning Laptop , before and after the minor modifications proposed in this submission.

Parameter	**Unmodified inReach System K081379**	**Modified inReach System**
Indications for use	Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.	Same
Anatomical sites	Airways and tracheobronchial tree	Same
Basic principle	Guide bronchoscope and bronchial tool to target on path indicated by CT scan or PET/CT scan, provide visualization of tract interior and target	Same
Visualization Principle	Position predicted based on measured position and orientation of tip and localizing device as determined by electromagnetic sensors	Same
Method of visualization of path	CT scan or PET/CT scan	Same
Method of visualization of organs	Bronchoscope	Same

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Parameter	Unmodified inReach System K081379	Modified inReach System
CT Display Methods	3 CT cross-section planning viewports (axial, sagittal, and coronal), a 3D-Map Viewport, and a Virtual Bronchoscopy (VB) viewport	Same
Method by which organs are visualized during procedure	Computer Screen	Same
Maker of Sensors	superDimension	Same
Interventional instrument	inReach and Bronchoscope	Same
Method for tracking location of instrument	Electromagnetic sensors on tip	Same
Use of computer and computer type	Yes, PC provided by superDimension as part of the system	Same
Computer function	Display. Calculation of position and orientation of sensors.	Same
Energy Released into body	Negligible RF energy	Same
Compatibility with other devices	User manual provides list of compatible bronchoscopes and tools	Same
Indication of sensors are out of range	Yes	Same
Accuracy check	Yes	Same
Compatibility with associated devices	Operation through the bronchoscope's instrument channel	Same
Sterility	Disposables provided by superDimension (EWC, LG, BA, BC) supplied sterile	Same
Reusability of device sold sterile	EWC, LG, BA, BC not reusable	Same
Biocompatibility	Per ISO 10993-1	Same
Electrical and Mechanical Standards Compliance	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-2-18	Same

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The modified and unmodified device have the following similarities to those which previously previously received 510(k) concurrence:

- Have the same indicated use
- Use the same operating principle
- Have the same CT-viewing capabilities
- Have the same software
- Have the same hardware

In summary, the inReach™ Planning Laptop described in this submission is, in our opinion, substantially equivalent to the predicate device.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Proposed Labeling

superDimension, Ltd.
Special 510(k) Submission
Proposed Minor Modifications to inReach™ Planning Laptop

The proposed inReach System User Manual (P/N: PMB00155-01) is attached with the indicated minor modifications highlighted in yellow.

The proposed modifications are summarized in the attached User Manual Change document.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

(b) (4)



Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

superDimension

INREACH

Expanding the Boundaries

User Manual

August 2008

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.

CE 0473

P/N: PMB00155-01

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Israel Corporate Office

superDimension, Ltd.

Ofek House, 8 Hamenofim Street
Herzliya 46120, Israel

Telephone: +972-(0)9-971-3700
Fax: +972-(0)9- 971-3701

Info.il@superdimension.com

www.superdimension.com

United States Corporate Office

superDimension, Inc.

161 Cheshire Lane, Suite 100
Plymouth, MN 55441-5433, U.S.A.

Office: 1-800-387-9016
Customer Service: 1-888-586-4767
Fax: 1-866-706-9639

Info.us@superdimension.com

www.superdimension.com

Europe Corporate Office

superDimension (Europe) GmbH

Grossenbaumer Weg 10
D-40472 Düsseldorf
Germany

Telephone: +49-(0)211-436-156-0
Fax: +49-(0)211-436-156-29

Info.de@superdimension.com

www.superdimension.com

EC/REP EC REP

Quality First International Limited

Suites 317/318, Burford Business Centre
11 Burford Road, Stratford
London, United Kingdom. E15 2ST

Telephone: +44-(0)208-221-2361
Telefax: +44-(0)208-221-1912

http://www.qualityfirstint.com

Software Version 5.0

© 2008 **superDimension, Ltd.**

All rights reserved. All text and figures included in this publication are the exclusive property of superDimension, Ltd. and may not be copied, reproduced, transmitted or used in any way without the express permission in writing of superDimension, Ltd. The information in this manual was accurate and reliable at the time of its release. superDimension, Ltd. reserves the right to change the specifications of the product described in this manual without prior notice. The **superDimension inReach™** System is a registered trademark of superDimension, Ltd. **Windows™**, **Windows 2000™** and **Windows XP Professional™** are registered trademarks of Microsoft Corporation. Patents granted. Patents pending.

All other product and brand names are registered trademarks, trademarks, or service marks of their respective owners.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Table of Contents

Chapter 1: About this Manual 1-1

Document Conventions 1-1

Symbols 1-3

Chapter 2: Introduction 2-1

Indications for Use 2-1

Patient Indications 2-1

Contraindications 2-2

Safety 2-3

Warnings 2-3

Cautions 2-7

Symbols on Equipment and Labeling 2-12

Chapter 3: System Description 3-1

Introduction to superDimension/inReach™ 3-1

System Overview 3-1

Software Modules 3-2

Procedure Overview 3-3

System Components 3-7

Localization System 3-7

Remote Planning Station 3-9

Sensing Volume 3-10

Locatable Guide 3-11

The Extended Working Channel (Guiding Sheath) 3-12

Bronchoscope Adapter Unit 3-12

Bronchoscope Clip 3-13

Measuring Tube 3-14

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

41

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Required Equipment that is not Provided 3-15
Compatible Bronchoscopes 3-15
Compatible Endoscopic Tool 3-18
Compatible Marker Delivery Tools 3-19
Fluoroscopes 3-20
Endoscopic Video camera 3-20

Chapter 4: Specifications 4-1

Guidance on Electromagnetic Compatibility (EMC) 4-5

Chapter 5: Getting Started 5-1

Initial Setup 5-1
Software 5-3
Setting Up System Components 5-3
Setting up the System 5-11
System Logon 5-14
Opening Screen Layout and Functionality 5-17
Module Selection 5-17

Chapter 6: The Planning Module 6-1

The Planning Module Overview and Workflow 6-1
Planning Module Screen Layout 6-2
Planning Viewports 6-4
Graphical Objects 6-10
Planning Module Controls and Functionality 6-11
Control Modes 6-11
Controlling the Camera 6-14
Planning Phases 6-18
Required CT Parameters 6-19

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Phase 1 - Loading a patient's study in DICOM format 6-21
Phase 2 - Marking the Registration Points 6-36
Phase 3.1 - Marking the Target Locations and Dimensions 6-42
Phase 3.2 - Pathway construction to Target 6-45
Phase 4 - Saving the Planning File and Exiting 6-51
Phase 5 - Exporting the Planning File 6-54

Chapter 7: Procedure Module 7-1

Module Overview and Workflow 7-1
Procedure Phases 7-2
Phase 1 - Procedure Module Setup 7-2
Phase 2 - "CT-to-Body" Registration 7-10
Phase 3 - Navigation 7-18
Phase 4 - Arriving at the Target's Location 7-18
Phase 5 - Ending the Current Procedure 7-20
Navigating to the Target 7-22
Navigation Screen Layout 7-22
Navigating to the Target using Waypoints 7-28
Screen Layout Options 7-29
Error Message Signal 7-31
Viewports 7-36
The Crosshairs and Average Mode 7-41
View Modes 7-43
Window/Level 7-43
Graphical Objects 7-43
Measuring Distances 7-47
Show or Hide Names 7-48
Show/Hide Waypoints 7-48

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Graphic Control 7-49
Patient Sensors View 7-55
Printing a Screen to File 7-56
Shut-Down Process 7-57
Procedure Backup 7-60
Data Recovery Procedure 7-62
Using the Locatable Guide and Extended Working Channel 7-63
Assembly 7-63
Inserting the Locatable Guide into a Bronchoscope 7-65
Holding Methods for the Locatable Guide and Bronchoscope 7-70
Controlling the Locatable Guide's Tip 7-71
Operating the Locatable Guide 7-72
Operating the Locatable Guide During Navigation 7-73
Marking the Endoscopic Tool Length 7-74
Inserting a Endoscopic Tool into the EWC 7-75
Marker placement in soft lung tissue 7-76
Using the CT and Video Guided Navigation together with the Locatable Guide 7-78
Using the Remote Control 7-79
Button Controls for the Registration Phase 7-80
Button Controls for the Navigation Phase 7-80
Using the Foot Switch 7-82
Procedure Module Settings 7-82
Display 7-84
Video 7-85
Locatable Guide 7-85
Input Devices 7-86
Editing Point Settings 7-90

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Log and Status Views 7-92
Status View 7-92
Log View 7-94

Chapter 8: Cleaning 8-1

Cleaning Components Located on the Cart 8-1

Chapter 9: Troubleshooting 9-1

Error Handling 9-1
Planning Module Error Messages 9-1
Procedure Module Error Messages 9-7
General Troubleshooting 9-17
Locatable Guide, EWC, Bronchoscope Adapter, Bronchoscope Clip and PC Troubleshooting 9-17

Chapter 10: Quick Reference 10-1

Planning Module 10-1
DICOM File Selection Menu Bar Options 10-1
DICOM System Toolbar Buttons 10-1
Planning Menu Bar Options 10-2
Planning Toolbar Buttons 10-5
3D Camera Control Buttons 10-9
Planning Module keyboard Shortcuts 10-10
Procedure Module 10-11
Navigation Menu Bar Options 10-11
Navigation Toolbar Buttons 10-14
Procedure Module keyboard Shortcuts 10-17

Chapter 11: Ordering Accessories 11-1

Chapter 12: Customer Service 12-1

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 13: Glossary 13-1

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 1: About this Manual

This User Manual provides a description of the features of superDimension®/inReach™ and describes its operating procedures.

This section contains important information that must be read before proceeding to any of the other chapters within this User Manual.



Warning

The superDimension inReach™ System may only be used by a qualified bronchoscopist (referred to in this manual as the 'physician'), who has read the operating instructions of this User Manual and has successfully completed the required training course on how to use the system.

Read and understand the entire manual before using the system.

Document Conventions

The following conventions are used throughout the manual:

Procedures that must be followed sequentially are shown as numbered steps, or bulleted single steps. You must complete the steps in the sequence in which they are presented in order to ensure a reliable result.

Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.

Only information that you require at each stage in the process is presented, in an effort not to interrupt the general workflow. Descriptions of all other menu options and toolbar buttons that are featured throughout the application can be found on page 10-1.

Menu items are indicated in the following format: Menu name>Menu item. For example, File>Save Planning File would indicate choosing Save Planning File from the File menu.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This text style...	Identifies...	Example
Text	Normal descriptive text.	
Text	Emphasized text or a reference to another section in the document.	
`Text/`**`Text`**	Words or figures that appear on the screen or that should be typed, or a key to be pressed. < > The name of a file or directory.	`C:/<file name>`
TEXT	The name of a physical component.	LOCATABLE GUIDE
Text	A component of a screen or a name of an application component	...and click Enter.
■	A bulleted list.	■ xxx ■ xxxx
➢ **To....:**	The title of a procedure.	➢ **To save:**
1. 2.	A numbered procedure.	3. From the drop-down menu, select **xxx**.
!	A single-step procedure.	! Right-click the required option.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

49

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Symbols

A number of symbols are used throughout this manual in order to draw attention to safety issues and other important information.

The following symbols are used:

	**Warning** Indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the patient, equipment, user, or surrounding staff.
	**Caution** Indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories
	**Notes** This symbol informs you of important general information for using the system efficiently.
	**Tip** This symbol gives you important tips on using the system.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

49

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

50

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 2: Introduction

Indications for Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Patient Indications

The superDimension inReach™ System is indicated in patients when it is necessary to guide an endoscopic tool in the pulmonary tract when the indications for such an examination are present in the patient.

Bronchoscopy Planning/CT-Viewing

The inReach™ Planning Laptop can be used stand-alone for bronchoscopy planning or CT-Viewing or with the other system components. If the Planning Laptop is used stand-alone disregard the information related to the inReach™ System procedure module.



Warning

The superDimension inReach™ System may only be used by a qualified bronchoscopist (referred to in this manual as the 'physician'), who has read the operating instructions of this User Manual and has successfully completed the required training course on how to use the system.



Caution

Federal (US) law restricts this device to sale by or on the order of a physician.

S1

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Contraindications

Flexible bronchoscopy should be performed only when the relative benefits outweigh the risks.

Absolute contraindications include but are not limited to:

- Absence of consent from the patient or his/her representative unless a medical emergency exists and patient is not competent to give permission.
- Absence of an experienced bronchoscopist to perform or closely and directly supervise the procedure.
- Lack of adequate facilities and personnel to care for such emergencies as cardiopulmonary arrest, pneumothorax, or bleeding.
- Inability to adequately oxygenate the patient during the procedure.
- Pediatric patients
- The safety of use of the superDimension inReach™ in patients with electrically or magnetically activated implanted medical devices has not been evaluated.

The danger of a serious complication from bronchoscopy is especially high in patients with the disorders listed below, and these conditions are usually considered absolute contraindications unless the risk-benefit assessment warrants the procedure:

- Coagulopathy or bleeding diathesis that cannot be corrected.
- Severe obstructive airways disease.
- Severe refractory hypoxemia.
- Unstable hemodynamic status including dysrhythmias.

Relative contraindications (or conditions involving increased risk), according to the American Thoracic Society Guidelines for Fiber-optic Bronchoscopy in adults, include:

- Lack of patient cooperation.
- Recent myocardial infarction or unstable angina.
- Partial tracheal obstruction.
- Moderate-to-severe hypoxemia or any degree of hypercarbia.
- Uremia and pulmonary hypertension (possible serious hemorrhage after biopsy).

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

52

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

- Lung abscess (danger of flooding the airway with purulent material).
- Obstruction of the superior vena cava (possibility of bleeding and laryngeal edema).
- Debility, advanced age, and malnutrition.
- Respiratory failure requiring mechanical ventilation.
- Disorders requiring laser therapy, biopsy of lesions obstructing large airways, or multiple transbronchial lung biopsies.
- Known or suspected pregnancy, because of radiation exposure.

The safety of bronchoscopic procedures in asthmatic patients is a concern, but the presence of asthma in most cases does not preclude the use of these procedures.

Safety

The following section contains a complete list of warning and cautions relevant to the superDimension inReach™ System. These warning and cautions are repeated in other appropriate sections of this manual. Read and understand all warnings and cautions prior to operation of the superDimension inReach™ System.

In some cases the wording of the warnings and cautions in this overview section has been modified slightly to ensure its correct interpretation out of the context of the specific instructions contained in each section of the manual.

Warnings



- The superDimension inReach™ System may only be used by a qualified bronchoscopist (referred to in this manual as the 'physician'), who has read the operating instructions of this User Manual and has successfully completed the required training course on how to use the system. Read and understand the entire manual before using the system.
- Prior to applying any resuscitation equipment to the patient, switch off the main power switch of the superDimension inReach™ System and remove the PATIENT SENSORS and the LOCATABLE GUIDE away from the patient's body.
- To avoid potential of electrical shock, do not use the Remote Planning Station inside the patient environment as specified in EN60601-1-1.
- To avoid potential patient or user injury, endoscopic

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

53

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	equipment and endoscopic accessories (tools) used in conjunction with superDimension inReach™ System shall comply with the requirements of standard IEC 60601-2-18, IEC/EN 60601-1, IEC/EN 60601-1-2 or their equivalent, and shall be used only according to their respective User Manuals. ▪ Use of bronchoscopes that are not compatible with the superDimension inReach™ System may lead to inaccuracy of the system. ▪ To avoid potential patient or user injury, fluoroscopes used in conjunction with superDimension inReach™ System shall comply with the requirements of standards IEC/EN 60601-1, IEC/EN 60601-1-2 and IEC/EN 60601-1-3 or their equivalent. ▪ To avoid potential patient or user injury, an endoscopic video camera used in conjunction with superDimension inReach™ System must comply with the requirements of standard IEC/EN 60601-1 and IEC/EN 60601-1-2 or their equivalent. The final configuration must meet the requirements for safety of medical systems prescribed by standard IEC/EN 60601-1-1 or equivalent. ▪ Risk of explosion if used in the presence of flammable anesthetics, or flammable gases or liquids. ▪ Connect the system to an earthed (grounded) electrical outlet only. If connected to an incorrectly grounded outlet, electrical shock could result. For connection, use only the medical grade mains plug with protective earth (ground) terminal according to your National Electrical cord. If a medical grade mains plug is not used, electrical shock could result. Inspect the system power cord and plug on a regular basis. To avoid risk of electrical shock, replace them if they are damaged in any way. ▪ Do not remove the system component's covers. There are no serviceable parts inside the system. Refer installation and service only to an authorized superDimension Ltd. customer service representative. Tampering with the components inside the system can result in equipment failure and patient / user injury. ▪ The superDimension inReach™ System should not be used adjacent to equipment other than that which is required by the procedure. If adjacent use is necessary, the superDimension inReach™ System should be observed to verify normal operation in the configuration in which it will be used. ▪ To avoid electrical shock and/or system failure, do not pinch, crimp, or otherwise stress cables and connectors. To avoid electrical shock and/or system failure, use only the cabling that was supplied with the system.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

54

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	▪ To avoid electrical shock and system damage, do not spill liquids on the system, except for the LOCATION BOARD, LOCATABLE GUIDE, LOCATABLE GUIDE CABLE, PATIENT SENSOR, and FOOT SWITCH which are designed to be fluid resistant. ▪ To avoid potential patient or user injury, external video equipment used in conjunction with superDimension inReach™ System shall comply with the requirements of standard IEC/EN 60601-1 or IEC/EN 60950 or IEC/EN 60065 or equivalent. The final configuration must meet the requirements for safety of medical systems prescribed by IEC/EN 60601-1-1 or equivalent. ▪ Significant changes to the configuration of the bronchoscopy suite, including introduction of new metallic equipment or movement of existing metallic equipment can affect the accuracy of the system. Contact superDimension customer service to schedule a recalibration of the instrument prior to making bronchoscopy suite reconfigurations. ▪ Excessive patient movement during use of the inReach™ System can affect the accuracy of the system, potentially resulting in tissue irritation and possible injury to the bronchial airways. The patient must be kept in a supine position. ▪ CT-to-Body divergence values in excess of 10mm can affect the accuracy of the system potentially resulting in tissue irritation and possible injury to the bronchial airways. ▪ To maintain accurate CT-to-Body registration during the procedure, it is recommend to retain the bronchial tree in its natural shape during the procedure, as it appears in the pre-operative CT images. It is therefore recommended, during navigation of the LOCATABLE GUIDE towards the target, to position the distal tip of the bronchoscope so that it does not apply any pressure to the endobronchial walls. ▪ To avoid potential for infection, before opening any sterile packages containing system accessories, check that the packaging is intact, sealed, and is free from damage that could compromise the sterile barrier. ▪ When handling the EXTENDED WORKING CHANNEL and the LOCATABLE GUIDE, be sure not to bend, twist, drop, or otherwise roughly handle these accessories as damage can result. Damage to the system accessories can cause tissue irritation and possible injury to the bronchial airways. ▪ Never operate the LOCATABLE GUIDE without the EWC attached. Before each use, check the outer surfaces of the LOCATABLE GUIDE and EWC, which are intended for insertion into a patient, to ensure there are no rough surfaces, sharp edges or protrusions. Sharp edges on

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
55

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	these accessories can cause bleeding and/or pneumothorax. When handling the EWC and the LOCATABLE GUIDE, be sure not to bend, twist, drop, or otherwise roughly handle these accessories as damage can result. Damage to the system accessories can cause tissue irritation and possible injury to the bronchial airways. ▪ To avoid damage to the EWC, potentially resulting in tissue irritation and possible injury to the bronchial airways, never use excessive force (1 Kg force (10N)) during the insertion or extraction of the Locatable Guide or endoscopic tools through the EWC. In case of difficulties during the insertion or extraction of the LOCATABLE GUIDE, endoscopic tools or marker delivery tools through the EWC, first straighten the bronchoscope distal tip, then un-lock the LOCATABLE GUIDE and gently pull out the LOCATABLE GUIDE, endoscopic tool or marker delivery tools together with the EWC. In case that is not possible, then pull the entire bronchoscope out together with whatever is inserted through its working channel. Afterwards, replace EWC and/or LOCATABLE GUIDE and/or endoscopic tool and/or marker delivery tool if damaged. Reinsert and navigate back towards the target area as needed. ▪ To avoid potential injury to the bronchial airways always use the chosen compatible tool as specified in the User Manual supplied with the tool. For a list of Compatible Endoscopic Tool see page 3-18. ▪ To avoid electrical shock, always disconnect the system from the wall outlet prior to cleaning the system and replacing fuses. To avoid health hazards, comply with the detergent manufacturer's instructions. ▪ To avoid electrical shock and system damage, replace fuses only with fuses that have the same ratings for blow characteristics, current, and voltage as the fuses supplied with the device. ▪ Inspect the system power cord and plug on a regular basis. To avoid risk of electrical shock, replace them if they are damaged in any way. ▪ The Locatable Guide, Extended Working Channel, Bronchoscope Clip and Bronchoscope Adapter are all intended for single use only. To avoid potential for infection or cross contamination, do not reuse these accessories. ▪ To avoid potential tissue irritation and possible injury to the bronchial airways, always use the Locatable Guide in conjunction with the Extended Working Channel. ▪ To avoid potential accuracy problems, repeating visual registration verification is required after the LG is retrieved and reinserted to commence a new navigation, as well as after any replacement of the LG. The procedures may also

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

56

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

be performed, at the physician's discretion, should the accuracy of the system be in doubt at any point in the course of the bronchoscopic procedure.

- Use of bronchoscopic tools that do not comply with the specifications contained in this manual have the potential to cause damage to the EWC.
- To avoid potential injury to the lungs pleura, exercise caution when deploying markers near pleura target sites.
- The 3D-MAP is a geometric rendering of the bronchial airways. It is not an anatomical representation of the airways and should be used for general reference only.

Cautions



- Federal (USA) law restricts this device for sale by or on the order of a physician.
- There is no guarantee that bronchoscopes selected solely using the minimum specification stated in this user manual will be compatible with the superDimension inReach™ System .
- Use of bronchoscopic tools that do not comply with the specifications in this user manual have the potential to cause damage to the EWC.
- When a fluoroscope is available, make sure to position the nearest part of the fluoroscope at least 75 cm from the LOCATION BOARD unless determined differently by the superDimension technician during system installation.
- There is no guarantee that instruments selected solely using the minimum instrument channel width stated in the user manual will be compatible in combination.
- The superDimension inReach™ System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Manual. Portable and mobile RF communications equipment, such as mobile telephones and walkie-talkies, can affect the superDimension inReach™ System . Do not operate mobile phones in the vicinity of the system.
- The use of accessories and cables other than specified may result in increased EMISSIONS or decreased IMMUNITY of the superDimension inReach™ System .
- The superDimension inReach™ System should not be used adjacent to equipment other than that which is

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

57

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	required by the procedure. If adjacent use is necessary, the superDimension inReach™ System should be observed to verify normal operation in the configuration in which it will be used. ▪ Do not unpack any sealed boxes or packages. An authorized customer service representative must do all unpacking. ▪ An authorized customer service representative must perform the initial installation of the system and components. ▪ There are certain minimum distances between various components that must be maintained throughout the operation of the system in order to enable the proper functioning of the system. Specifically: The minimum distance between the SYSTEM CART and the LOCATION BOARD is 50 cm. The minimum distance between LOCATABLE GUIDE's handle and the LOCATION BOARD is 40 cm. ▪ Do not place any ferromagnetic material within the space above or below the Location Board.When a fluoroscope is available make sure to position the nearest part of the fluoroscope at least 75 cm. from the Location Board unless determined differently by the SuperDimension technician during system installation. ▪ Installing any other software on the superDimension inReach™ System will damage the system. No other software should be installed on the superDimension inReach™ System . ▪ To prevent damage to the inReach™ System , do not cover the ventilation openings in the LOCATION AMPLIFIER, LOCATION PROCESSOR, or the PC. ▪ Connecting components while the system is running is generally not allowed. Such "hot swaps" are only allowed for the following components: LOCATABLE GUIDE PATIENT SENSORS LOCATION AMPLIFIER connection to the LOCATION PROCESSOR. LOCATION BOARD and power connection of the LOCATION AMPLIFIER. Such hot swaps should be limited to the minimum. Do not connect or disconnect the LOCATION PROCESSOR power connector while the Power Supply is turned on. Do not connect or disconnect the LOCATION AMPLIFIER from the LOCATION PROCESSOR while the

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Power Supply is turned on.

- The AUXILIARY SENSOR port on the SENSORS' CONNECTIONS panel as well as the ANALOG input and EXTERNAL ports on the SERVICE CONNECTIONS panel are for future implementation. Do not use them.
- Do not connect or disconnect the LOCATION PROCESSOR power connector while the power supply is turned on. Do not connect or disconnect the LOCATION AMPLIFIER from the LOCATION PROCESSOR while the power supply is turned on.
- Before switching any ECG units included in the original installation configuration you must contact a superDimension representative to verify compatibility of the new ECG with the superDimension/ inReach™ System .
- Before initializing the system, make sure all system components ("*Setting Up System Components*," on page 5-3) are in place and have been cleaned as required. ("Cleaning" on page8-1).
- Always ensure to route the system cables away from possible tripping and stepping situations. Avoid excessive bending or twisting of any/all system cables.
- There are certain details that must be verified before the daily setup in order to assure location accuracy.

  Specifically:

  The LOCATION BOARD's pads must be kept bonded onto the table at their original setup location.

  The LOCATION BOARD must be located correctly on the LOCATION BOARD pads so that it is parallel to the table, see Figure 5-5. Each of the four pads must be located within a corresponding groove on the underside of the LOCATION BOARD.

  The table arrangement (e.g. table-top position with respect to its support leg, protection rail position) must be identical to its arrangement during system setup. The procedure room should be arranged according to the Procedure Room Configuration form provided by the superDimension technician following the installation of the system and as appears in the Procedure Room Configuration page see Phase 1 – Procedure Module Setup on page 7-2.
- The superDimension inReach™ System supports only CT and/or PET/CT scans made in a supine patient position. Using a different patient position will result in a wrong display of the CT cross-sections in the application viewports.
- For accurate CT-to-Body registration, it is advised to retain the bronchial tree in its natural shape as it appears in the pre-operative CT images. It is therefore recommended that

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

you mark registration points in such anatomical locations to which access by the LOCATABLE GUIDE does not require forceful maneuvering which may temporarily affect the shape of the bronchial tree.

- There are certain details that must be verified before the setup in order to assure accuracy of location.

  Specifically:

  The LOCATION BOARD PADS must be kept bonded on the table at their original setup location.

  The LOCATION BOARD must be located correctly on the LOCATION BOARD pads. See Figure Figure 5-5.

  The table arrangement (for example, table-top position with respect to its support leg) must be identical to its arrangement during system setup.
- In rare cases, sensitive individuals may have a mild transient skin rash after the use of the Patient Patches.
- The patient should be immobile for five seconds from the time that the Finish button is clicked.
- To minimize error during the registration process Instruct the patient to hold his/her breath as long as possible during each Registration Point acquisition.
- Fluoroscopy, performed on at least two perpendicular angles or other external position verification technique should be used to verify the location of the Locatable Guide at the target.
- Any movement of the bronchoscope while the LG is being removed and the EWC is locked in place will affect the position of the EWC, which may cause it to move off target. If the Bronchoscope was unintentionally moved, insert the LG and re-navigate to the Target.
- Navigation of the bronchoscope and Locatable Guide through the airways should not rely solely on data from the viewports. Rather, the viewport data should be used to augment the traditional bronchoscopic navigation through the airways.
- Using the Average by Time mode, the Averaging Time being used is recommended to be equal to the duration of a normal respiratory cycle. In such case, there is a higher accuracy in the displayed location of the crosshairs relative to the CT images in faster-than-normal and normal respiration. However, there may be a lower accuracy in case of slower-than-normal respiration.
- The superDimension inReach™ System is not a diagnostic device. The accuracy of the distance measurement function is dependent on many factors including registration, patient movement, and breathing and therefore should be used for purposes of general reference only.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

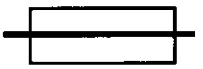
	▪ Check that the tip of the LOCATABLE GUIDE protrudes 5mm (± 3mm) from the end of the EWC. Perform the connection procedure described on page 7-65 only when the LG is in a straight position. If the tip does not protrude or protrudes further than shown in the figure below, refer to Troubleshooting on page 9-1. ▪ If the LOCATABLE GUIDE does not move smoothly through the working channel, there could be an obstruction. Check that the working channel is free of any obstruction and that the LOCATABLE GUIDE is free of any debris. If problem persists, refer to Locatable Guide, EWC, Bronchoscope Adapter, Bronchoscope Clip and PC Troubleshooting on page 9-17. ▪ The tool length marking process must be performed on all tools that will be used during the procedure and should be performed during procedure preparation. ▪ Any tool, from the approved tool list, intended for insertion into the EWC, must undergo the tool length marking process beforehand. Refer to Marking the Endoscopic Tool Lengthon page 7-74. ▪ To avoid the possibility of static shock and damage to the system, do not use aerosol spray cleaners on the monitor. Do not clean the system with chlorinated or aromatic solvents, acidic or basic solutions, isopropyl alcohol, or strong cleaners such as ammoniated products, as these may damage the surface of the system. Use the cleaning procedure recommended on page 8-1. Do not use spray cleaners on the system as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components. ▪ To safely extract the Removable Disk (USB) wait until the LED on the USB stops blinking. Removal of the USB while the LED is blinking may lead to data loss or damage to the Planning file. It is recommended to use only the Removable Disk (USB) that is supplied with the superDimension inReach™ System.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

61

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

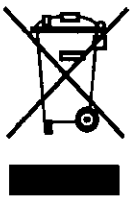
Symbols on Equipment and Labeling

Equipment Label	Description
I / O	Power switch ON/OFF
	Consult instructions for use
	Degree of protection against electric shock – Applied Part Type BF
	External Accessible Fuses
LOT	Lot Number
SN	Serial Number
STERILE | LOT	Sterilization Lot Number
STERILE | EO	Ethylene Oxide Sterilization
REF	Catalog Number/Product Code
EC | REP	Authorized representative in the European Community
	Single use only
	Store in a dry place at room temperature
	Use by date
	Do not use if package opened or damaged
	Date of Manufacture
	Manufacturer

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

62

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	For environmentally safe disposal and recycling (with the exception of all potentially infected products) please contact: superDimension (Europe) GmbH Grossenbaumer Weg 10 D-40472 Düsseldorf Germany Telephone: +44 - (0)211 - 436156-0 Fax: +44 - (0)211 - 436156-29
CE 0473	This device complies with applicable requirements of the Council Directive 93/42/EEC

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 3: System Description

Introduction to superDimension/inReach™

System Overview

The superDimension inReach™ System is an image-guided localization system used to guide Endoscopic tools to predetermined Target(s) within the pulmonary tract. Such Targets are first determined on a routine CT scan of the lungs and the tools are then guided to these points. Thus, Targets well into the pulmonary tract can be accessed.

The superDimension inReach™ System can also use scans originating from a combined PET/CT scanner for the purpose of marking Targets.

The inReach™ Planning Laptop can be used stand-alone for bronchoscopy planning or CT-Viewing or with the other system components. If the Planning Laptop is used stand-alone disregard the information related to the inReach™ System procedure module.

The superDimension inReach™ System consists of the LOCATABLE GUIDE (LG) that contains a position sensor in its distal tip, the EXTENDED WORKING CHANNEL (EWC), the localization components, and the PC-based image processing workstation. The EXTENDED WORKING CHANNEL is a sheath that is inserted through the working channel of a bronchoscope. The LOCATABLE Guide is a flexible guide fitted with an electromagnetic position and orientation sensor at the distal tip, which is inserted through the EXTENDED WORKING CHANNEL.

In many cases, the Target (for example, a lesion) is situated *inside* the tracheobronchial tree. In such cases, the LOCATABLE GUIDE and the EXTENDED WORKING CHANNEL are guided all the way to the Target. In other cases, the Target (for example, a lesion or a lymph node) may be situated *adjacent* to the tracheobronchial tree. In such cases, the LOCATABLE GUIDE and the EXTENDED WORKING CHANNEL are guided to the point that is still inside the tracheobronchial tree that is closest to the Target. Therefore, regardless of whether the Target is inside the tracheobronchial tree or adjacent to it, the LOCATABLE GUIDE and the EXTENDED WORKING CHANNEL always remain inside the tracheobronchial tree and are guided to a point that is still inside the tree.

Prior to the procedure, the CT or PET/CT scan is imported into the system and the Targets are marked.

The system's three-dimensional CT reconstruction capabilities allow the physician to perform a "virtual bronchoscopy" and to

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
65

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

mark one or multiple Targets as well as Registration Points. The Registration Points, readily identifiable "landmarks", will be used during the Procedure phase to relate the CT scan and the actual anatomy.

On CT scans with specified parameters, an optional Pathway to the Target can be constructed using a geometric rendering of the bronchial tree. The 3D-Map presents a three-dimensional virtual representation of the bronchial tree where distinct intermediate points to the Target are marked.

At the beginning of the bronchoscopic procedure, the correlation of the CT or PET/CT scan with the patient's actual anatomy and current position (also known as the Registration) is accomplished.

During the procedure, the position and orientation of the tip of the LOCATABLE GUIDE are tracked by the localization components of the system. These coordinates are transmitted to an image data processor (a Personal Computer). The image data processor makes the necessary calculations to depict continuously the current position of the tip of the LOCATABLE GUIDE and the planned target location, overlaid on the CT images of the patient's anatomy in different cross-sections (e.g., coronal, axial and sagittal). This graphic overlay is used for real-time guidance during the bronchoscopic procedure.

There are two navigation modes, one in which only CT images are being used ("CT Guided") and another where both the CT images and the video images from the bronchoscope are being used ("CT and Video Guided"). An example for using the CT Guided mode for navigating in the pulmonary tract is for approaching peripheral lesions. An example for using the CT and Video Guided mode for navigating in the pulmonary tract is for approaching lymph nodes.

Upon arriving to the Target with the LOCATABLE GUIDE, the LOCATABLE GUIDE is retracted from the EXTENDED WORKING CHANNEL and a standard endoscopic instrument can be introduced, via the lumen of the EXTENDED WORKING CHANNEL, for the purpose of biopsy or other procedures.

PATIENT SENSORS, attached to the patient, are also tracked by the SYSTEM so that changes during the procedure in the position and orientation of the patient are compensated for.

Software Modules

The superDimension inReach™ System is comprised of two software modules, which are accessed via the system's Opening Screen:

- The Planning module – allows the physician to plan the bronchoscopy procedure ahead of time, mark the Target(s) and generates the planning file. A separate laptop computer is

66

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

supplied for this purpose. However, if desired, the computer for the procedures can also be used.

- The Procedure module – the marked Targets are obtained from the planning file after the registration of the planning data to the patient's actual position. The physician can then navigate the LOCATABLE GUIDE to the Target and perform the procedure. The actual procedure is under the control of the supplied Personal Computer. Only the supplied computer should be used for this purpose.

Procedure Overview

Planning Module

In order to navigate with the superDimension inReach™ System , the system must be able to correlate the pre-operative CT images of the patient with the anatomy of patient's body (Registration) so that the physician can locate the position and orientation of the LOCATABLE GUIDE (which has a sensor incorporated in its distal tip), in real-time.

Before the Procedure, CT or PET/CT data from the patient's CT or PET/CT examination, stored on a CD or DICOM system, is inserted into the system. Such CT or PET/CT data is imported into the superDimension software in the standard DICOM format. The CT or PET/CT data is reconstructed and then reviewed, in the superDimension software, in axial, coronal and sagittal views.

Using the system's three-dimensional CT reconstruction capabilities in the pre-operative Planning Module, the physician can perform a virtual bronchoscopy and mark Targets as well as Registration Points. The Registration Points, readily identifiable "landmarks"', will be used during the Procedure phase to relate the CT scan and the patient's actual anatomy. For each of these landmarks, a small 3D 'virtual bronchoscopy' segment is constructed from the 3D CT slices, with the landmark subsequently marked on it for further precision.

On CT scans with specified parameters, a 3D-Map of the airways can be used to construct a pathway to the Target(s).

Typically, those Registration Points are major bifurcations in the bronchial tree such as the Main Carina, Left Upper Lobe (LUL) junction, Right Upper Lobe (RUL) junction, Left Lower Lobe (LLL) junction, and Right Lower Lobe (RLL). Also, one or more targets, for example, Space Occupying Lesions (SOL), are marked.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Module

The physician begins by entering the lungs with the bronchoscope and reaching the same Registration Points as marked in the Planning module. General orientation is thus attained, just as in a typical non-guided bronchoscopy procedure.

In a superDimension procedure, The LOCATABLE GUIDE is inserted through the lumen of EXTENDED WORKING CHANNEL, with the two of them inserted through the bronchoscope's WORKING CHANNEL. When the physician touches, with the LOCATABLE GUIDE's tip, the same Registration Points that were previously marked on the CT data, their current coordinates in the 'superDimension world' are recorded. The system now correlates (also known as registers), using its algorithms, the pre-operative CT data with the patient's current position. As a result, the Target(s) is/are now displayed on the superDimension screen at their current locations.

Multiple Targets in a single procedure are also possible.

As mentioned previously, the Procedure module supports two navigation modes. The first mode is the "CT Guided" navigation mode in which only CT images are being used. The second mode is the "CT and Video Guided" in which both CT images and bronchoscope video image capture are being used.

CT-Guided Navigation:

An image of the tip of the LOCATABLE GUIDE (which incorporates a location sensor) is overlaid graphically on the CT images. That allows the physician to navigate and steer the LOCATABLE GUIDE to the designated Target.

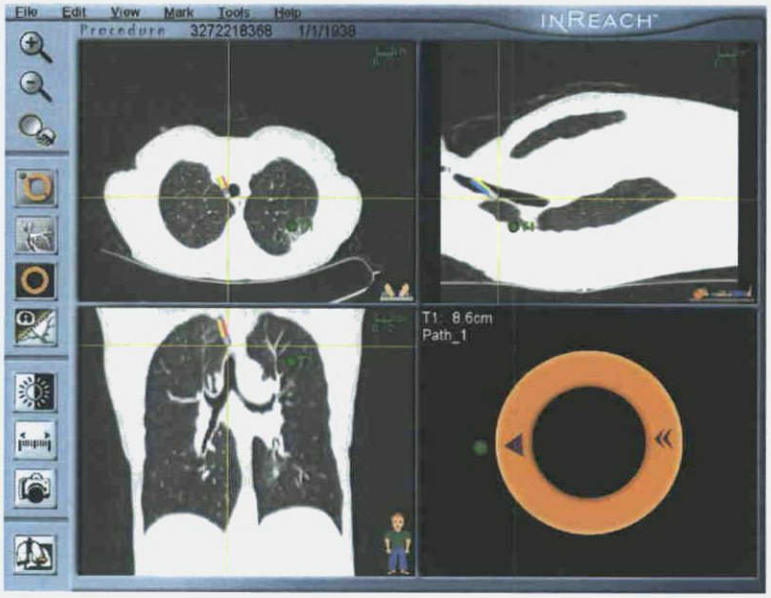


Figure 3-1: CT Guided Navigation *(updated)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Once the LOCATABLE GUIDE has reached the Target, an enveloping sheath called the EXTENDED WORKING CHANNEL (EWC) is locked in place while the LOCATABLE GUIDE itself is retracted, leaving a clear pathway to the designated Target area.

Standard endoscopic instrument can now be introduced, via the lumen of the EXTENDED WORKING CHANNEL, for the purpose of biopsy or other procedures.

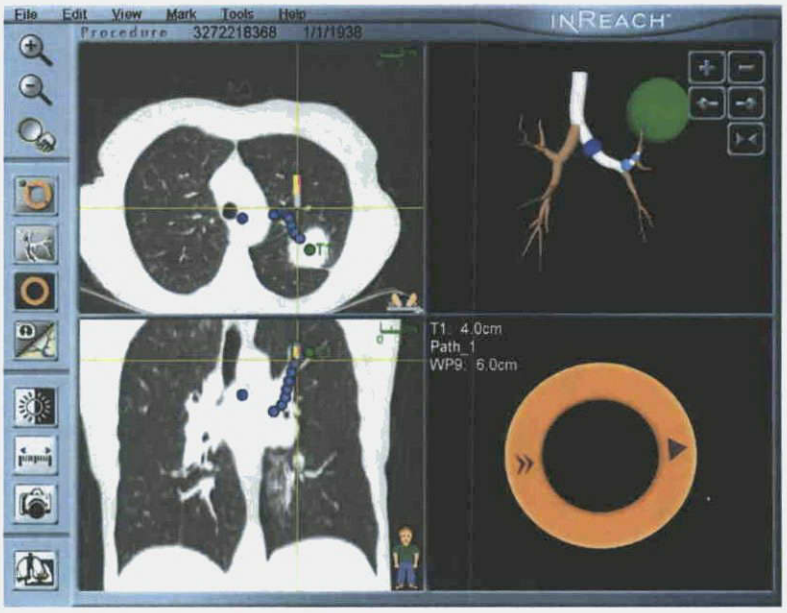


Figure 3-2: CT Guided Navigation with 3D-Map viewport *(new)*

69

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

CT and Video Guided Navigation:

An image of the tip of the LOCATABLE GUIDE (which incorporates a location sensor) is overlaid graphically on the CT images

In addition, a live video image from the Bronchoscope and a 'virtual bronchoscopy' image of the Target are displayed. Together, those allow the physician to navigate and steer the bronchoscope together with the LOCATABLE GUIDE towards the designated Target.

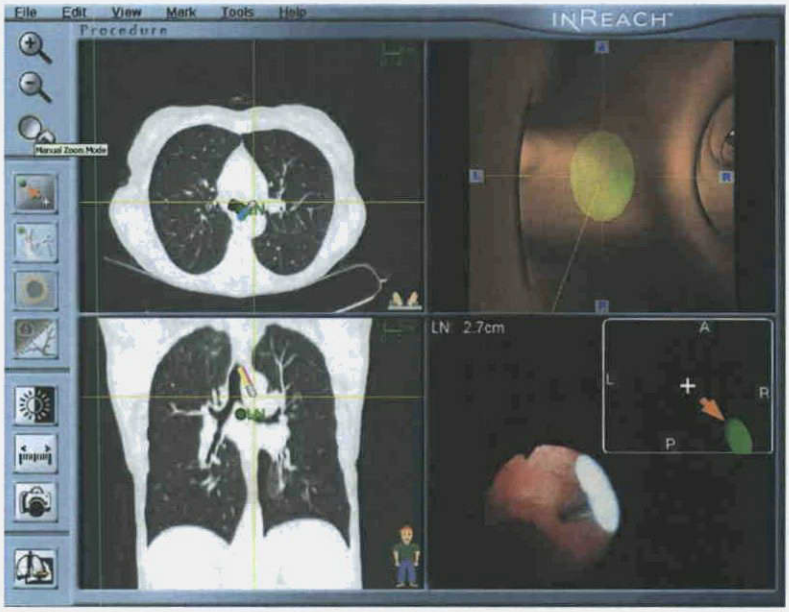


Figure 3-3: CT and Video Guided Navigation *(updated)*

Once the bronchoscope together with the LOCATABLE GUIDE is positioned towards the Target, the user is able to freeze the live video images showing the positioning of the tip of the LOCATABLE GUIDE.

The LOCATABLE GUIDE is then retracted. An endoscopic instrument is inserted. The user positions the endoscopic instrument by comparing the above-mentioned freeze images to the live video images, for the purpose of biopsy or other procedures.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

System Components

Localization System

The Localization system includes the following items:

- PC, with power supply, isolation transformer, touch-screen monitor, keyboard, and mouse (on cart)
- Localization components comprising:
  - LOCATION PROCESSOR (on cart)
  - LOCATION AMPLIFIER (on cart)
  - LOCATION BOARD
- PATIENT SENSOR TRIPLET
- FOOT SWITCH
- INFRARED RECEIVER
- REMOTE CONTROL



Warning

The superDimension inReach™ System may only be used by a qualified bronchoscopist (referred to in this manual as the 'physician'), who has read the operating instructions of this User Manual and has successfully completed the required training course on how to use the system.

Read and understand the entire manual before using the system.

71

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

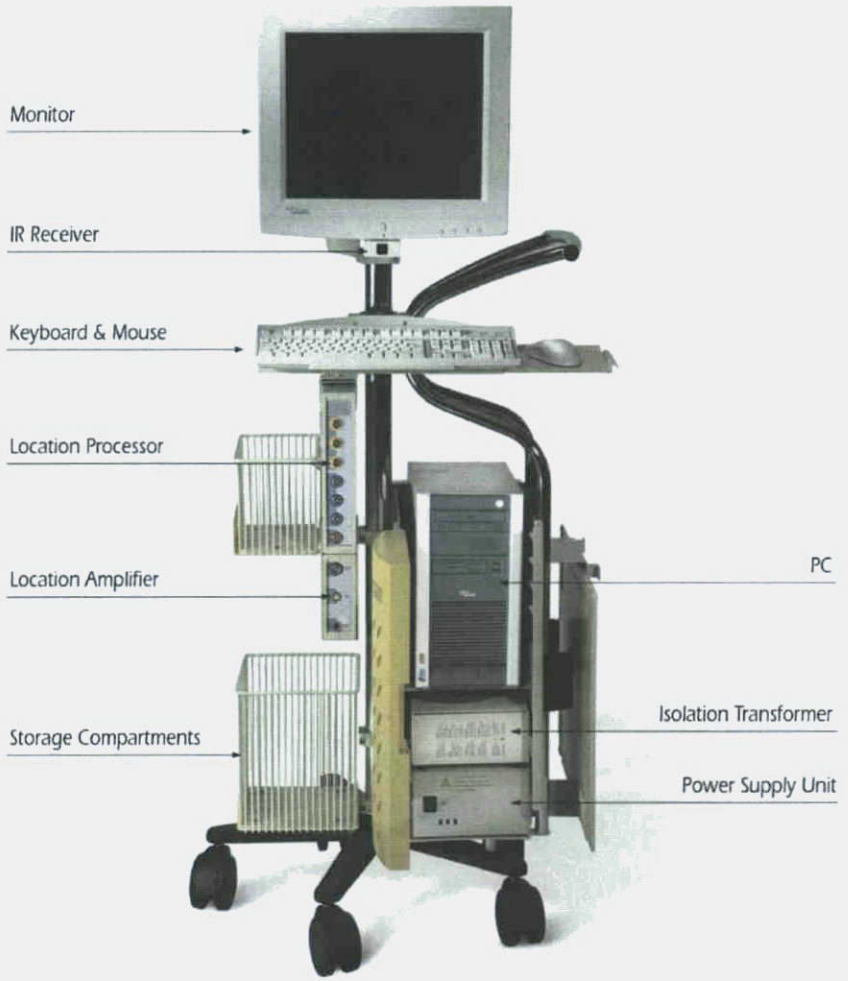


Figure 3-4: The superDimension inReach™ System Cart

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Remote Planning Station

The Remote Planning Station is intended to enable the physician to perform the planning phase in places outside the endoscopy room setting.

The remote planning station includes the following items:

- Dedicated Laptop PC
- Removable Disk



Warning

To avoid potential of electrical shock, do not use the Remote Planning Station inside the patient environment as specified in EN60601-1-1.

73

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Sensing Volume

The Locatable Guide's Sensing Volume

The LOCATABLE GUIDE's Sensing Volume is a volume above the LOCATION BOARD in which the LG will perform properly. When the LG is positioned outside this volume, an on-screen alert appears, the LG's accuracy is not guaranteed and the system will disable the navigation functions. The working volume for the LG starts at 50mm from the LOCATION BOARD surface and extends up to 280mm. (See Figure 3-5.)

The Patient Sensor's Sensing Volume

The PATIENT SENSOR's Sensing Volume is a volume above the LOCATION BOARD in which the PATIENT SENSORS will perform properly. When one or more of the PATIENT SENSORS are outside this volume, an on-screen alert appears, and the PATIENT SENSOR accuracy is not guaranteed. In such a case, Patient Setup cannot be completed and the system will disable the navigation functions. The working volume for the patient sensors starts at 50mm from the LOCATION BOARD's surface and extends up to 380mm. (See Figure 3-5.)

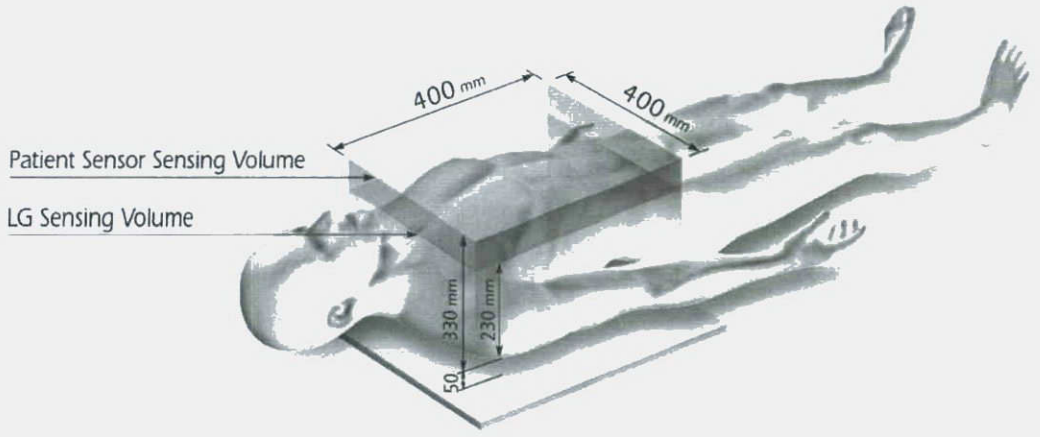


Figure 3-5: Sensing Volume above the Location Board

74

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Locatable Guide

The LOCATABLE GUIDE (LG) is a flexible guide fitted with a position and orientation sensor at the distal tip. The sensor picks up the magnetic field generated by the Localization system. The dial of the LG allows for deflection of the distal tip. It also allows for selecting the direction of deflection. A Luer-type connector is provided for connection to the EWC.

The LG is supplied sterile and intended for single use.

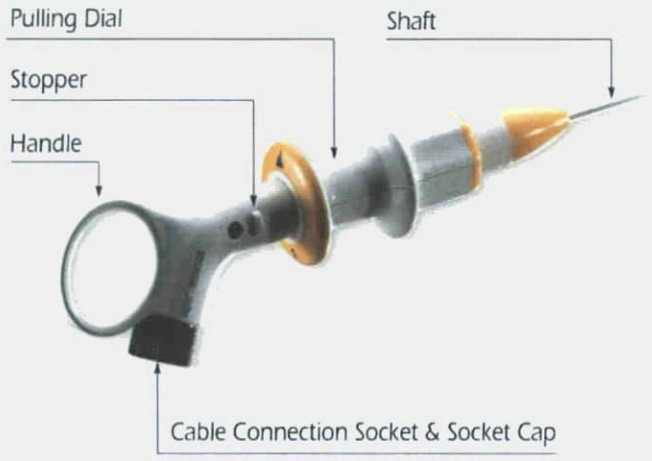


Figure 3-6: The Locatable Guide

Components

The LG consists of the following components:

- **LG handle**: serves as a holding ring.
- **LG body**: incorporates the tip deflection control mechanism.
- **Connection cable**: connects to the relevant connector on the LOCATION AMPLIFIER Unit.
- **Connection Socket Cap**: covers the connection socket.
- **LG shaft:** is inserted into the bronchoscope's working channel.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Extended Working Channel (Guiding Sheath)

The EXTENDED WORKING CHANNEL (EWC), which acts as a guiding sheath, is a plastic tube with a lumen. It is inserted into the working channel of a bronchoscope in conjunction with the LG. The EWC is designed to guide an endoscopic tool to the Target after retraction of the LG. A Luer-type connector is provided for connection to the LG. The EWC is radio-opaque to allow fluoroscopic imaging.
The EWC may be used, at the discretion of the physician, when the endobronchial path to the Target is likely to require sharp turns.

The EWC is supplied sterile and intended for single use.

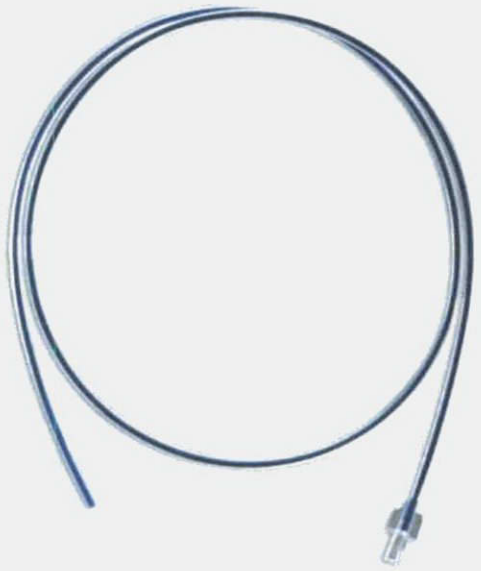


Figure 3-7: The Extended Working Channel (EWC)

Bronchoscope Adapter Unit

The BRONCHOSCOPE ADAPTER (BA) unit enables to fixate the EWC alone or together with the LG to the bronchoscope.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

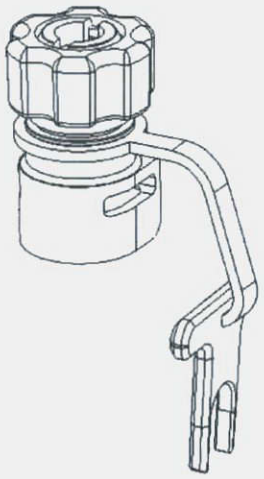


Figure 3-8: The Bronchoscope Adapter (BA) Unit

Using the BA unit will allow for subsequent retraction of the LG without moving the EWC, with respect to the coupled bronchoscope.

The BRONCHOSCOPE ADAPTER is supplied sterile and intended for single use.

Bronchoscope Clip

The BRONCHOSCOPE CLIP (BC) is used to anchor the LG when that is helpful in the course of the procedure, thus facilitating the use of the LG during the procedure.

The BRONCHOSCOPE CLIP is supplied sterile and intended for single use.



Figure 3-9: The Bronchoscope Clip (BC) Unit

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Measuring Tube

The MEASURING TUBE is used to define the protrusion of the endoscopic instruments inserted into the EWC. It is supplied sterile and is intended for single use.

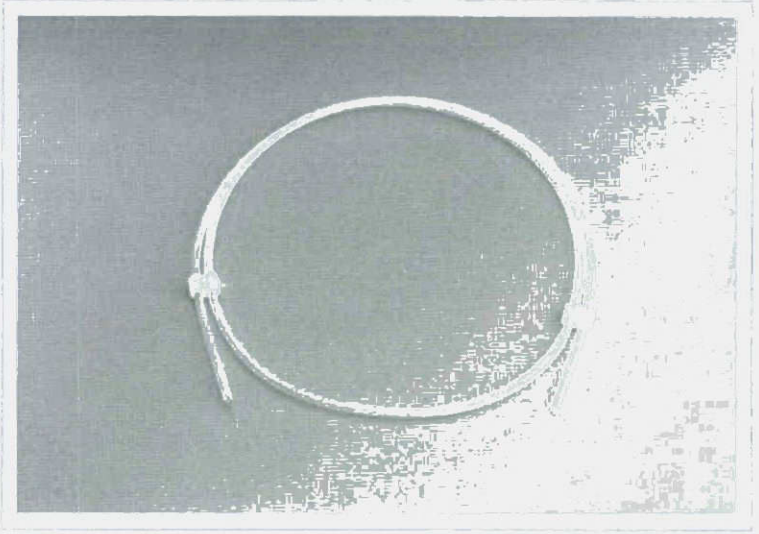


Figure 3-10: The Measuring Tube

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Required Equipment that is not Provided

The following equipment is used in conjunction with the superDimension inReach™ System but is not provided by superDimension.



Warning

To avoid potential patient or user injury, endoscopic equipment and endoscopic accessories (tools) used in conjunction with superDimension inReach™ System must comply with the requirements of standard IEC 60601-2-18, IEC/EN 60601-1, IEC/EN 60601-1-2 or their equivalent, and shall be used only according to their respective User Manuals.

Compatible Bronchoscopes

The following bronchoscopes can be used with the superDimension inReach™ System:

Model	Working Channel Width (mm)	Outer Diameter (mm)	Working length (insertion portion) (mm)	Working Channel Length (mm)
Pentax FB-18P (fiber)	2.8	5.9	600	700
Pentax EB-1970K	2.8	6.2	600	705
Olympus BF-1T40	2.8	6	550	675 (Estimated)
Olympus BF-1T160	2.8	6	600	725
Olympus BF-1T180	3.0	6.0	600	725 (Estimated)
Olympus BF-1T260	2.8	6	600	<720

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Model	Working Channel Width (mm)	Outer Diameter (mm)	Working length (insertion portion) (mm)	Working Channel Length (mm)
Olympus BF-XT20	3.2	6.2	550	650
Olympus BF-XT40	3.2	6.2	550	650
Fujinon EB-270T	2.8	5.9	600	<720
Fujinon EB-470T	2.8	5.9	600	870



Warning

Use of bronchoscopes that are not compatible with the superDimension inReach™ System may lead to inaccuracy of the system.

The compatibility of bronchoscopes to be used in conjunction with the superDimension inReach™ System should be verified with superDimension's representative by calling superDimension customer service or discussing the bronchoscopes to be used with the installing technician.

Only bronchoscopes that were verified with superDimension's representative and meet the following specifications can be used with the superDimension inReach™ System:

Working Channel Width (mm)	Working Channel Length (mm)
≥2.8	<725

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

There is no guarantee that bronchoscopes selected solely using this minimum specification will be compatible with the superDimension inReach™ System.

Consult with superDimension customer service before using additional bronchoscopes.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

81

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Compatible Endoscopic Tool

Only endoscopic tools that meet the following specifications can be used with the superDimension inReach™ System:

Tool Type	Specification
Biopsy Forceps	Insertion portion width: ≤ 1.8 mm Insertion portion length (working length): ≥ 1050 mm
Aspiration Needle	Insertion portion width: ≤ 1.8 mm Insertion portion length (working length): > 1050 mm
Cytology Brush	Insertion portion width: ≤ 1.8 mm Insertion portion length (working length): > 1050 mm
Endo Bronchial Ultrasound	Insertion portion width: ≤ 1.8 mm Insertion portion length (working length): > 1050 mm

Consult with superDimension customer service before using additional tools.



Caution

Use of bronchoscopic tools that do not comply with the specifications above have the potential to cause damage to the EWC.

82

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Compatible Marker Delivery Tools

Only tools that meet the following specifications can be used with the superDimension inReach™ System:

Tool Type	Specification
Needle-Catheter	Needle Gauge 23 - 25 g. Needle Length: 4 - 6 mm Insertion portion length (working Length): > 1050 mm Insertion portion width (outer diameter): ≤ 1.8 mm
Guide Catheter	Insertion portion width (outer diameter): ≤ 1.8 mm Insertion portion length (working Length): > 1050 mm
Guide Wire	Insertion portion width (outer diameter): ≤ 0.035 in (0.89 mm) Insertion portion length (working Length): ≥ 1050 mm Stiff core, straight tip
Sterile Radiosurgical Marker	Inert Material Length: ≤ 30 mm Diameter: ≤ 0.8 mm
Sterile Dye	Common marking dyes such as Indigo Carmine and Methylene Blue

Consult with superDimension customer service before using additional tools.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Fluoroscopes

Fluoroscopy can also be used to verify the location of the LG on the Target, if performed on at least two perpendicular angles.



Warning

To avoid potential patient or user injury, fluoroscopes used in conjunction with superDimension inReach™ System must comply with the requirements of standards IEC/EN 60601-1, IEC/EN 60601-1-2 and IEC/EN 60601-1-3 or their equivalent.



Caution

When a fluoroscope is available, make sure to position the nearest part of the fluoroscope at least 75 cm from the LOCATION BOARD unless determined differently by the superDimension technician during system installation.

Endoscopic Video camera

An endoscopic camera may be connected to the superDimension inReach™ System to display the bronchoscopic image as part of the application screen.



Warning

To avoid potential patient or user injury, an endoscopic video camera used in conjunction with superDimension inReach™ System must comply with the requirements of standard IEC/EN 60601-1 and IEC/EN 60601-1-2 or their equivalent.

The final configuration must meet the requirements for safety of medical systems prescribed by standard IEC/EN 60601-1-1 or equivalent.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 4: Specifications



Warning

Risk of explosion if used in the presence of flammable anesthetics, or flammable gases or liquids.

Dimensions

Cart	Height: 1700 mm
	Foot Print: 800 mm X 800 mm
Location Board	Thickness: 10 mm
	Footprint = 470 mm X 560 mm
Locatable Guide	Insertion portion width: 1.9 mm
	Working length: 970 mm
Extended Working Channel	Insertion portion width: 2.6 mm
	Working length: 948 mm
	Minimum instrument channel width: 2.0 mm



Caution

There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PS

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Power Requirements

Input voltage	100VAC 50/60 Hz 110-120VAC 50/60 Hz 230VAC 50/60 Hz
Input Power	400VA

Standards

Conforms to IEC/EN 60601-1 Medical Electrical Equipment Part I, General Requirements for Safety.

Equipment Classification	Class I
Degree of protection against electric shock	Type BF Applied Part
Mode of operation	Continuous Operation
Flammable Anesthetics	Unsuitable for use in the presence of flammable anesthetics.
Protection against ingress of liquids	Unprotected against ingress of liquids, excluding the following splash proof components with Protection Class IP64 – Patient Sensors, Location Board and IP67 – Locatable Guide, Foot Switch.

Conforms to IEC60601-2-18 Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment.

Conforms to IEC/ EN60601-1-2: 2001 Medical electrical equipment Part 1: General requirement for safety - 2. Collateral standard: Electromagnetic compatibility – Requirements and tests

86

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Operating Environment

The localization system is designed for operation in a hospital environment.

Temperature range	15° C to 35° C (59°F to 95°F)
Relative humidity range	30% - 75%
Atmospheric pressure range	525mmHg – 760mmHg

The LOCATABLE GUIDE, EXTENDED WORKING CHANNEL AND PATIENT SENSOR TRIPLET are designed for operation in an approximate body temperature of 37 ° C.

Transport Specifications

Temperature range	-20° C to +60° C (-4°F to + 140°F)
Relative humidity range	10% - 85%
Atmospheric pressure range	525mmHg – 760mmHg

Storage Specifications

Store at room temperature

Personal Computer - Procedure Station

CPU	Intel Core 2 Duo E4500
Memory	2GB DDR2 667MHz RAM
Hard Disk Drive	160 GB/7200 RPM
Optical Drive	DVD +/-RW
Video Adapter	Leadtek – PCI Express x16, nVidia GeForce 8600 GTS, 512MB DDR
Monitor	17 " TFT-LCD Resolution: 1280x1024

87
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Personal Laptop Computer – Remote Planning Station	
CPU	Intel Core 2 Duo T7500
Memory	2GB DDR2 667MHz RAM
Hard Disk Drive	120 GB/5400 RPM
Optical Drive	DVDRW X 8 Drive
Video Adapter	Intel® X3100 Graphics Media Accelerator
Monitor	15 " TFT-LCD Resolution: 1024x768
superDimension inReach™ System Accuracy	≤3mm Root Mean Square (RMS) based on a rigid simulated lung model.
Low Frequency Emissions	The Location Board transmits frequencies of 2.5 kHz, 3.0 kHz, and 3.5 kHz. The maximum magnetic field generated is 123.5 mG.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Guidance on Electromagnetic Compatibility (EMC)



Caution

The superDimension inReach™ System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below in this User Manual.

Portable and mobile RF communications equipment, such as mobile telephones and walkie-talkies, can affect the superDimension inReach™ System .

Do not operate mobile phones in the vicinity of the system.

List of cables and accessories that may affect EMC compliance of the superDimension inReach™ System



Caution

The use of accessories and cables other than specified below may result in increased EMISSIONS or decreased IMMUNITY of the superDimension inReach™ System.

List of Cables

Item	Description	Part No.	Length
1.	Mains Power cable	ECB00015-02 ECB00028-01 - USA	5m
2.	Locatable Guide cable	ACA00083-01	5m
3.	Location Board cable	ACA00047-01	3m

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Item	Description	Part No.	Length
4.	Endoscope Video Camera Coax cable	ACA00070-01 or ACA00067-01	10m 5m
5.	Endoscope Video Camera S-video cable	ACA00072-01 or ACA00071-01	10m 5m
6.	Monitor Video Output Coax cable	ACA00070-01 or ACA00067-01	10m 5m
7.	Monitor Video Output S-video cable	ACA00072-01 or ACA00071-01	10m 5m

List of Accessories

Item	Description	Part No.	Length
1.	Locatable Guide	AKI00017-01	1.5m
2.	Patient Sensor Triplet	AAS00060-01	With 5m cable
3.	Footswitch	AED00033-01	With 5m cable

Guidance and manufacturer's declaration – electromagnetic emissions

The superDimension inReach™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the superDimension inReach™ System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Group 1	The superDimension inReach™ System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Class A	The superDimension inReach™ System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	



Caution

The superDimension inReach™ System should not be used adjacent to equipment other than that which is required by the procedure. If adjacent use is necessary, the superDimension/ inReach™ System should be observed to verify normal operation in the configuration in which it will be used.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The superDimension inReach™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the superDimension/ inReach™ System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. There is a very low incidence of software freeze at 6 kV. If this occurs, reboot the system and continue the procedure.
Electrical fast transient/burst IEC 61000-4-4	+ 2 kV for power supply lines + 2 kV for input/output lines	+ 2 kV for power supply lines + 2 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1 kV differential mode + 2 kV common mode	+ 1 kV differential mode + 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

92

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the superDimension/ inReach™ System requires continued operation during power mains interruptions, it is recommended that the superDimension inReach™ System be powered from uninterruptible power supply.
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level			

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
93

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The superDimension inReach™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the superDimension/ inReach™ System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the superDimension inReach™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ 150 kHz to 80 MHz $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-6	3 V/m 80 MHz to 2,5 GHz	3 V/m	

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the superDimension/ inReach™ System is used exceeds the applicable RF compliance level above, the superDimension inReach™ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the superDimension inReach™ System.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
95

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the superDimension inReach™ System

The superDimension inReach™ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the superDimension inReach™ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the superDimension inReach™ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,001	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	38

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 5: Getting Started

Initial Setup

Your superDimension Customer Service Representative will handle the initial setup of your superDimension inReach™ System.



Caution

Do not unpack any sealed boxes or packages. An authorized customer service representative must do all unpacking.



Caution

An authorized customer service representative must perform the initial installation of the system and components.



Caution

There are certain minimum distances between various components that must be maintained throughout the operation of the system in order to enable the proper functioning of the system.

Specifically:

The minimum distance between the SYSTEM CART and the LOCATION BOARD is 50 cm.

The minimum distance between LOCATABLE GUIDE's handle and the LOCATION BOARD is 40 cm.

98

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Warning

Connect the system to an earthed (grounded) electrical outlet only. If connected to an incorrectly grounded outlet, electrical shock could result.

For connection, use only the medical grade mains plug with protective earth (ground) terminal according to your National Electrical cord. If a medical grade mains plug is not used, electrical shock could result.

Inspect the system power cord and plug on a regular basis. To avoid risk of electrical shock, replace them if they are damaged in any way.



Warning

Do not remove the system component's covers. There are no serviceable parts inside the system. Refer installation and service only to an authorized superDimension Ltd. customer service representative. Tampering with the components inside the system can result in equipment failure and patient / user injury.



Warning

The superDimension inReach™ System should not be used adjacent to equipment other than that which is required by the procedure. If adjacent use is necessary, the superDimension/ inReach™ System should be observed to verify normal operation in the configuration in which it will be used..

98

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

Do not place any ferromagnetic material within the space above or below the LOCATION BOARD.

When a fluoroscope is available make sure to position the nearest part of the fluoroscope at least 75 cm. from the LOCATION BOARD unless determined differently by the SuperDimension technician during system installation.

Software

Your superDimension inReach™ System comes with all the necessary application software preinstalled. No further software installation is required.



Caution

Installing any other software on the superDimension inReach™ System will damage the system. No other software should be installed on the superDimension inReach™ System.

Setting Up System Components

The superDimension inReach™ System is used during a bronchoscopic procedure, in conjunction with standard practices. The room used for the procedure must conform to the customary requirements of bronchoscopic procedures.



Warning

To avoid electrical shock and/or system failure, do not pinch, crimp, or otherwise stress cables and connectors.

To avoid electrical shock and/or system failure, use only the cabling that was supplied with the system.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

100

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Warning

To avoid electrical shock and system damage, do not spill liquids on the system, except for the LOCATION BOARD, LOCATABLE GUIDE, LOCATABLE GUIDE CABLE, PATIENT SENSOR, and FOOT SWITCH which are designed to be fluid resistant.



Caution

To prevent damage to the inReach™ System, do not cover the ventilation openings in the LOCATION AMPLIFIER, LOCATION PROCESSOR, or the PC.



Caution

Connecting components while the system is running is generally not allowed.

Such "hot swaps" are only allowed for the following components:

- LOCATABLE GUIDE
- PATIENT SENSORS
- LOCATION AMPLIFIER connection to the LOCATION PROCESSOR.
- LOCATION BOARD and power connection of the LOCATION AMPLIFIER.

Such hot swaps should be limited to the minimum.

Do not connect or disconnect the LOCATION PROCESSOR power connector while the Power Supply is turned on.

Do not connect or disconnect the LOCATION AMPLIFIER from the LOCATION PROCESSOR while the Power Supply is turned on.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Note

At the middle of each cable, the superDimension p/n will appear on a label (excluding cable tails such as LOCATION BOARD cable tail, PATIENT SENSOR CABLE etc').

Near each connector, a label with the name of the Target connector is attached.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

102

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Connecting to the Location Processor

The LOCATION PROCESSOR is located on the cart. The system components are connected as follows:

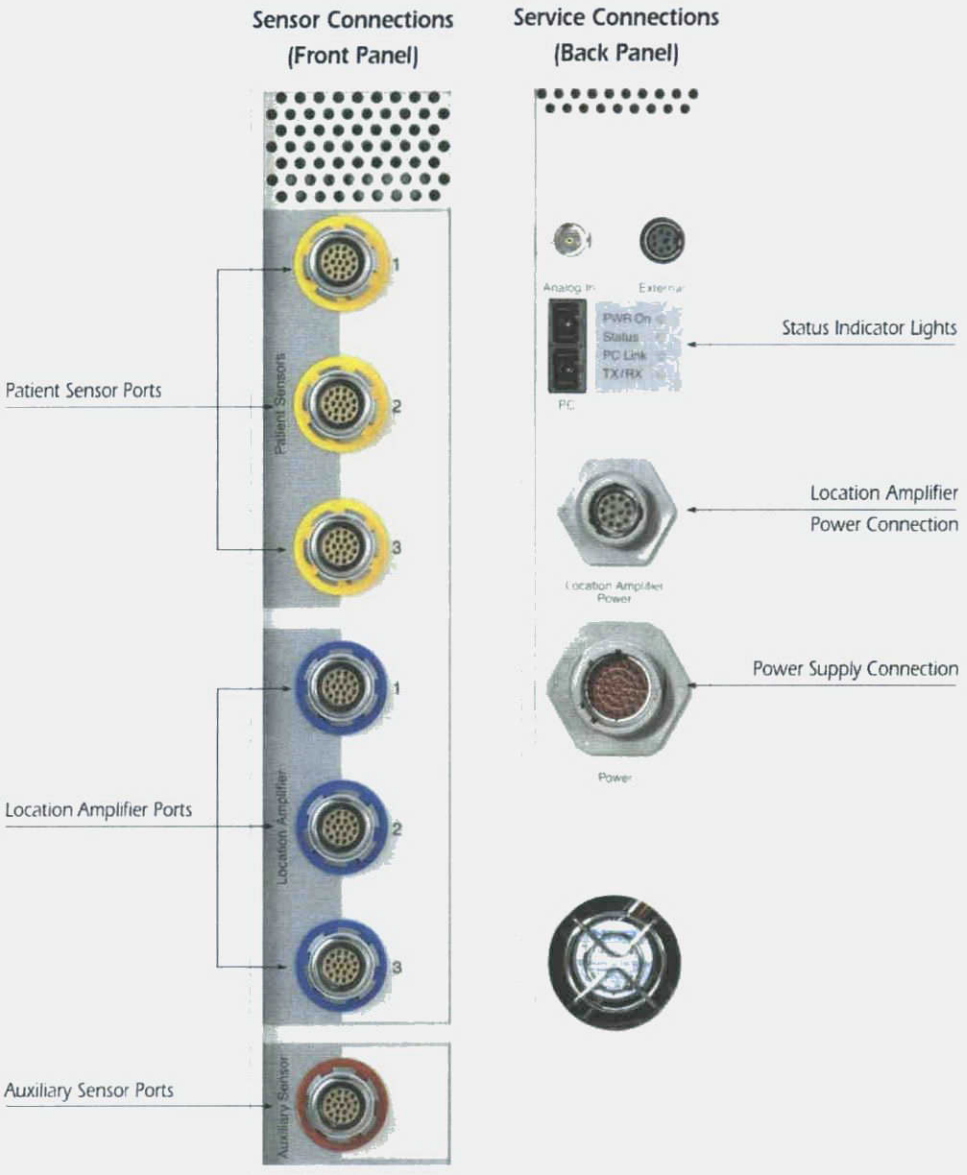


Figure 5-1: Location Processor Connections

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

The AUXILIARY SENSOR port on the SENSORS' CONNECTIONS panel as well as the ANALOG input and EXTERNAL ports on the SERVICE CONNECTIONS panel are for future implementation. Do not use them.

Connecting to the Location Amplifier

The LOCATION AMPLIFIER is located on the cart. The system components are connected as follows:

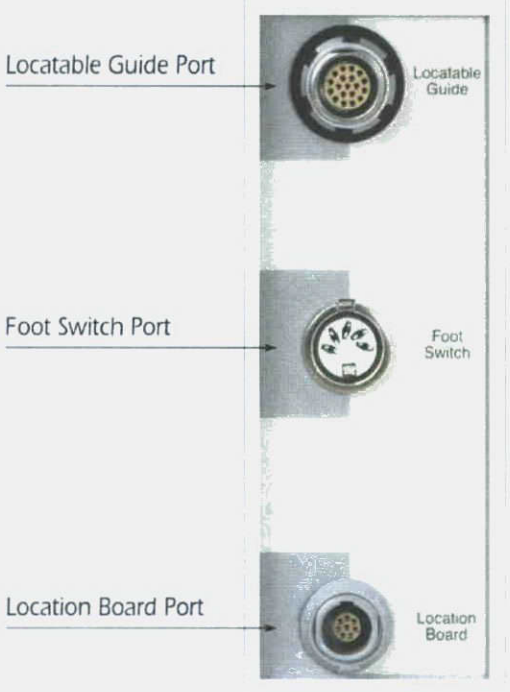


Figure 5-2: Location Amplifier Connections

104

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Connecting the Locatable Guide

The LOCATABLE GUIDE is connected to the LOCATABLE GUIDE port on the LOCATION AMPLIFIER. See *Using the Locatable Guide and Extended Working Channel,* on page 7-63, for further details on using the LOCATABLE GUIDE.

Video In connection

An endoscopic camera may be connected to the superDimension inReach™ System.

The endoscopic video camera is connected to the VIDEO IN port on the superDimension inReach™ System cart. *See Figure 5-3: Video Connection Panel.*



Figure 5-3: Video Connection Panel

Warning

To avoid potential patient or user injury, an endoscopic video camera used in conjunction with superDimension inReach™ System must comply with the requirements of standards IEC/EN 60601-1 and IEC/EN 60601-1-2 or their equivalent

The final configuration must meet the requirements for safety of medical systems prescribed by IEC/EN 60601-1-1 or equivalent.

105

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Video Out port connection

External video equipment may be connected to the Video Out port on the superDimension inReach™ System cart. *See Figure 5-3: Video Connection Panel.*

Warning

To avoid potential patient or user injury, external video equipment connected to the Video Out port of the superDimension inReach™ System must comply with the requirements of standard IEC/EN 60601-1 or IEC/EN 60950 or IEC/EN 60065 or equivalent.

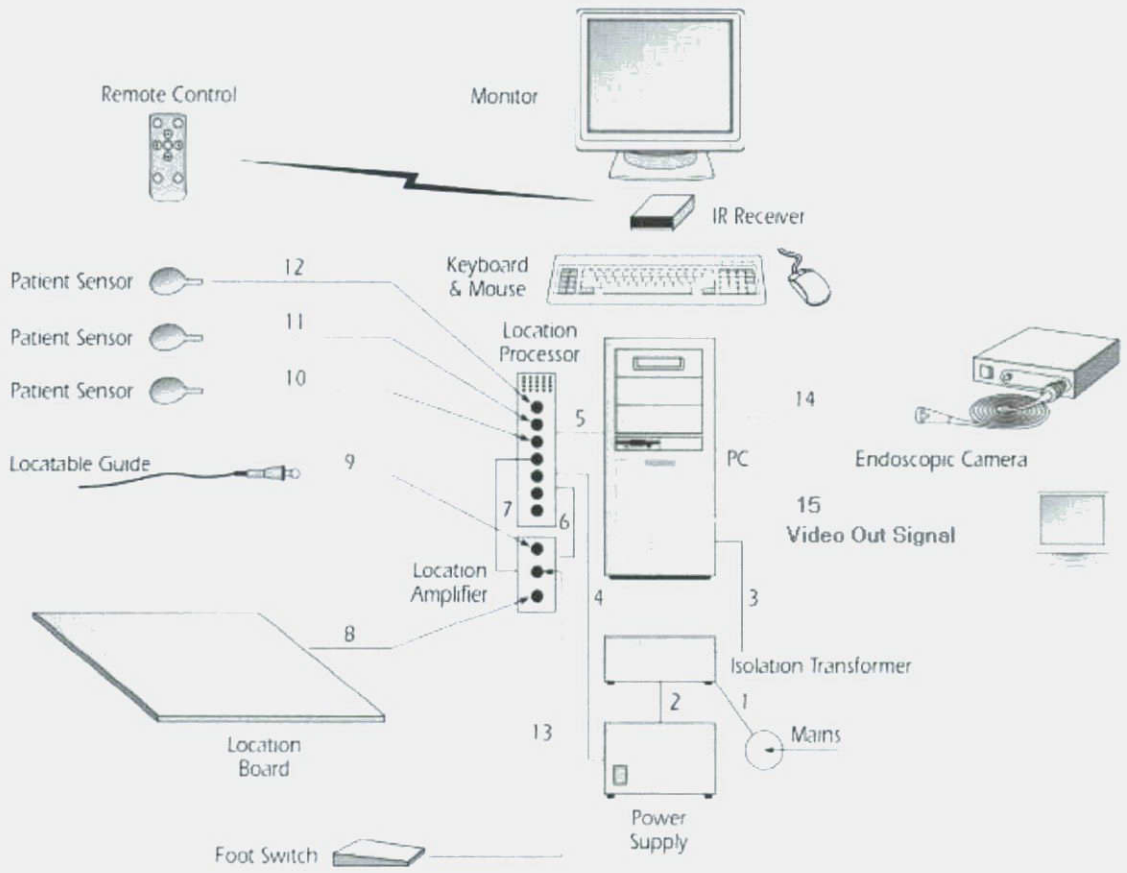


Figure 5-4: System Connection Diagram

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

106

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Connection Number	Connection Description
1	Mains to ISOLATION TRANSFORMER.
2	ISOLATION TRANSFORMER to Power Supply.
3	ISOLATION TRANSFORMER to PC.
4	Power Supply to LOCATION PROCESSOR.
5	PC to LOCATION PROCESSOR – Optical link.
6	LOCATION PROCESSOR to LOCATION AMPLIFIER power.
7	LOCATION PROCESSOR to LOCATION AMPLIFIER.
8	LOCATION AMPLIFIER to LOCATION BOARD.
9	LOCATABLE GUIDE to LOCATION AMPLIFIER.
10	PATIENT SENSOR to LOCATION PROCESSOR.
11	PATIENT SENSOR to LOCATION PROCESSOR.
12	PATIENT SENSOR to LOCATION PROCESSOR.
13	FOOT SWITCH to LOCATION AMPLIFIER.
14	Endoscopic camera to Video In port.
15	External video equipment to Video Out port.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Setting up the System



Warning

Significant changes to the configuration of the bronchoscopy suite, including introduction of new metallic equipment or movement of existing metallic equipment can affect the accuracy of the system. Contact superDimension customer service to schedule a recalibration of the instrument prior to making bronchoscopy suite reconfigurations.



Caution

Do not connect or disconnect the LOCATION PROCESSOR power connector while the power supply is turned on.

Do not connect or disconnect the LOCATION AMPLIFIER from the LOCATION PROCESSOR while the power supply is turned on.



Caution

Before switching any ECG units included in the original installation configuration you must contact a superDimension representative to verify compatibility of the new ECG with the superDimension /inReach™ System.



Caution

Before initializing the system, make sure all system components (“*Setting Up System Components*,” on page 5-3) are in place and have been cleaned as required. (“Cleaning” on page8-1).

108

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

Always ensure to route the system cables away from possible tripping and stepping situations.

Avoid excessive bending or twisting of any/all system cables.



Caution

There are certain details that must be verified before the daily setup in order to assure location accuracy.

Specifically:

The LOCATION BOARD's pads must be kept bonded onto the table at their original setup location.

The LOCATION BOARD must be located correctly on the LOCATION BOARD pads so that it is parallel to the table, see Figure 5-5 below. Each of the four pads must be located within a corresponding groove on the underside of the LOCATION BOARD.

The table arrangement (e.g. table-top position with respect to its support leg, protection rail position) must be identical to its arrangement during system setup.

The procedure room should be arranged according to the Procedure Room Configuration form provided by the superDimension technician following the installation of the system and as appears in the Procedure Room Configuration page *see Phase 1 – Procedure Module Setup* on page 7-2.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

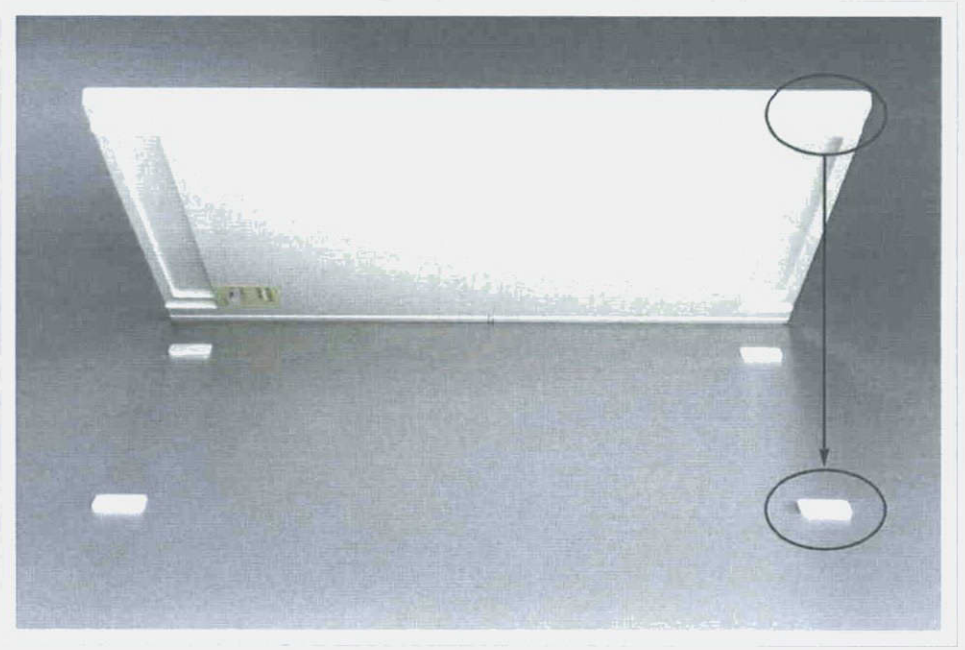


Figure 5-5: Position Location Board on Pads

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

110

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

System Logon

This section takes you step-by-step through the setup process to make sure that all the system's components are properly configured for use.

➢ **To Log on to the System:**

1. Ensure that the system is turned off.
2. Ensure that all the cables are correctly connected.

   For information on the proper cable connections, see *"Setting Up System Components,"* on page 5-3.
3. Turn on the main power using the green MAIN SWITCH located on the right side of the cart and ensure that the green light indicator is switched on, see Figure 5-6.

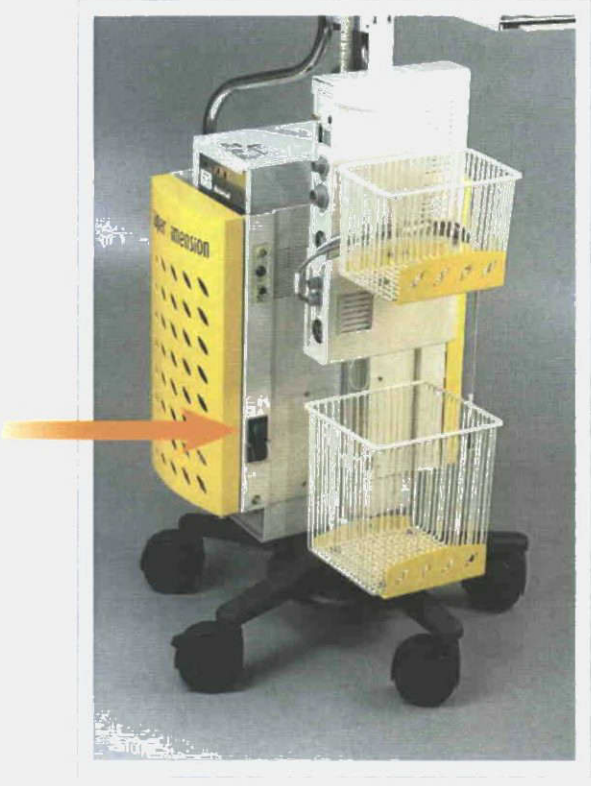


Figure 5-6: The Main Switch

4. Make sure that the green switch located on the front of the POWER SUPPLY UNIT is switched on. For an illustration, see Figure 5-7.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

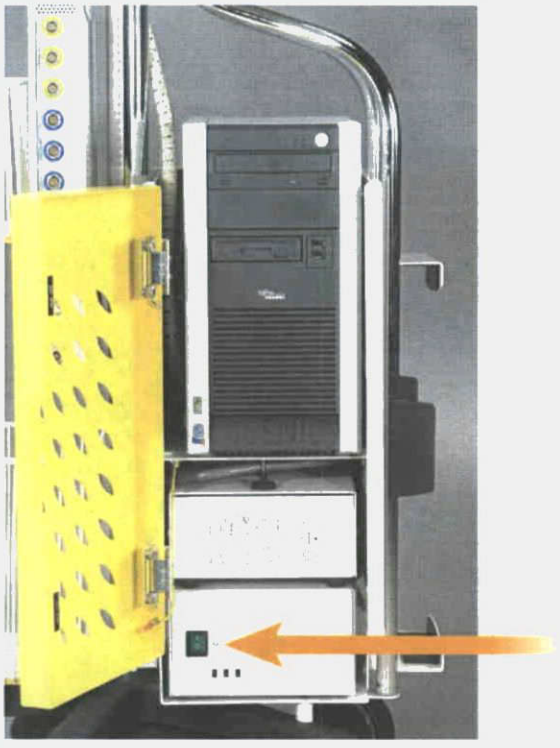


Figure 5-7: Turning on the System's Power Supply

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
112

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

5. Turn on the PC by using the power switch located on the computer box (see Figure 5-8,) and make sure the monitor is turned on. If the monitor is not on, press the monitor's power button.

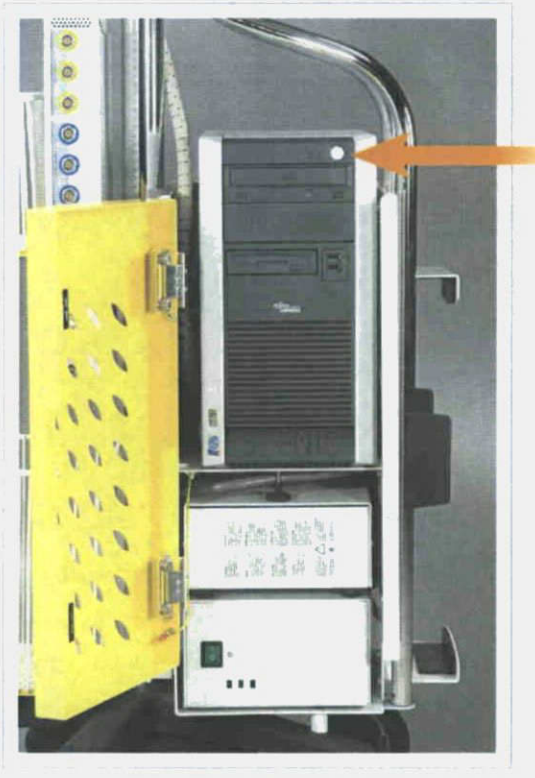


Figure 5-8: The PC Power switch

The system is now activated, and the WINDOWS Login Window will appear.

6. Enter your User Name and Password and click OK.

   The Opening Screen will appear.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Opening Screen Layout and Functionality

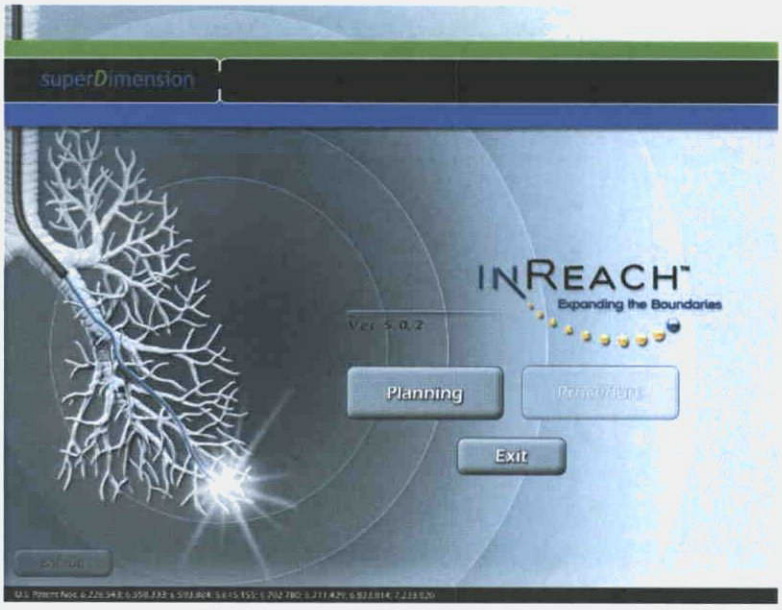


Figure 5-9: The Opening Screen *(updated)*

Module Selection

You can access the following modules and options by clicking on the relevant button on the opening screen:

- **Planning** – Opens the Planning module, in which Planning is carried out ahead of the procedure using a patient's CT or combined PET/CT scan (DICOM format).
- **Procedure** – Opens the Procedure module, which is used to navigate the LG while performing a procedure.
- **Exit** – Shuts down the system.
- **Backup** – Initiates backup of procedures to external media. Backup is performed to provide data for customer support purposes.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 6: The Planning Module

The Planning Module Overview and Workflow

You use the Planning module to prepare a Planning File, which will be used during the actual procedure using the Procedure Module. Using the patient's study file in DICOM format, the superDimension inReach™ System generates three cross-section planning viewports and a 3D virtual image. Using these viewports you can identify and mark the Registration Points and Targets. The Planning file will then be used in the Procedure Module, where the marked Targets will be displayed.

The inReach™ Planning Laptop can be used stand-alone for bronchoscopy planning or CT-Viewing or with the other system components. If the Planning Laptop is used stand-alone disregard the information related to the inReach™ System procedure module.

Planning comprises four phases:

- **Phase 1 – Loading a patient's study in DICOM format**– A patient's file is opened and a sequence of CT slices, on which the procedure will be planned, is selected. For further details on *Phase 1 – Loading a patient's study in DICOM format* see page 6-19.
- **Phase 2 – Marking the Registration Points** – Registration Points are marked using the CT cross-sections Planning viewports and the generated virtual image viewport. These Registration Points are later registered in the Procedure module during the CT-to-Body Registration phase. During this phase, the Registration Points from the Planning File are matched to actual landmarks on the patient. This allows the physician to navigate the LG to the Target within the patient using the cross-section viewports, which were generated in the Planning phase. For further details on *Phase 2 – Marking the Registration Points* see page 6-36.
- **Phase 3.1 – Marking the Target Locations and Dimensions** –The location of the Target(s) is marked using the CT cross-sections Planning viewports and the generated virtual image viewport. In the Procedure module the marked Target(s) are displayed in four different viewports, to help you accurately navigate to the Target. For further details on *Phase 3.1 – Marking the Target Locations and Dimensions* see page 6-42.

  Phase 3.2 - Pathway construction to Target (Optional)

  On CT scans with specified parameters, a pathway to the Target(s) can be marked. This option enables a virtual path to

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

115

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

the target using intermediate Waypoints. Refer to *Required CT Parameters* on page 6-19.

- **Phase 4 – Saving the Planning File and Exiting** – Once the required Registration Points and Target(s) have been marked, the file is saved. The Planning File will be loaded and used in the Procedure Module. For further details on *Phase 4 – Saving the Planning File and Exiting* see page 6-51.
- **Phase 5 – Exporting Planning File** – The Planning File can be exported to a CD or a removable disk, in cases in which the planning was done on a remote planning station. For further details on *Phase 5 – Exporting the Planning* File see page 6-54.

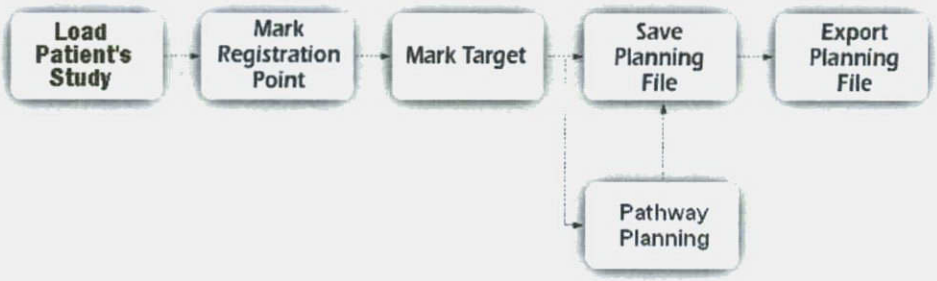


Figure 6-1: Planning Workflow *(updated)*

Planning Module Screen Layout

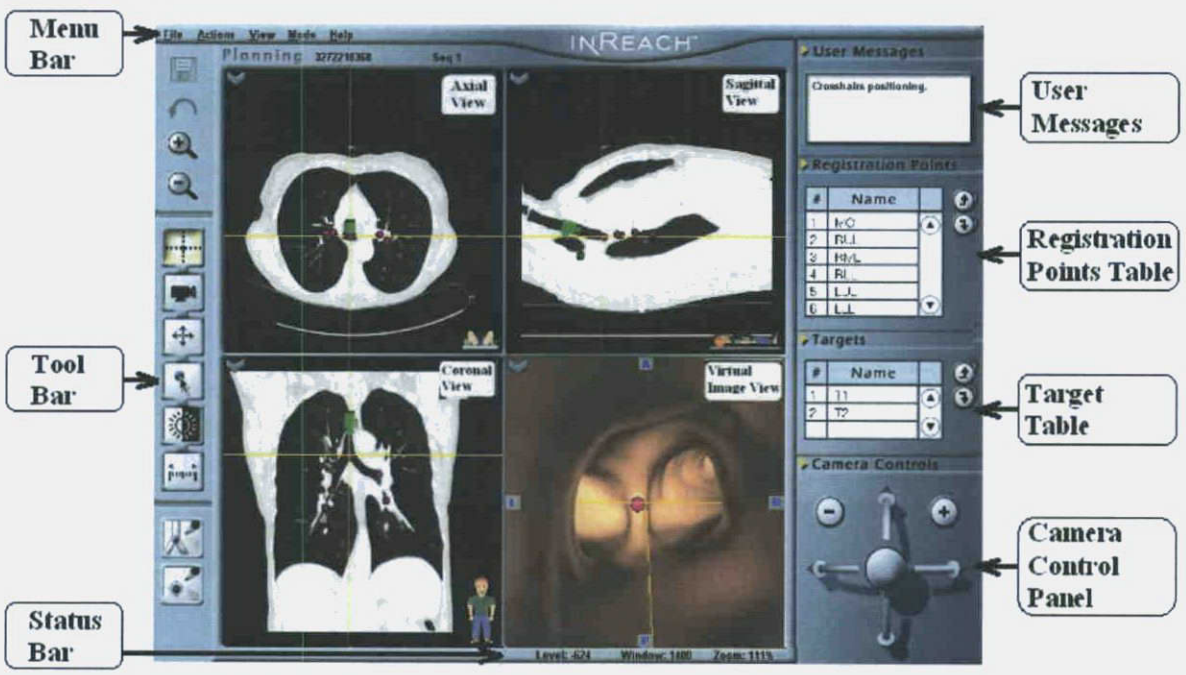


Figure 6-2: The Planning Module Screen *(updated)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

116

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Note

For details on menu bar options and toolbar buttons, refer to *Planning Menu Bar Options* on page 10-2 and *Planning Toolbar Buttons* on page 10-5, respectively.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

117

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning Viewports

The superDimension inReach™ Views takes a standard CT sequence and displays three different viewing planes simultaneously - axial, sagittal, and coronal - as follows:

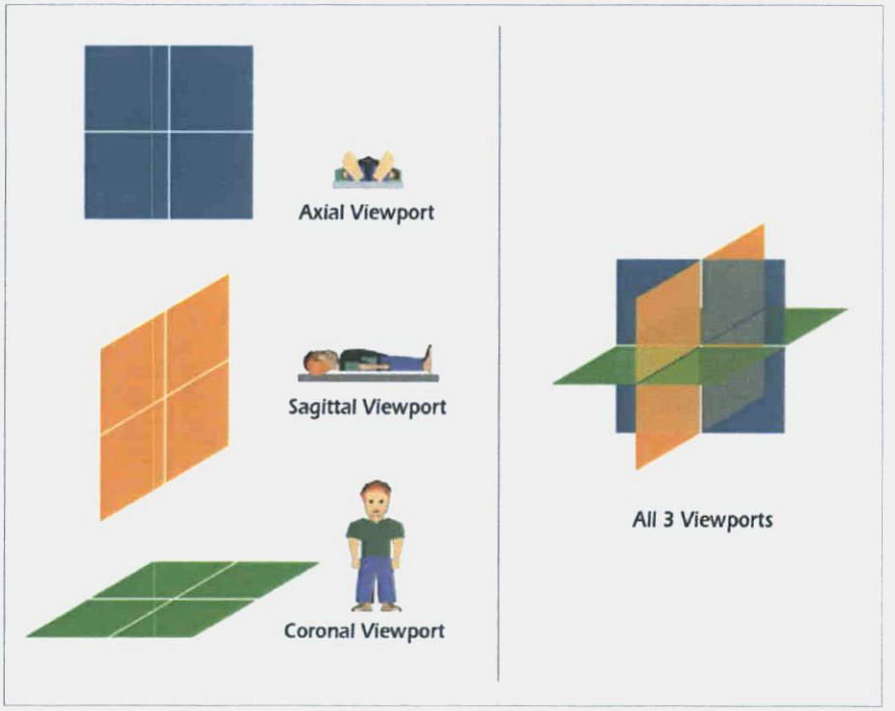


Figure 6-3: The Planning Viewports Relationship

The crosshairs connects all three viewports. The position of the crosshairs in one viewport defines the cross-section that is displayed in the other viewports. For example, if we lower the horizontal axis in the Axial viewport, a different cross-section is displayed, and the Coronal viewport will therefore be updated to display the correct cross-section for the lower horizontal axis. Moving the position of the crosshairs in any of the cross-section viewports will therefore automatically display the corresponding cross-section in the other viewports.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

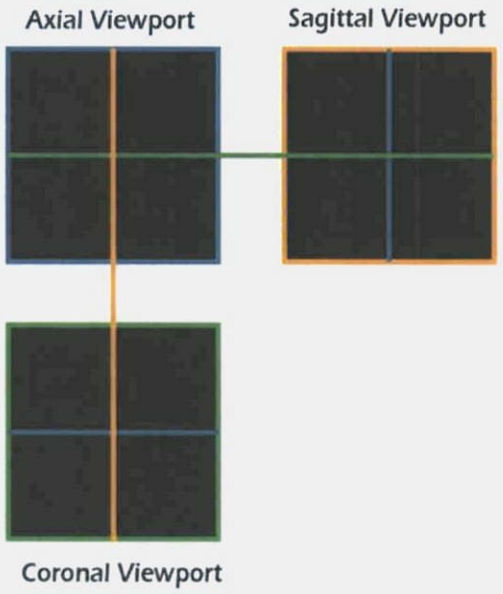


Figure 6-4: Connected Cross-section viewports

Axial Viewport

Displays the axial view of patient.



Figure 6-5: Axial viewport

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Sagittal Viewport

Displays the right/left lateral view of the patient.

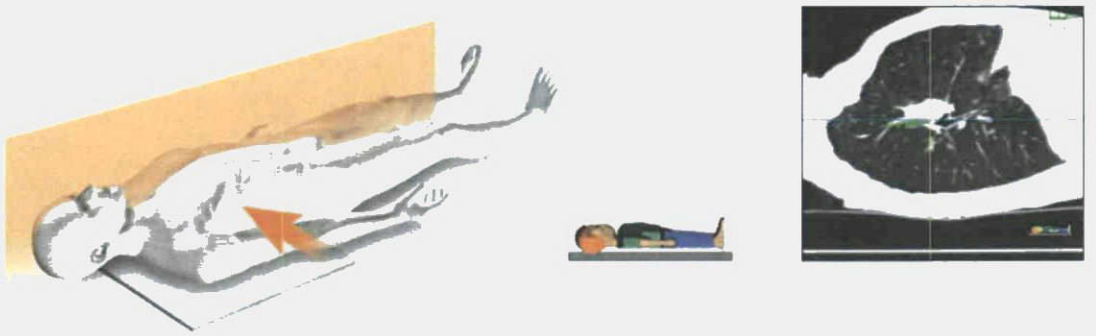


Figure 6-6: Sagittal viewport

Coronal Viewport

Displays the anterior/posterior view of the patient.

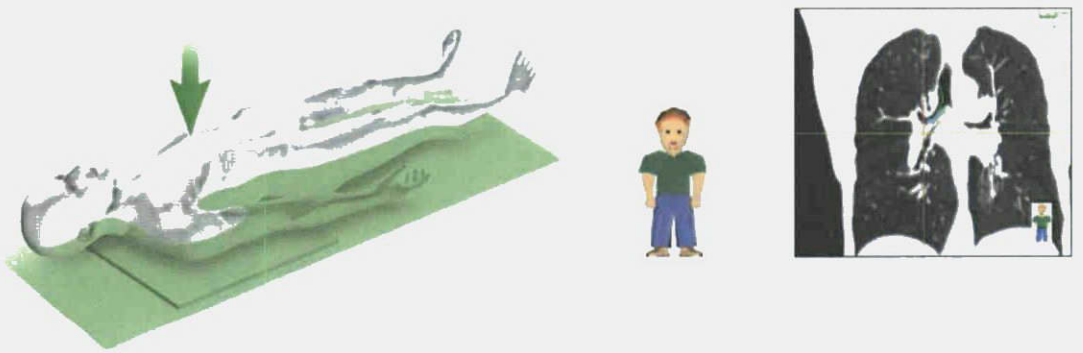


Figure 6-7: Coronal viewport

3D-Map viewport

The 3D-MAP viewport is a three-dimensional roadmap visualization of the patient's bronchial airways. The 3D-MAP view assists in planning a pathway to the target. This feature is supported only on CT scans that enable 3D-Map generation, for more information on compatibility see *Required CT Parameters* on page 6-19.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Warning

The 3D-MAP is a geometric rendering of the bronchial airways. It is not an anatomical representation of the airways and should be used for general reference only.

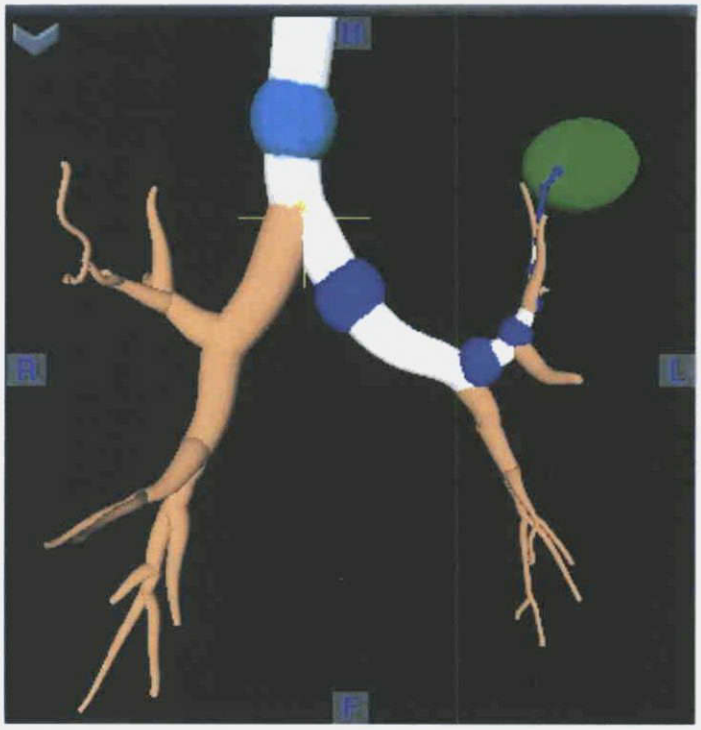


Figure 6-8: 3D-Map viewport *(New)*

The 3D-Map can be controlled in the following ways:

- Rotate: with the mouse cursor located on the black background, move the mouse left and right while clicking and holding the left mouse button.
- Zoom In / Zoom Out: move the mouse up and down while clicking and holding the right mouse button.
- Pan: move the mouse while clicking and holding the middle mouse button

Virtual Bronchoscopy Viewport

The Virtual Bronchoscopy viewport displays a virtual image of the interior of the bronchial tree as if viewed by a bronchoscope.

121

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

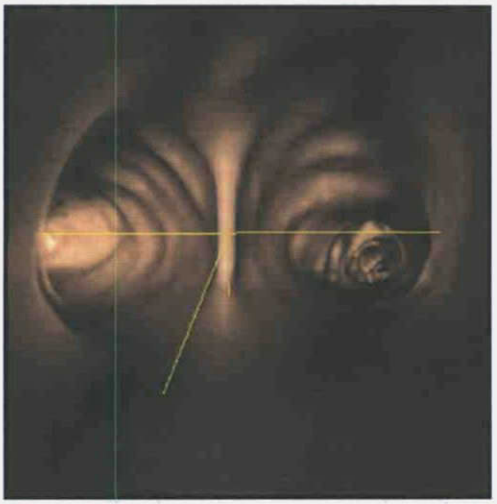


Figure 6-9: Camera Position in the Virtual Bronchoscopy viewport

Controlling the Virtual Bronchoscopy Opacity Level

The opacity of the Virtual Bronchoscopy can be controlled during the Target marking process to better visualize a Target behind the tracheobronchial wall.

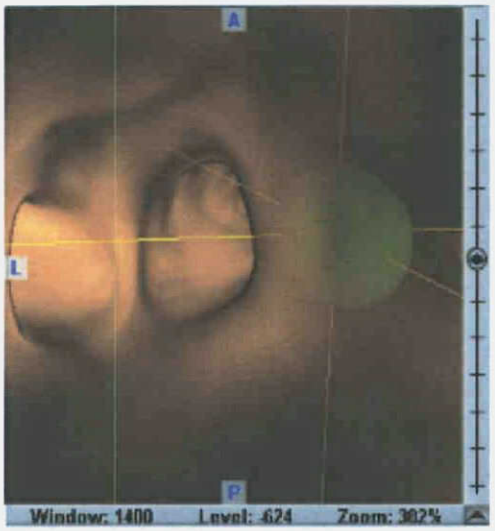


Figure 6-10: Virtual Bronchoscopy Opacity Control

Position the camera in front of bronchial wall of the Target in a way that simulates the bronchoscope's angle of view. Click the Opacity Control button  and set the opacity level as needed.

Controlling the Virtual Bronchoscopy view settings

The Virtual Bronchoscopy viewport enables enhanced viewing options. The Enhanced Tissue mode displays a clearer rendering of the tracheobronchial walls. The Enhanced Airways mode enables for

122

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

a more pronounced display of the peripheral airways. For more information on using this feature refer to *Setting the Viewport* on page 6-9.

Setting the Viewport

The Set Viewport feature enables several display options for the Planning viewports.

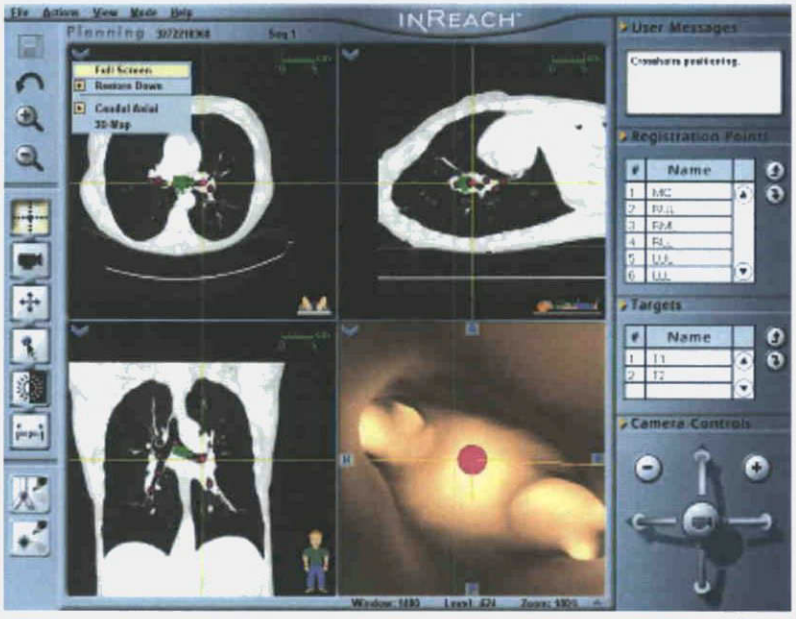


Figure 6-11: Setting the Planning Viewports *(new)*

Clicking the Set Viewport button located on the top left corner of the viewport, provides the Full Screen of the image and Restore Down to normal quadrant size.

123

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

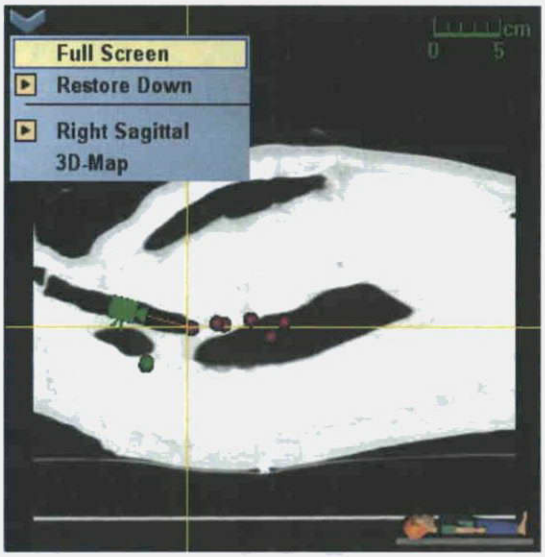
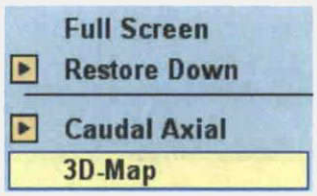
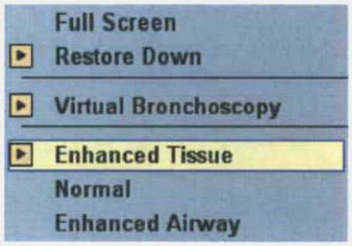


Figure 6-12: Setting viewport to full screen *(new)*

Additionally, the Axial, Sagittal and Coronal cross-section viewports may be set to display a 3D-Map or corresponding CT cross-section.



The Virtual Bronchoscopy view enables three Presets: Normal, Enhance Tissue, and Enhance Airway.



Graphical Objects

The following describes the graphical objects that can be marked and displayed over the Planning viewports.

Registration Points

Registration Points can be marked on the Virtual Bronchoscopy view and displayed over the CT cross-sections in all three cross-section viewports. Registration Points are displayed as purple points ( ).

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Targets

The Target represents the point that should be reached with the LG during the navigation phase. The location of the Target is marked during the planning stage in the CT cross-sections and the Virtual Image views. The Target is automatically acquired after the Registration phase during the procedure.
On CT scans with specified parameters, the Target can also be displayed on the 3D-Map.
Targets are displayed as green points ( ).

Waypoints (optional)

When 3D-Map generation is possible, Waypoints can be marked over the CT cross-sections viewports and displayed over the 3D-Map and the Virtual Bronchoscopy Viewports. Waypoints represent intermediate points to the Target and are displayed as blue points ( ).

Planning Module Controls and Functionality

Control Modes

You can select any of the following control modes by clicking with the left mouse button on the relevant button on the toolbar:



Crosshairs

Allows positioning of the crosshairs for creation of Registration Points and Targets and also enables specific crosshairs mode buttons. You can move the crosshairs by either clicking on the required spot in a viewport or clicking on the crosshairs and dragging it to the required location. The position of the crosshairs in one viewport automatically defines the cross-section that is displayed in the other viewports.



Camera

Allows positioning of the camera and enables specific camera mode buttons. You can control the position of the camera. The camera rotates on a sphere around the location of the crosshairs as set by you on the cross-section viewports when the image was generated.

125
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The camera is represented by a small icon with a directional line that always points in the direction of the crosshairs. The 3D virtual image displays from the perspective of the virtual camera towards the crosshairs.

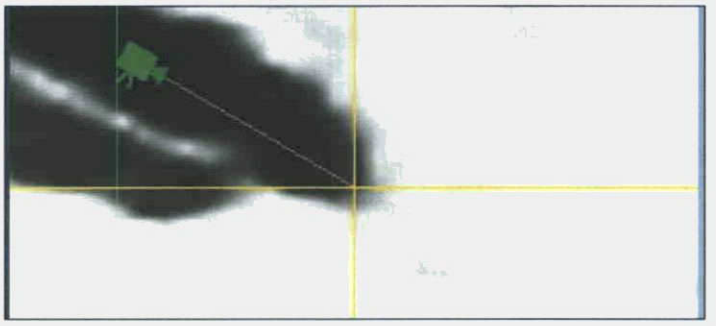


Figure 6-13: Camera's Directional Line points towards Crosshairs



Pan

This button allows you to move the viewing area. By clicking the left-mouse button and dragging the mouse simultaneously, the panning action moves the viewing area of all three CT cross-sections simultaneously in a synchronized action.



Select

This option can be used to select Registration Points and Targets. It also enables specific select mode buttons that allow you to bring the selected point back into view, rename and also to delete points.



Window/Level

This option allows you to set the Window and Level of all CT cross-sections for the best viewing options. CT images generally have a dynamic range of 4096 levels. Out of these possible levels, there is usually a range of intensity that is most suited to what you need to

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

see. This range is defined by setting the Window value, while the distance between the two ends of the range is called the Window Width. The intensity of irrelevant pixels, with values outside the Window, is mapped to black or white to highlight more relevant pixels.

The intensity of each image also has a certain distribution, which is defined by the Level setting.

To set the Window move the mouse left or right with the left-mouse button pressed. To set the Level, move the mouse up or down with the left-mouse button pressed. The Window/Level is automatically changed in all three CT cross-sections with the Window and Level values displayed on the screen.

The W/L Reset button is also enabled and allows you to return to preset Window and Level values. These image parameters are saved with the planning file, per each Target, and will be used during the display of CT cross-sections during the procedure.

Note

The images in the Procedure Module will be displayed at the Window and Level values that are set in the Planning module per each Target. These values can be changed in the Procedure Module as needed.



Distance Measurement

You can measure point-to-point distances over each of the CT cross-sections.




Zoom Options

You can increase or decrease the zoom level of the displayed images. The zoom level is automatically changed in all three CT cross-sections simultaneously. When the zoom level is changed, the system uses the crosshairs as the focal point and centers the other viewports simultaneously. You can also increase or decrease the zoom level by moving the mouse up and down respectively, keeping the right

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

button of the mouse pressed. You can also reset the zoom level to the original starting level.

Controlling the Camera

A 3D virtual image is displayed in the lower right viewport of the screen. There are two possible methods to navigate the camera in the virtual bronchoscopy view:

Attached Camera

In this method the camera is always directed on the location of the crosshairs. You have full control over the camera's location and distance from the crosshairs' intersection. The camera can be moved on a virtual sphere around the location of the crosshairs' intersection. The figure below shows that as the camera moves on the virtual sphere, it 'turns' so that it is always directed towards the crosshairs' intersection.

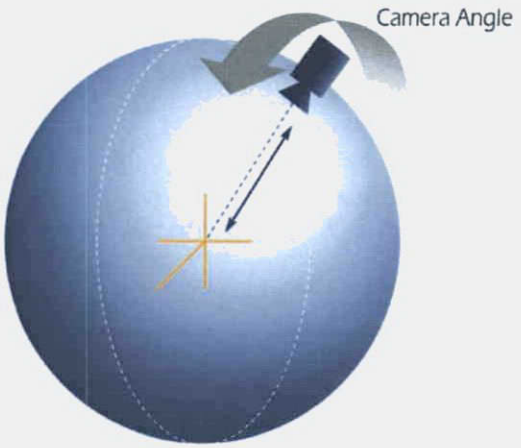


Figure 6-14: Camera's Rotational Sphere

Free Camera

In this method the camera can be moved freely without being always directed at the location of the crosshairs. While working in this mode the camera can be moved in the virtual image around its location.

You can use the following options to control the camera:

Controlling the Camera from the CT cross-sections viewport

Click the Camera button  to enable the Camera Control mode. You can move the camera's position by clicking on the left-mouse button and dragging the camera cursor in any of the CT cross-sections. While in the Crosshairs mode you can direct the free

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

camera to point in the direction of the crosshairs by clicking the right mouse button in the virtual image viewport.

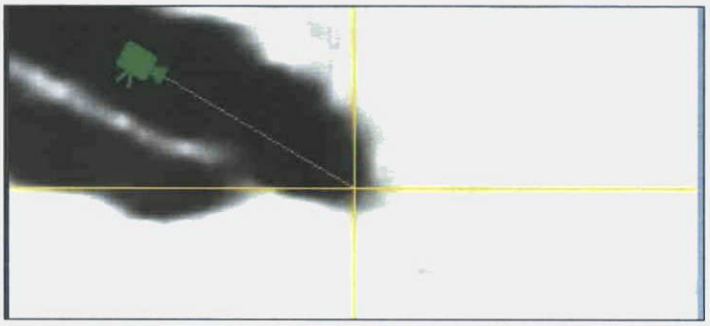


Figure 6-15: Camera's Directional Line points towards Crosshairs

Controlling the Camera from the Virtual Bronchoscopy Viewport

Click the Camera button  to enable the Camera Control Mode. To move the camera left or right, click on the left-mouse button and drag the camera in the Virtual Bronchoscopy viewport.

To move the camera forwards or backwards, click on the right-mouse button and drag the camera up to move it forwards or down to move it backwards.

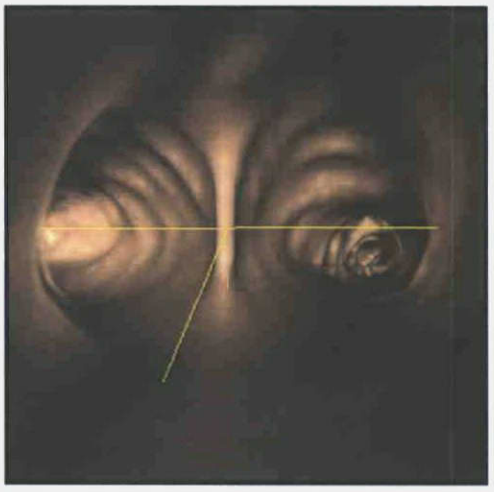


Figure 6-16: Camera Position in the Virtual Bronchoscopy viewport

Using the Camera Control Panel

The camera can also be controlled via the camera control panel.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 6-17: The Camera Control Panel *(updated)*

Use the following control panel buttons to position the camera as required.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Button	Description
	Moves the virtual view upwards.
	Moves the virtual view downwards.
	Moves the virtual view left.
	Moves the virtual view right.
	Moves camera backwards.
	Moves camera forwards.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning Phases

After you click the Planning button on the Opening Screen, the Planning module is activated.



Caution

The superDimension inReach™ System supports only CT and/or PET/CT scans made in a supine patient position.

Using a different patient position will result in a wrong display of the CT cross-sections in the application viewports.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Required CT Parameters

The superDimension inReach™ System loads CT scans in DICOM format. In order to generate the Virtual Bronchoscopy and 3D-Map views, it is necessary that the CT scan be performed within the following parameters:

	Virtual Bronchoscopy	Virtual Bronchoscopy and 3D-Map
Scanner Used	Multi-slice (4 and above) scanner	Multi-slice (4 and above) scanner
Image Dimensions	512x512 pixels (mandatory)	512x512 pixels (mandatory)
Area Scanned	Chest	Chest
Field of View	Optimized to include the whole chest	Optimized to include the whole chest
Scan Time	≤ 20 sec (single breath hold)	≤ 20 sec (single breath hold)
Slice Thickness Range	0.6 – 5.0 mm	2.0-3.5 mm
Slice Increment	0.5 -5.0 mm	1.5-2.0 mm
Overlap	No gaps. 0%-50%	25%-50%
Minimum number of slices	50 slices	50 slices
Maximum number of slices for 512X512	690 slices	690 slices
CT Reconstruction Filter	Soft Tissue	Soft Tissue: GE – STANDARD; Philips – B, C; Siemens – B30f-B41f; Toshiba – FC02-FC13

CT scans that cannot be loaded will be displayed as 'grayed out' in the Sequences window.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

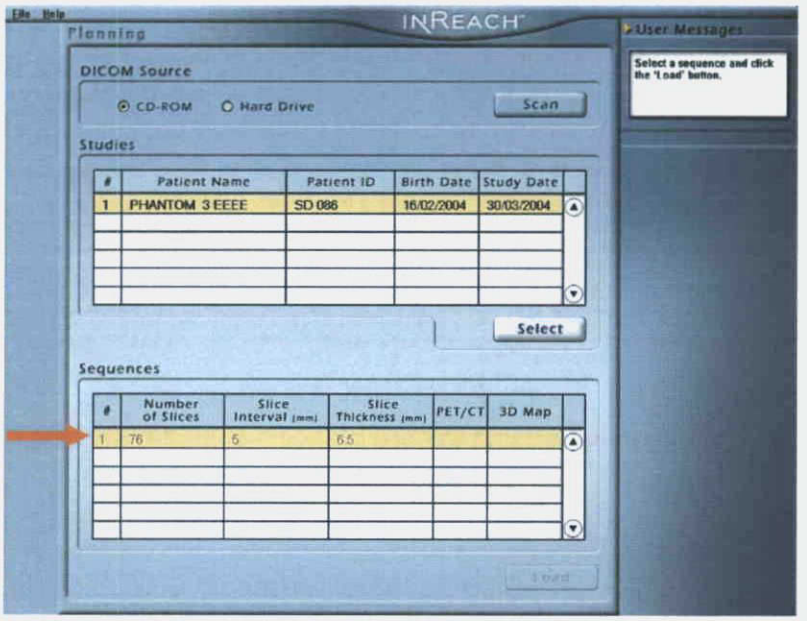


Figure 6-18: CT scans cannot load *(New)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Phase 1 - Loading a patient's study in DICOM format

The first phase requires you to select the required sequence of CT cross-section images from the patient's CT or PET/CT data, supplied from a CD or a DICOM system. Once loaded, the selected sequence is used for the creation of the planning file.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To load a patient's study from a CD:**

1. Insert the CD containing the patient's study into the CD drive.

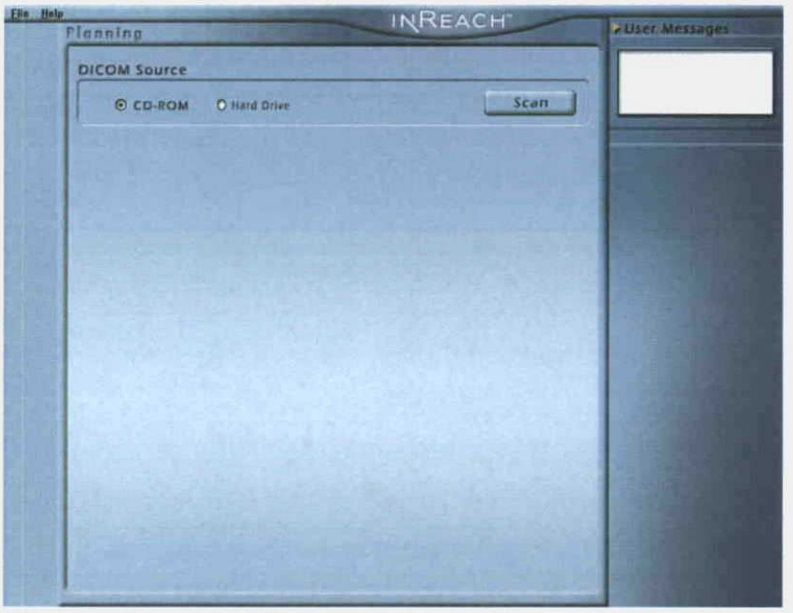


Figure 6-19: Loading a patient's study from a CD *(updated)*

2. Click the CD-ROM radio button, and then click the Scan button Scan.

Note
Do not open the CD driver during the DICOM loading phase.

The patient study list will appear.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

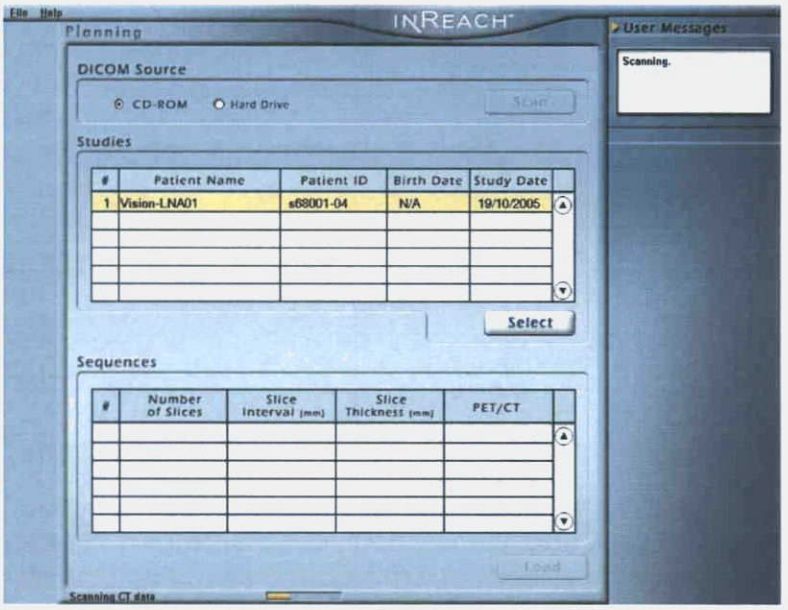


Figure 6-20: The Patient's Studies Selection *(updated)*

3. Click on the patient's name to select the patient, and then click the Select button Select.

   The available image sequences for the selected patient will appear.

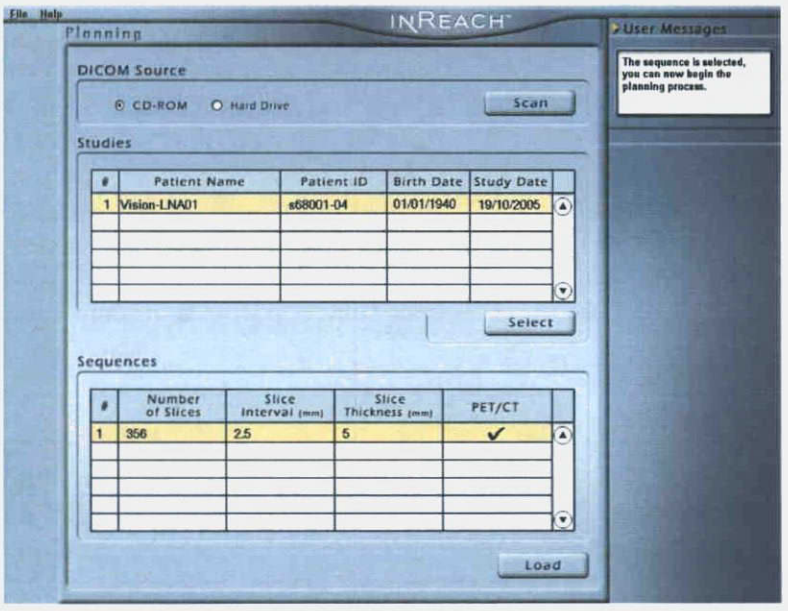


Figure 6-21: The Study Sequence Selection *(updated)*

4. Select the required sequence, and then click the Load button Load to load the sequence.

137

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Planning Screen, in which the registration points can be marked, will appear.



Tip

A sequence or study can also be loaded by double-clicking the selected row.

➢ **To load a patient's study from a DICOM System:**

The following steps are for systems with Query/Retrieve capabilities. In systems without Query Retrieve capabilities, the DICOM studies can be 'pushed' directly to the Remote Planning Station. In order to load the pushed studies from the hard drive follow the steps detailed in *To load a patient's study from Hard Drive* on page *6-30*.



Note

Before connecting to a DICOM System please consult with superDimension customer service for enabling the connection.

Connection to a DICOM System can only be established using a Remote Planning Station. Before connecting to the DICOM System, ensure that the Remote Planning Station is connected to an Ethernet outlet.

DICOM connectivity is not provided as a standard feature with the inReach™ System. Consult your superDimension representative for further information on DICOM feature installation.

1. Click the Scan DICOM System button , or select File>Connect to DICOM system.

   The Patient Query screen will appear.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

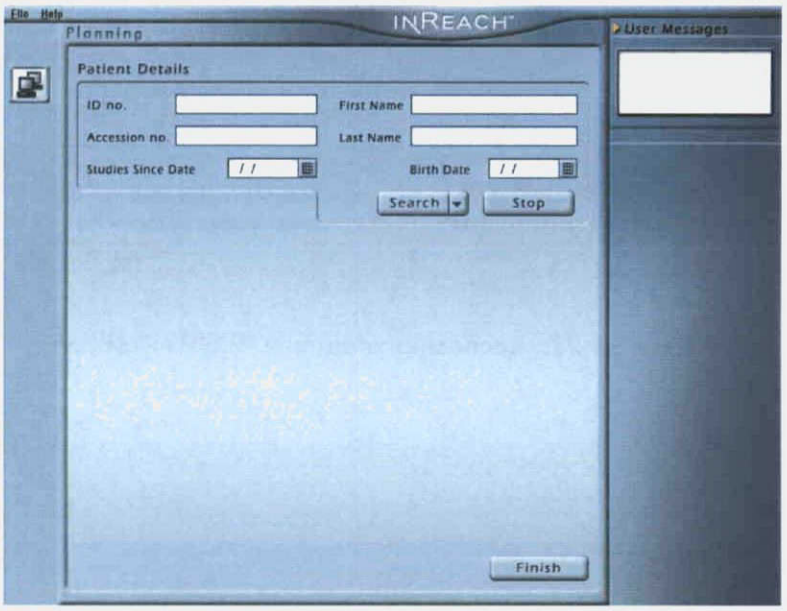


Figure 6-22: Patient Query screen *(updated)*

2. Enter the patient details in the search fields, and then click the Search button Search.

   In order to stop the query process click the Stop button Stop.



Tip

Try to enter as much information in the patient details fields. Entering only '*' (asterisk) in the patient details may result in a large amount of data being queried.

If more than one DICOM System is configured for query, click the Search button pull down menu to display the DICOM Systems. Select the desired DICOM System and click the Search button.

139

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

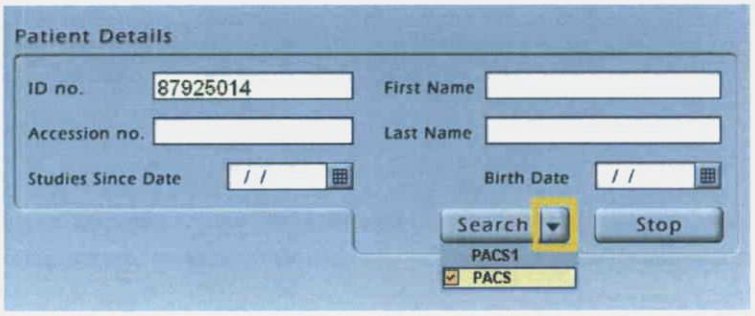


Figure 6-23: Accessing additional DICOM Systems

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

If the query retrieve is successful the query results will be displayed in the Studies table.

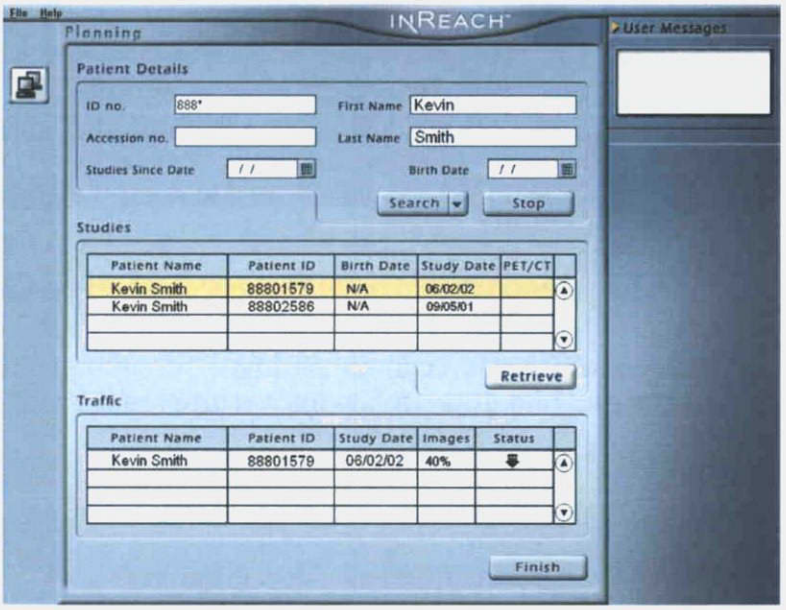


Figure 6-24: Query Retrieve to DICOM System *(updated)*

3. Select the required study, and then click the Retrieve button Retrieve.

   The lower window in Figure 6-24 displays the current loading activity and is illustrated in an enlarged form below.

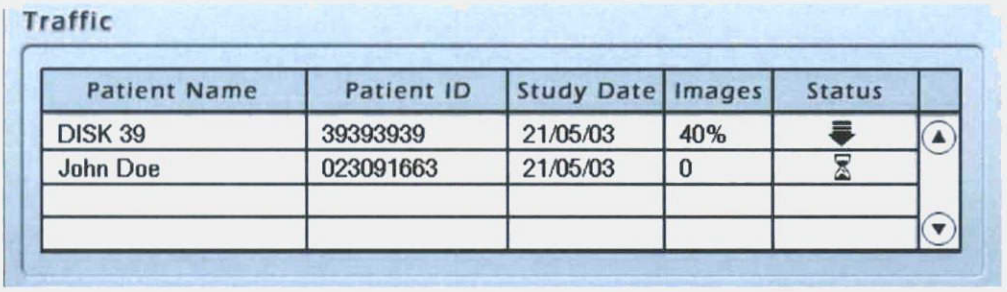


Figure 6-25: Traffic Table Window

The Status column of the Traffic activity window displays the following information:

- (Loading): The study is being loaded to the local hard drive.
- (Pending): The study is in queue and waiting to be loaded.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

141

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

- ✗ (Failed): Loading of the study failed due to a DICOM System connection problem. See Troubleshooting, on page 9-1 for further details.



Tip

A study can also be loaded by double-clicking the selected row.

The Studies table can be arranged by right clicking the table and selecting one of the following sorting criteria:

- Patient Name
- Patient ID
- Birth Date
- Study Date
- PET/CT Scan availability

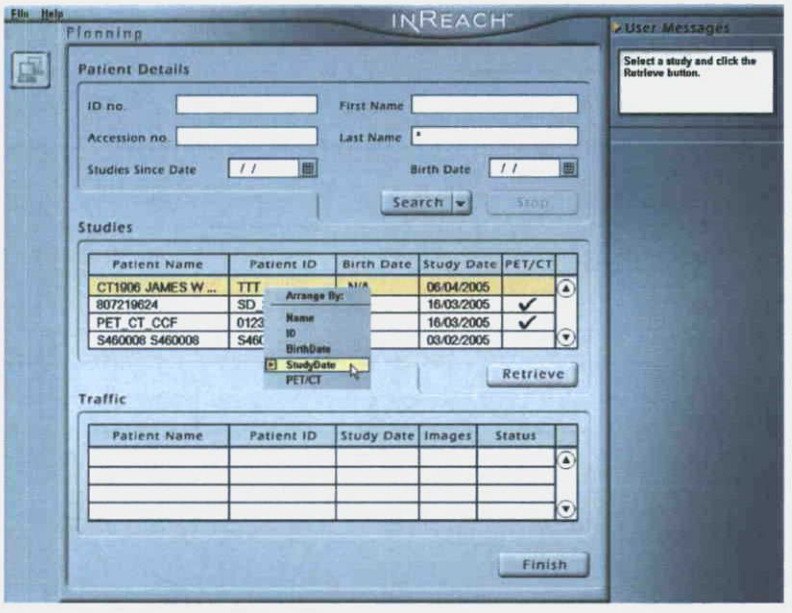


Figure 6-26: Arranging the studies table *(updated)*

Study and series information is displayed in a tooltip when the mouse cursor hovers over a study.

142

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

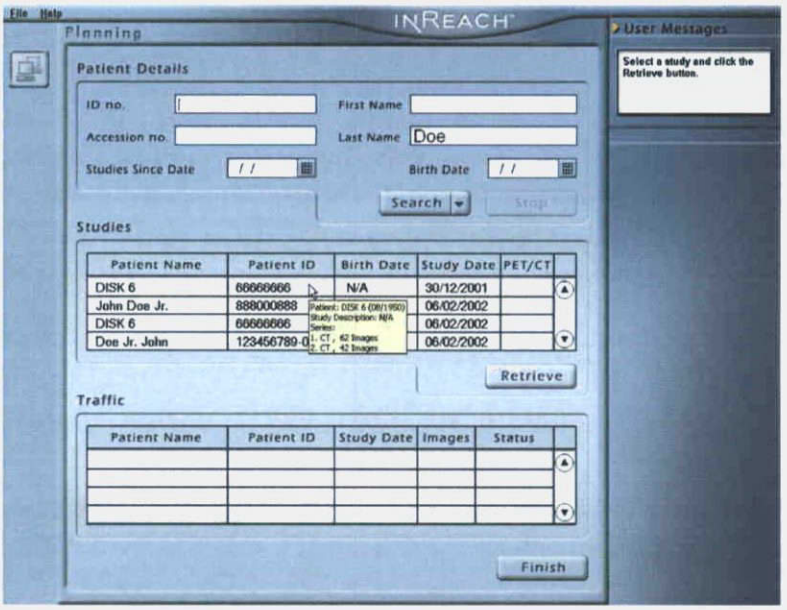


Figure 6-27: Mouse tooltip information *(updated)*

The Traffic activity window offers additional functionalities when right-clicking the studies:

- **Loading**: Cancel, Clear All Failed
- **Pending**: Cancel, Clear All Failed
- **Failed**: Restart, Clear, Clear All Failed.

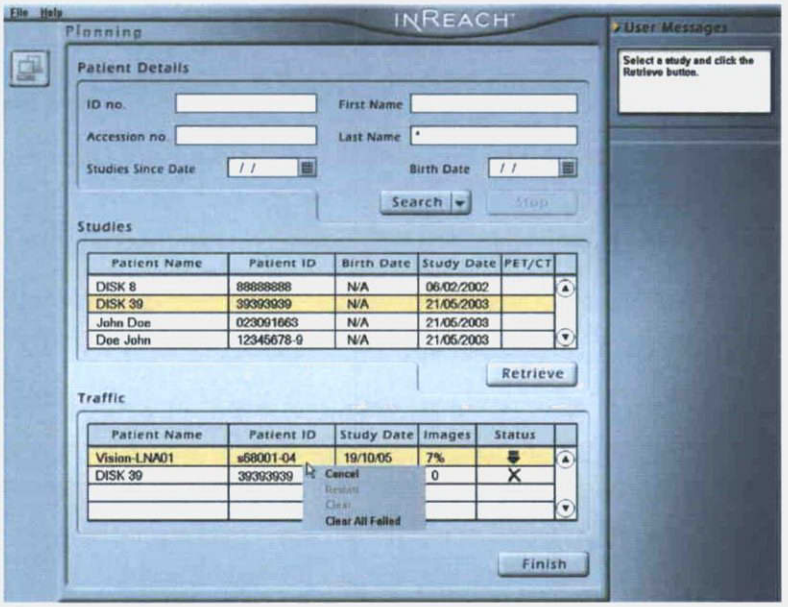


Figure 6-28: Traffic table attributes *(updated)*

143

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

4. Click the Finish button [Finish] to close the Query/Retrieve window and return to the Planning screen.

   Studies that were completely retrieved will be on the local hard drive. To access the studies follow the steps described in To *Load a patient's study from Hard Drive* on page 116-30.

➢ **To load a patient's study from Hard Drive:**

The following steps are for patient studies that were retrieved to the Hard Drive. Studies that were 'pushed' to the Remote Planning Station can also be loaded from the hard drive.

1. Click the Hard Drive radio button, and then click the Scan button [Scan].

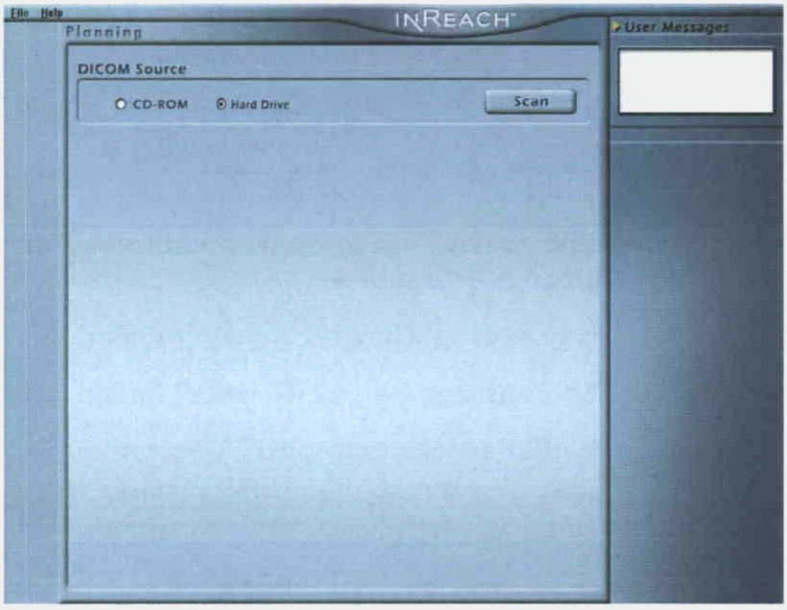


Figure 6-29: Loading patient study from Hard Drive *(updated)*

The patient study list will appear.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

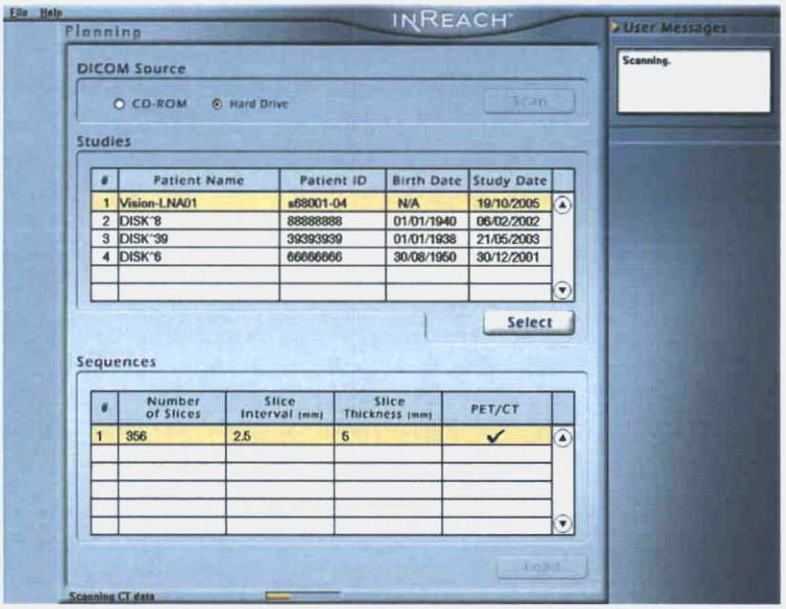


Figure 6-30: Patient's Studies Selection *(updated)*

2. The Studies table can be arranged by right clicking the table and selecting one of the following sorting criteria:

   - Patient Name
   - Patient ID
   - Birth Date
   - Study Date

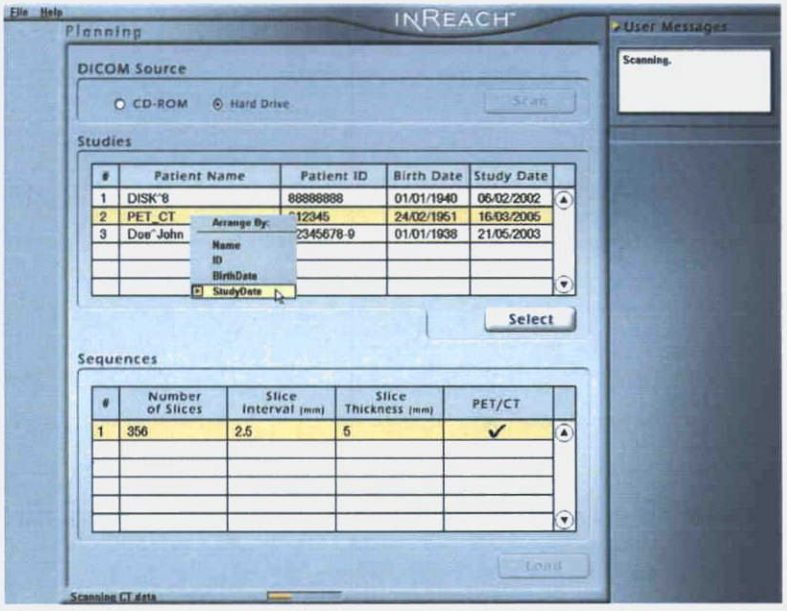


Figure 6-31: Arranging Patient's Studies *(updated)*

145
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

3. Click on the patient's name to select the patient, and then click the Select button Select.

   The available image sequences for the selected patient will appear.

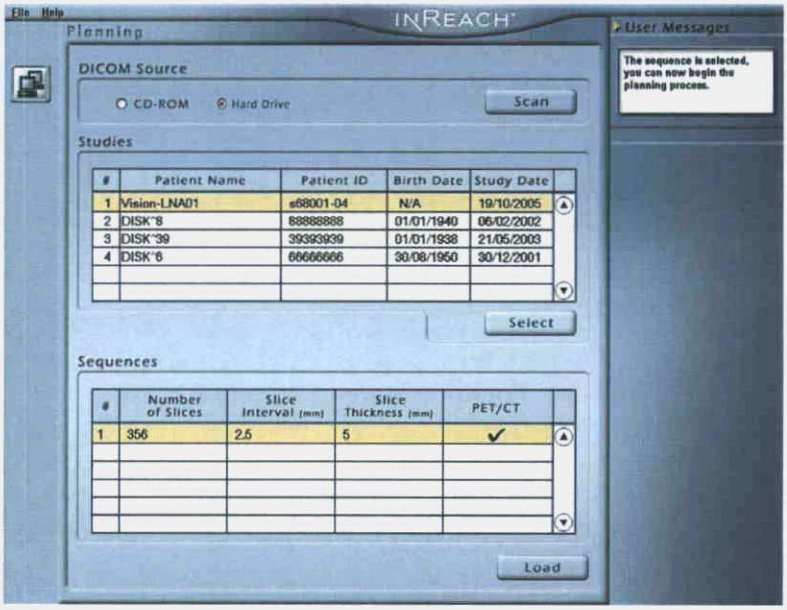


Figure 6-32: Patient Sequence Selection *(updated)*

4. Select the required sequence, and then click the Load button Load to load the sequence.

   The Planning Screen, in which the registration points can be marked, will appear.

➢ **To export the study to DICOM:**

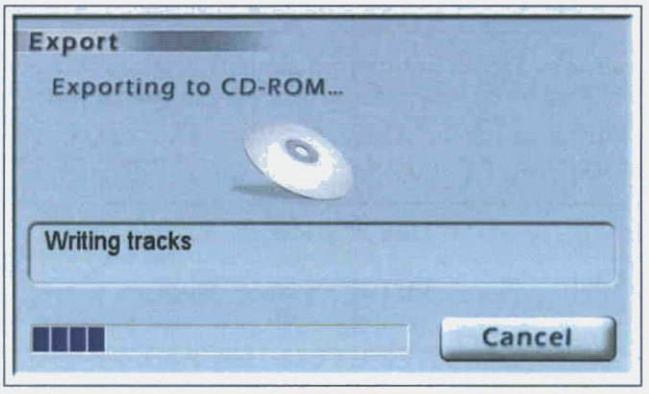
1. Select File>Export Study to DICOM.
2. Select the destination to export the study.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



3. If you choose to export the study to CD-ROM, insert a blank CD into the CD Writer.
4. Click Start.
   The following window will appear:



5. If you choose to export the study to a removable disk, insert a removable disk to the USB port and click Start.

PET/CT column

The PET/CT column identifies studies derived from a combined PET/CT modality.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

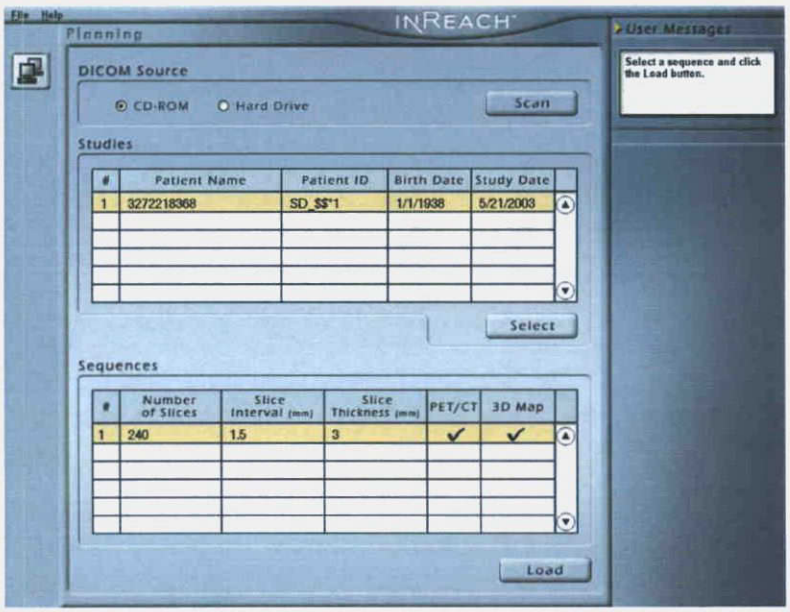


Figure 6-33: PET/CT column *(updated)*

The following table describes the combined PET/CT scan availability:

Icon	Description
✔	PET/CT Scan available.
Blank	PET/CT Scan not available.

For further details on PET/CT see *Combined PET/CT Scan* on page 6-41.

3D-Map parameters

The 3D-Map column identifies sequences that are suitable for 3D-Map generation. Scan parameters are displayed in a tooltip when the mouse cursor hovers over a sequence.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

148

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

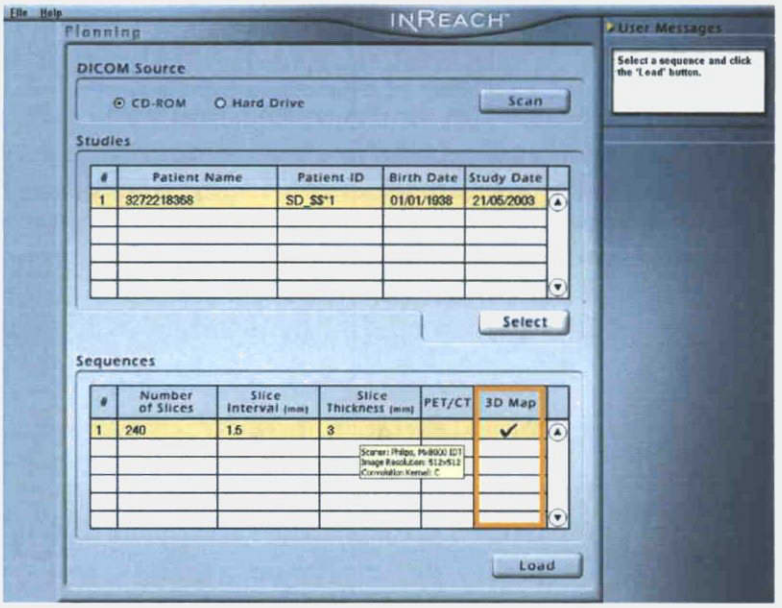


Figure 6-34: 3D-Map column *(updated)*

Note

3D-Map availability depends on compliance with the recommended CT parameters. For further information refer to *Required CT Parameters* on page 6-19.

The following table describes the 3D-Map quality levels:

Icon	Description
✓	CT parameters are suitable for 3D-Map generation.
✗	CT parameters are not suitable for 3D-Map generation.
!	The quality of the 3D-Map is not determined and the 3D-Map may not be displayed properly.

149

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Phase 2 – Marking the Registration Points

In this phase you mark the Registration Points, which will be matched to those of the actual anatomical locations of the patient during the procedure. Chose anatomical locations that are easily recognizable and that can be accurately located during the actual procedure registration process. The selection of registration points and the ability to locate these points and mark them during the procedure directly affects the accuracy of the overall system

➢ **To mark the Registration Points:**

1. Using any of the CT cross-section viewports, position the crosshairs onto the selected Registration Point or click on the required point.

   Note that the crosshairs will be automatically moved in the other viewports as well.

   Use the Zoom, Window/Level and Panning modes as needed, to achieve the best image display.

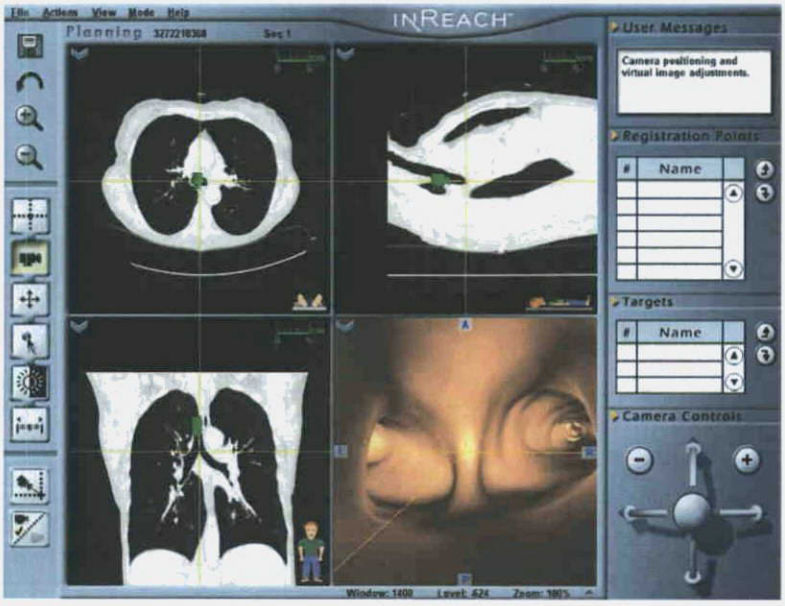


Figure 6-35: The Camera Mode *(updated)*

The position of the crosshairs appears in the Virtual Bronchoscopy viewport. The camera location and line of sight are displayed on the CT cross-sections. The camera location and distance can be adjusted using the 3D Camera Controls, as explained in *Controlling the Camera* on page 6-14.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

150

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

2. Click the Crosshairs mode and position the crosshairs on the required location in the Virtual Bronchoscopy view.
3. Once you have verified that the crosshairs are in the desired registration position, click the Add Registration Point button  or select Actions>Add Registration Point. Optionally, use the CTRL + R keyboard shortcut. It is important to select only positions that can be accurately located and marked during the actual procedure registration process.

   The Add Registration Point dialog box will appear.

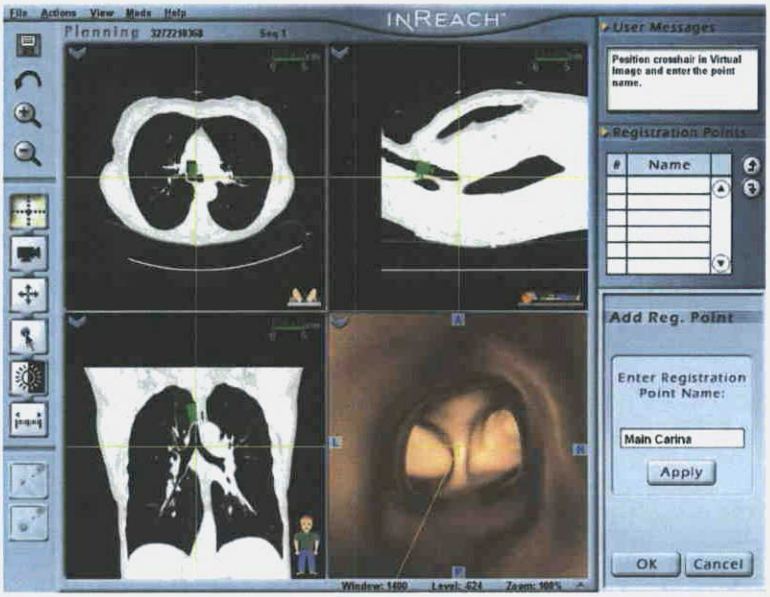


Figure 6-36: The Add Registration Points dialog box *(updated)*

4. Enter a name, without spaces at the end, for the currently marked Registration Point and click Apply to save it.

   The marked point will now appear in all viewports and will be listed in the Registration Points table section:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

151

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

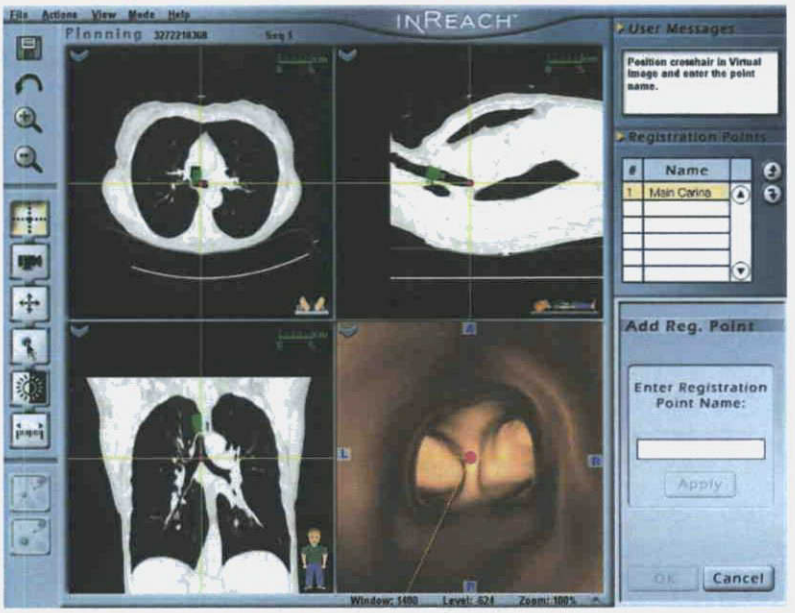


Figure 6-37: The Registration Points Table *(updated)*

5. Using any of the CT cross-section viewports, position the crosshairs to mark the next Registration Point or move to the location in the Virtual Bronchoscopy viewport.
6. Repeat this process until all the required Registration Points have been marked. On the last Registration Point click OK to close the dialog box.

Note

Five (or more) Registration Points are advised, specifically the Main Carina as well as two points in each lung, one in the lung's upper lobe and one in its middle/lower lobe.

152

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

For accurate CT-to-Body registration, it is advised to retain the bronchial tree in its natural shape as it appears in the pre-operative CT images. It is therefore recommended that you mark registration points in such anatomical locations to which access by the LOCATABLE GUIDE does not require forceful maneuvering which may temporarily affect the shape of the bronchial tree.

Editing a Registration Point Name

➢ **To edit a Registration Point Name:**

1. From the Registration Points table, select the Registration Point.
2. Double-click the selected point row or click the Edit Point button .
3. Edit the name as required and click OK.

Deleting a Registration Point

➢ **To delete a Registration Point:**

1. Select the Registration Point you want to delete from the list, and click the Delete Point button .
   The following message will appear:



2. Click Yes to delete the Registration Point.

153

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

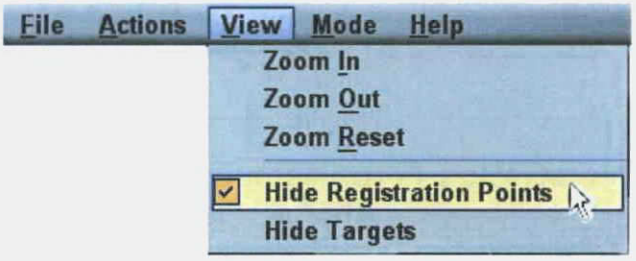
Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Hiding the Registration Points

➢ **To hide the Registration Points:**

Click View and select Hide Registration Points.

The Registration Points will be hidden in the CT sequences and Virtual Bronchoscopy Viewport. When in hidden mode, newly added Registration will be shown on the viewports.



Optionally, use the CTRL + SHIFT +R keyboard shortcut.

Display Directions

You can define the display direction of the three cross-section viewports to caudal or cranial. From the menu bar click View > Display Direction and select either the caudal or cranial view. Optionally, press F5 on your keyboard for caudal view or F6 for Cranial view.

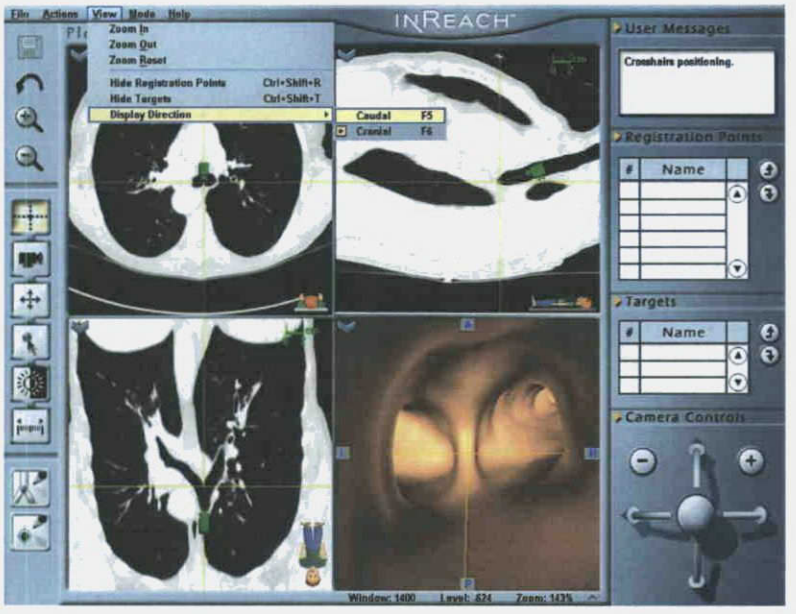


Figure 6-38: Selecting Display Direction *(updated)*

154

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Combined PET/CT Scan

➢ **To view a study in a combined PET/CT Scan:**

The CT view is loaded by default.

1. To view a study in a combined PET/CT Scan click View>PET/CT Fusion.

   Optionally, press F3 on your keyboard to toggle between CT and combined PET/CT views.

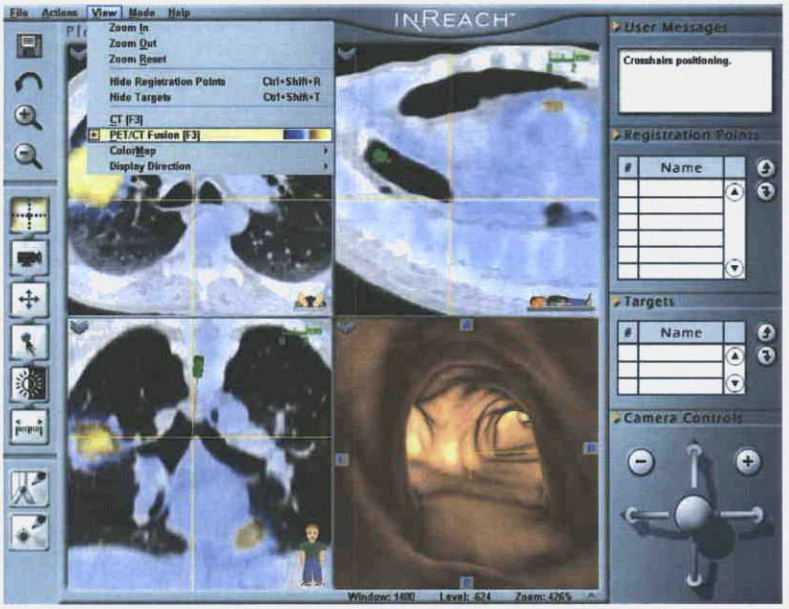
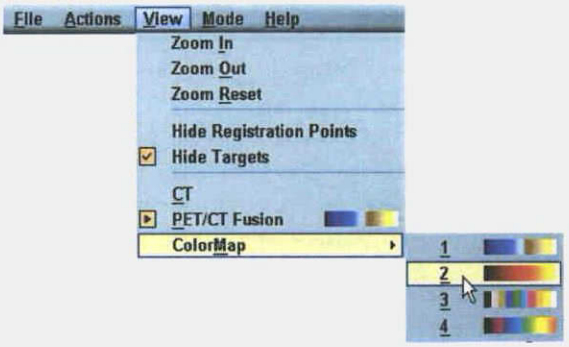


Figure 6-39: Accessing PET/CT function *(updated)*

2. Click View>ColorMap and select the desired PET/CT color tint in the lookup table. Optionally, press F4 on your keyboard to toggle between the available Color Maps.



Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

155

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Phase 3.1 – Marking the Target Locations and Dimensions

➢ **To mark the Target Locations and Dimensions:**

1. Using any of the cross-sections viewports, position the crosshairs onto the Target.

   Note that the crosshairs will be automatically moved in the other viewports as well.

2. Ensure that the marker is in the center of the Target.
3. Once you have verified that the marker is in the correct position, click the Add Target  button, or select Action>Add Target. Optionally, use the CTRL + T keyboard shortcut.

   The Enter Target Name dialog box will appear.

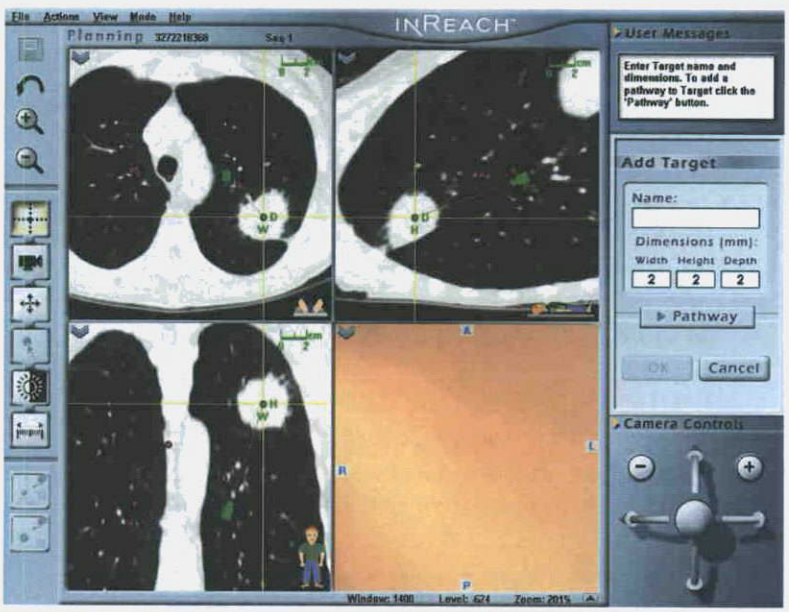


Figure 6-40: Enter Target Name dialog box *(updated)*

4. Set the dimensions of the marked Target so that the Target area is maximally covered in all CT cross-sections. Optionally, drag the Target area in all the CT cross-sections to the desired dimensions.
5. You may control the opacity level of the Virtual Bronchoscopy viewport during Target marking phase to better visualize the Target location on the Virtual Image as explained in *Controlling the Virtual Bronchoscopy Opacity Level* on page 6-8.

156

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

6. Enter a name for the currently marked Target and click OK to save it.

   The Target is listed in the Targets table section.

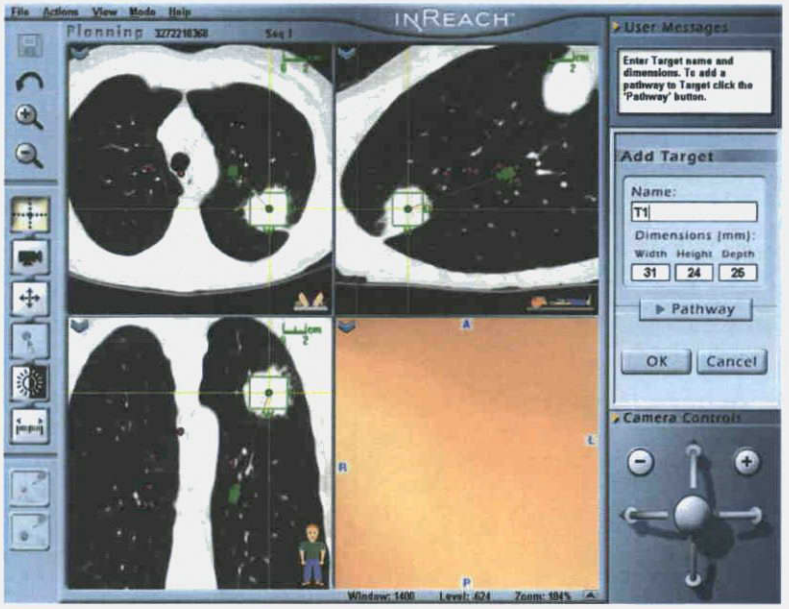


Figure 6-41: The Target *(updated)*

> **Note**
> There is no need to position the crosshairs on the Virtual Bronchoscopy viewport when marking Targets.

6. Repeat all the above steps until all the required Targets have been marked.

   To mark a Target with a Pathway see *Phase 3.2 - Pathway construction to Target* on page 6-45.

Editing a Target Name

➢ **To edit a Target name or dimensions:**

1. From the Target table, select the Target
2. Double-click the selected point row or click the Edit Point button 
3. Edit the Target name or dimensions in the dialog box as required, and click OK.

157

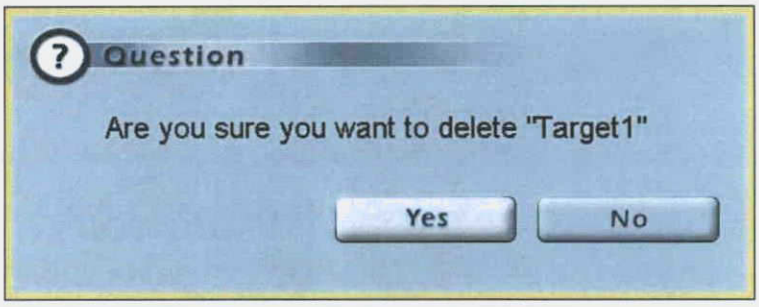
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Deleting a Target

➢ **To delete a Target:**

1. From the Target list, select the required Target and click the Delete Point button 
2. In the dialog box that appears, click Yes to confirm your command.





Note

Loading a Planning File, in the Navigation module, cannot be performed unless at least four Registration Points and at least one Target have been marked.

158

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

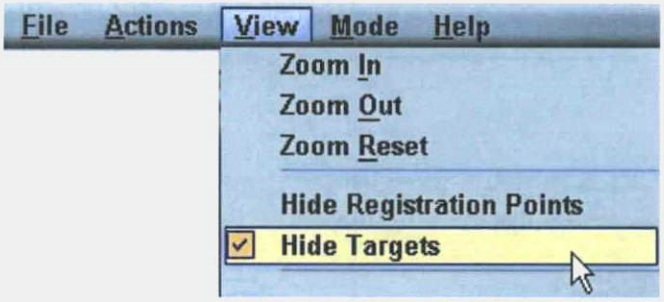
Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Hiding a Target

➢ **To hide a Target:**

1. Click View and select Hide Target.

The Target will be hidden in the CT sequences.



Optionally, use the CTRL + SHIFT +T keyboard shortcut.

Phase 3.2 - Pathway construction to Target

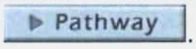
Once a 3D-Map is generated, one or more Pathways to Target can be constructed to assist in navigating to the Target. A Pathway is constructed using the 3D-Map as a reference.

The Pathway to the Target is marked using intermediate points, called Waypoints that lead to the Target. These Waypoints construct the Pathway. When the Target is outside of the periphery of the 3D-Map, Waypoints can be added to make up the remaining pathway to the Target.

The Pathway uses a 3D-Map geometrical representation of the bronchial airways. A 3D-Map is required for pathway construction.

3D-Map Generation

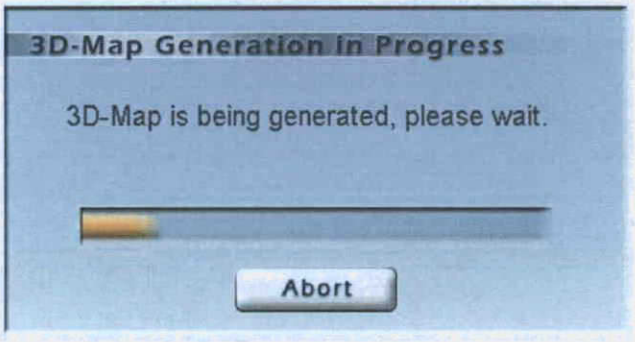
➢ **To generate a 3D-Map:**

1. The 3D-Map is generated only once during the Planning Module. The 3D-Map generation is initiated by clicking Actions > 3D-map on the menu bar or using the Set Viewport button  located on the top left corner of the viewport. The 3D-Map can also be initiated while in the Add Target dialog box by clicking the Pathway button 

.
2. The following dialog box will appear:

159
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



When the 3D-Map generation is complete, the 3D-Map View will appear.

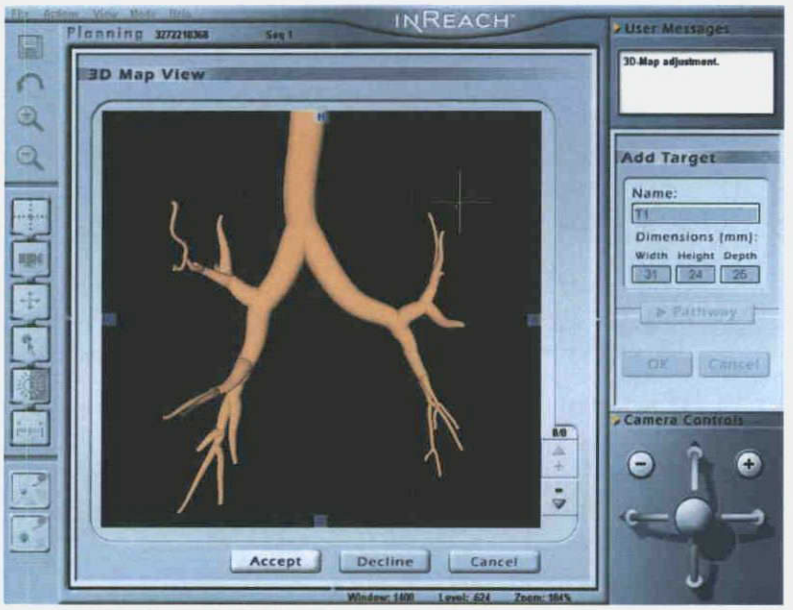
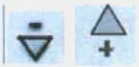


Figure 6-42: 3D-Map View *(New)*

3. To examine the 3D-Map use the following viewing controls:
   - Rotate: move the mouse while clicking and holding the left mouse button.
   - Zoom In / Zoom Out: move the mouse up and down while clicking and holding the right mouse button. Optionally, use the Camera Control Panel buttons.
   - Pan: move the mouse while clicking and holding the middle mouse button

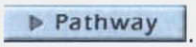
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

4. Click the Fine Tuning buttons  to the desired peripheral level of the 3D-Map.
5. Click the 'Accept' button if you wish to use the 3D-Map. If you do not wish to use the 3D-Map click the 'Decline' button.

Constructing a Pathway

➢ **To construct a Pathway with a Target inside the 3D-Map**

1. Click the Pathway button . The Pathway dialog box will appear. The pathway to the Target is constructed automatically and displayed on the 3D-Map viewport.
2. Using the CT cross-sections as reference, click on the 3D-Map to determine the end point of the Pathway.

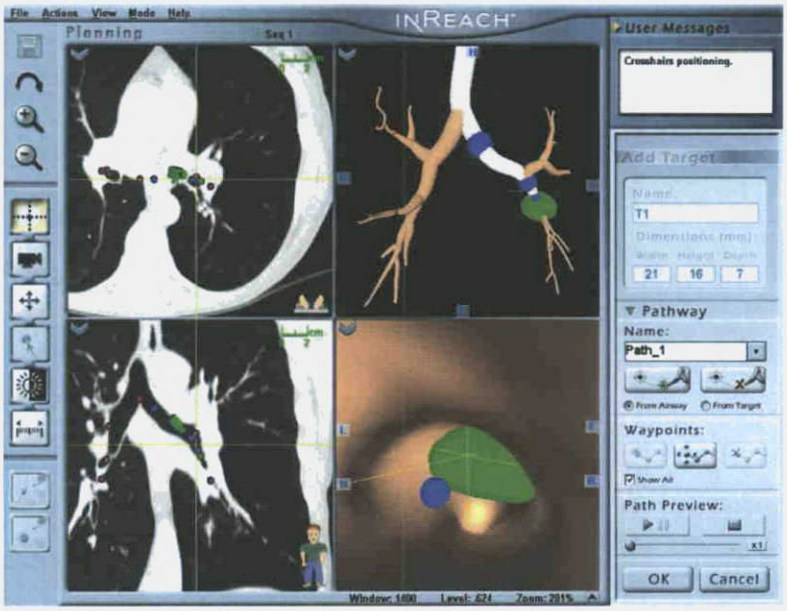


Figure 6-43: 3D-Map without exit point *(New)*

3. Enter the Pathway name and click OK to accept the automatically constructed Pathway.

➢ **To construct a Pathway with the Target outside the 3D-Map**

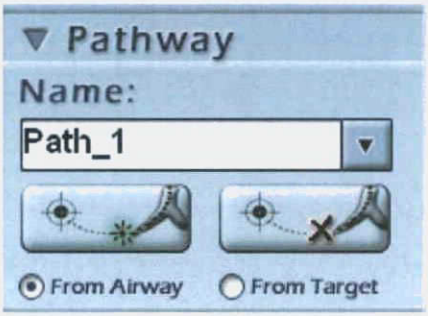
If the selected Target is located outside the periphery of the 3D-Map, intermediate Waypoints to the Target may be added manually.

1. Select if the Pathway is to be constructed 'From the Airways' or 'From the Target'. A pathway 'From the Airways' constructs a pathway from the airways toward the target. A pathway

161
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

'From the Target' constructs a pathway from the target toward the airways.



2. A gray-colored recommended pathway to the target appears on the 3D-Map. Using the CT cross-section viewports for reference, click on the desired Exit point on the 3D-Map. An Exit Point is the location on the airways on the 3D-Map leading the path to the Target. After clicking on the 3D-Map, the color of the pathway will change to white.

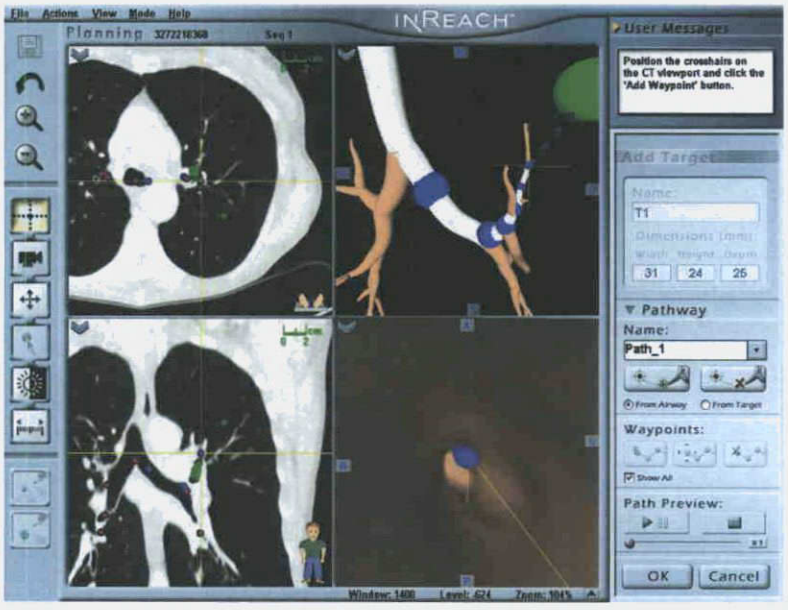


Figure 6-44: 3D-Map with exit point *(new)*

3. Using any of the CT cross-section viewports or the Virtual Bronchoscopy view, position the crosshairs on the desired location in the airways. Click the Add Waypoint button  to mark the Waypoint in the desired location.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

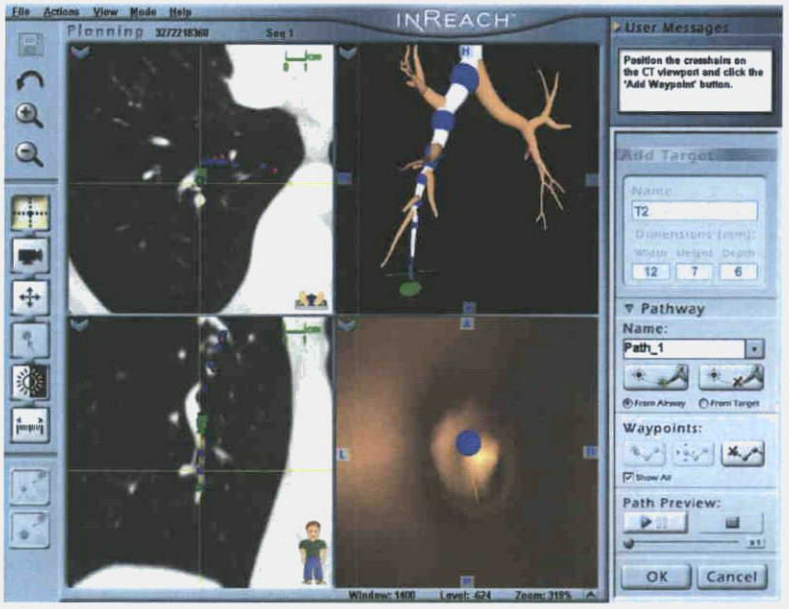


Figure 6-45: Adding Waypoint *(new)*

4. Repeat this process until all the desired Waypoints have been added.
5. To delete a marked Waypoint click the Delete Waypoint button . This will delete the last Waypoint added to the Pathway.
6. To reset all views to the last waypoint, click the Reset to Last Waypoint button .

Previewing the Pathway

Once the Pathway is complete a virtual navigation of the Pathway can be performed using the Pathway Preview feature.

The preview feature provides a virtual guided view of the selected Pathway to the Target.

Click the Play button to preview. The viewing speed can be adjusted by clicking the speed selector button .

The preview presents a virtual demonstration of the constructed pathway. The preview moves along the pathway toward the target and is also simultaneously displayed in the Virtual Bronchoscopy and CT cross-section viewports. The preview may be paused at any time and the 'Zoom In' and 'Zoom Out' buttons can be used in the CT cross-section viewports to further analyze the pathway.

163

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

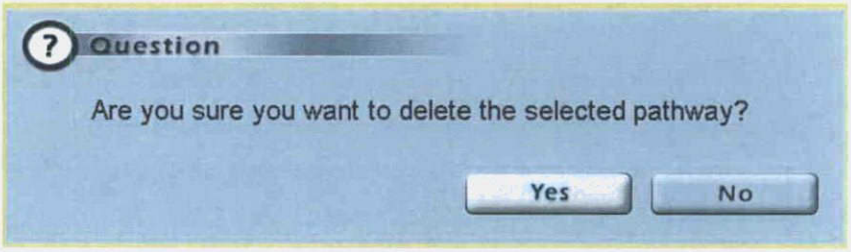
Note

It is recommended to use the Pathway Preview feature to thoroughly analyze and study the constructed pathway(s) to the target(s).

Deleting a Pathway

➢ **To Delete a Pathway**

1. Select the Pathway you want to delete from the list, and click the Delete Pathway button .
2. In the dialog box that appears, click Yes to confirm your command.



Deleting a Target with a Pathway

➢ **To delete a Target with a Pathway:**

1. From the Target list, select the required Target and click the Delete Point button .
2. In the dialog box that appears, click Yes to confirm your command.



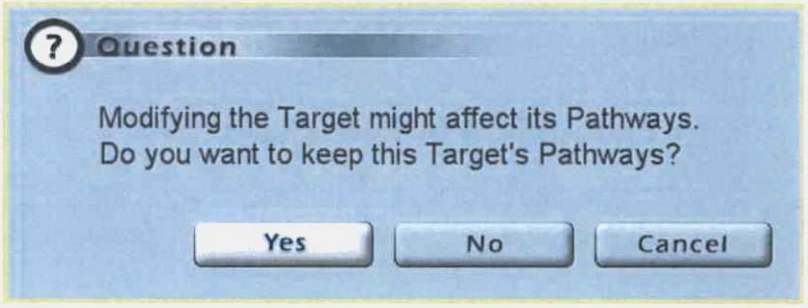
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Changing a Target's location

➢ **To change the location of Target with a pathway**

1. From the Target list, select the required Target and click the Edit Point button.
2. Using the cross-sections viewports, position the crosshairs on the newly located Target.
3. In the dialog box that appears, click Yes to retain the target's pathways. Click No to delete the existing pathways and reconstruct other pathway(s) to the target.



Hiding the Waypoints

➢ **To Hide the Waypoints**

1. Click View and select Hide Waypoints. Optionally, click the 'Show All' checkbox in the Waypoints dialog box

   The Waypoints will be hidden in the CT cross-section and Virtual Bronchoscopy viewports. When in hidden mode, newly added Waypoints will be shown on the viewports.

Phase 4 – Saving the Planning File and Exiting

➢ **To save the Planning File:**

1. Once all the required Registration Points and Targets have been set, click the Save Planning File button , or select File>Save Planning data.

   The Planning File will be saved to the local disk.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

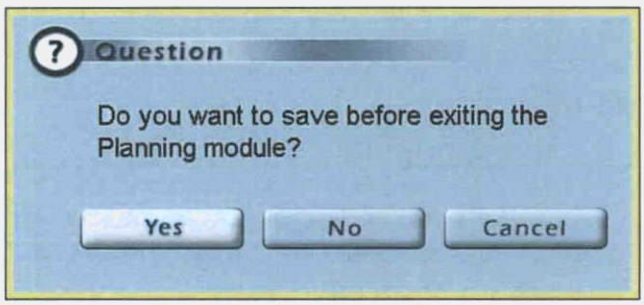
➢ **To exit the Planning Module:**

1. Select File>Exit.
2. To confirm your command, click Yes in the dialog box that will appear.



The Planning Module will be closed and the Opening Screen will appear.

If the file was not saved before you clicked Exit, the following dialog box will appear:



If you click No, the Planning Module will be closed and the data will not be saved.

If you are working with a Remote Planning Station (laptop), the following dialog box will appear:



Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

For information regarding Planning File export, please see *Phase 5 – Exporting Planning File on* Page 6-54.

If you click No, indicating that you do not want to export the planning file, the Planning Module will be closed and the data will not be exported.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Phase 5 – Exporting the Planning File

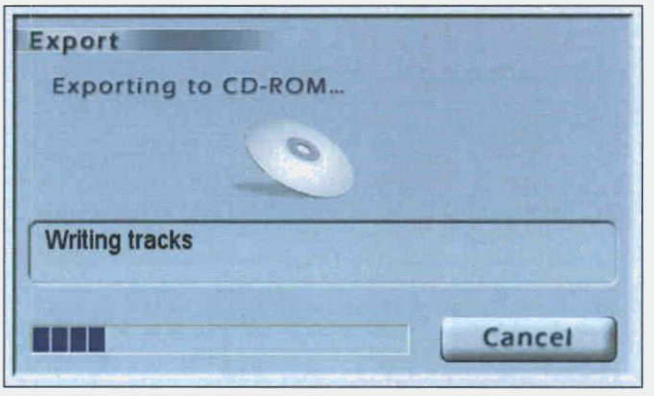
Note
This procedure is for a Remote Planning station.

➢ **To export the Planning File:**

1. Select File>Export Planning File.
2. Select destination to export the Planning File.



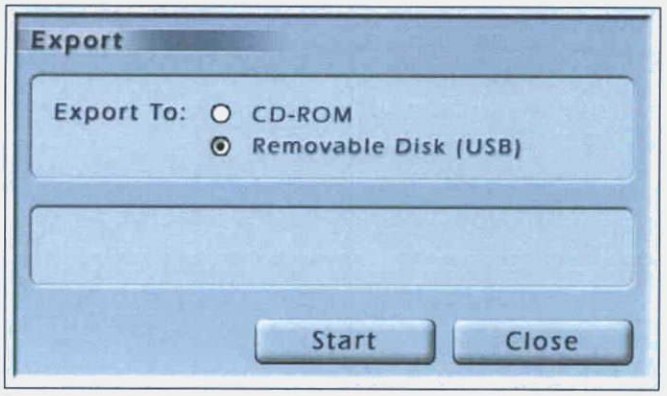
3. If you choose to export the file to CD-ROM, insert a blank CD into the CD Writer.
4. Click Start.
   The following window will appear:



5. If you choose to export the file to a removable disk, insert a removable disk to the USB port.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



6. Click Start.
   The following window will appear:





Caution

To safely extract the Removable Disk (USB) wait until the LED on the USB stops blinking. Removal of the USB while the LED is still blinking may lead to data loss or damage to the Planning file.

It is recommended to use only the Removable Disk (USB) that is supplied with the superDimension inReach™ System.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

169

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 7: Procedure Module

Module Overview and Workflow

The Procedure Module is used to direct the LG (refer to *Using the Locatable Guide and Extended Working Channel* on page 7-63 for further details) to the required Target. This maps a clear path to the Target along which you can perform the necessary bronchoscopic procedure. The patient's Planning File, created in the Planning Module, is loaded for use in the Registration process. The data from the Planning File and the patient's location is "matched" so that the marked Targets can be displayed during the Navigation procedure.

The inReach™ Planning Laptop can be used stand-alone for bronchoscopy planning or CT-Viewing or with the other system components. If the PlanningLaptop is used stand-alone disregard the information related to the inReach™ System procedure module.

With the Target(s) clearly marked in the Procedure viewports, insert the LG into the working channel of the bronchoscope and navigate it towards the selected Target. The Procedure viewports display both the tip of the LG and the current Target so that the position of the LG in relation to the Target is always visible.

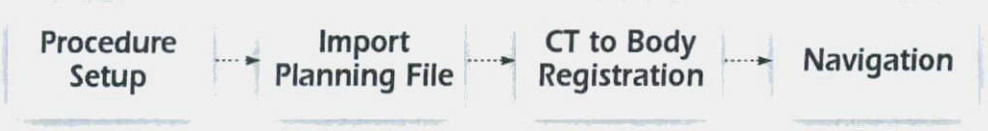


Figure 7-1: The Workflow of the Procedure Module

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Phases

Once you have selected the Procedure Module option from the Opening Screen, the Procedure Module is activated.

Phase 1 – Procedure Module Setup

➢ **Set up the Procedure Module:**



Caution

There are certain details that must be verified before the setup in order to assure accuracy of location.

Specifically:

- The LOCATION BOARD PADS must be kept bonded on the table at their original setup location.
- The LOCATION BOARD must be located correctly on the LOCATION BOARD pads. See Figure 5-5.

The table arrangement (for example, table-top position with respect to its support leg) must be identical to its arrangement during system setup.



Tip

Error messages may be displayed if the system detects any technical problems.

Refer to *Error Handling* on page 9-1.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

171

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

1. The Procedure Room Configuration page will appear:

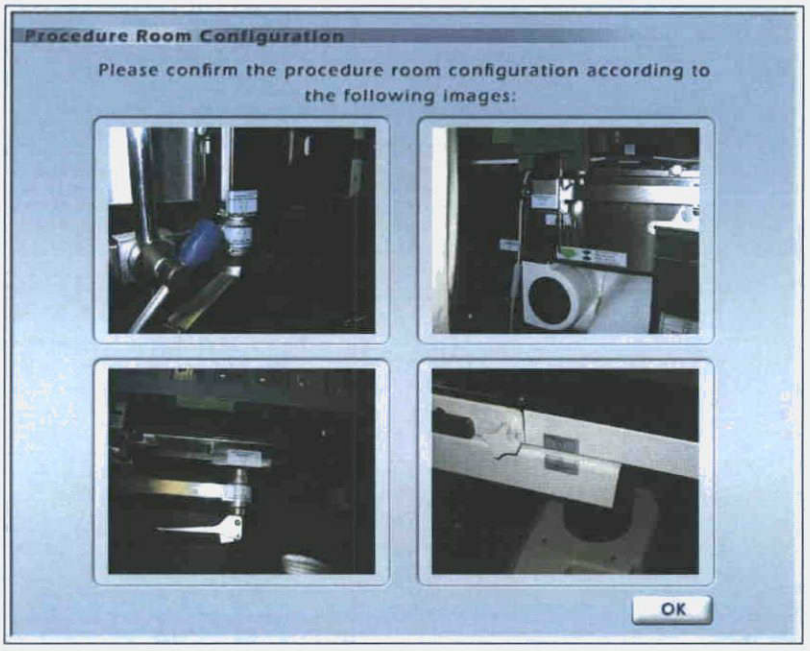


Figure 7-2: Procedure Room Configuration

2. Make sure that the room has been configured (for example, table-top position with respect to its support leg) according to the images displayed. Click OK to confirm.

	**Warning** Significant changes to the configuration of the bronchoscopy suite, including introduction of new metallic equipment or movement of existing metallic equipment can affect the accuracy of the system. Contact superDimension customer service to schedule a recalibration of the instrument prior to making bronchoscopy suite reconfigurations

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Load Planning File dialog box will appear.

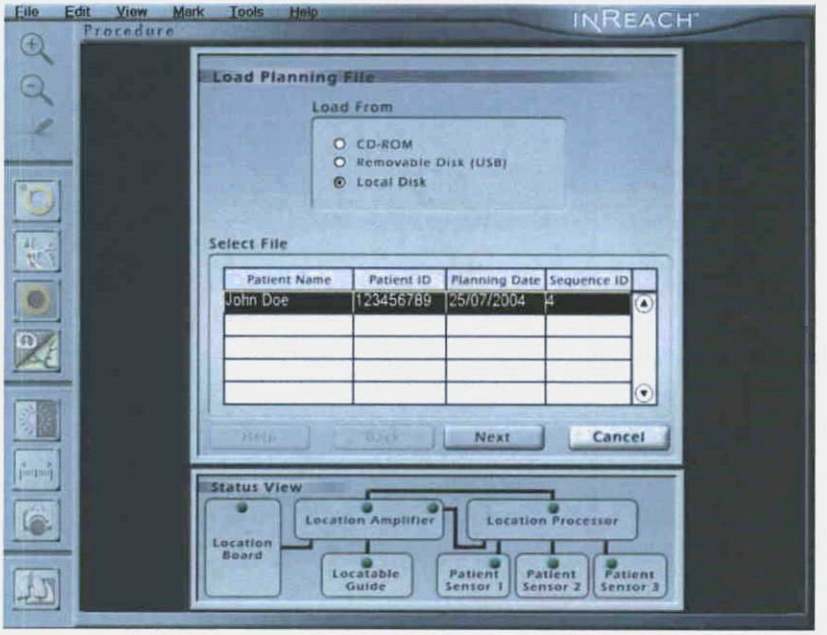


Figure 7-3: The Procedure Setup dialog box *(updated)*

The upper window displays the Planning File loading options, as shown in Figure 7-3.

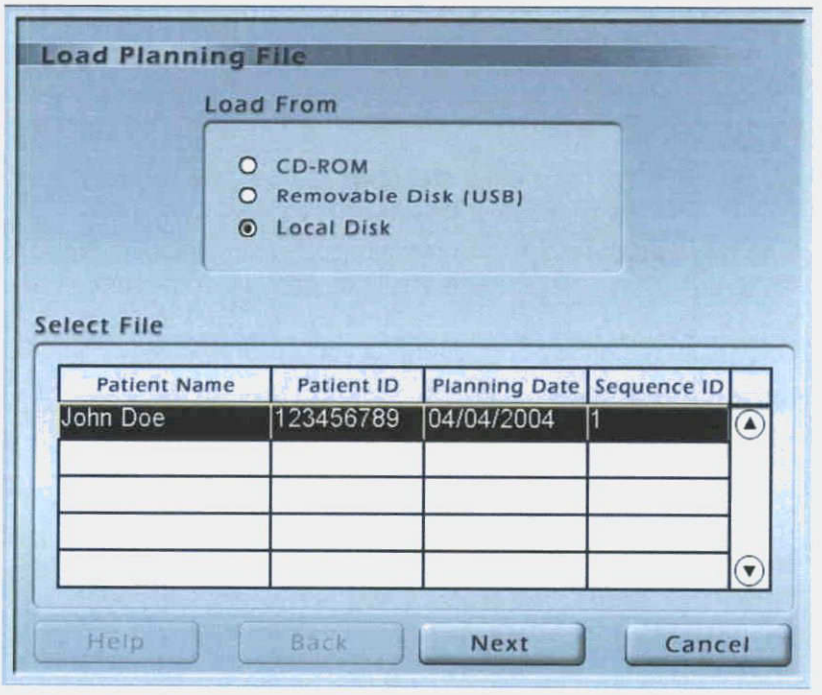


Figure 7-4: Loading Planning File *(updated)*

The lower window in Figure 7-3 displays the status of the system devices and is illustrated in an enlarged form, as shown in Figure 7-5.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

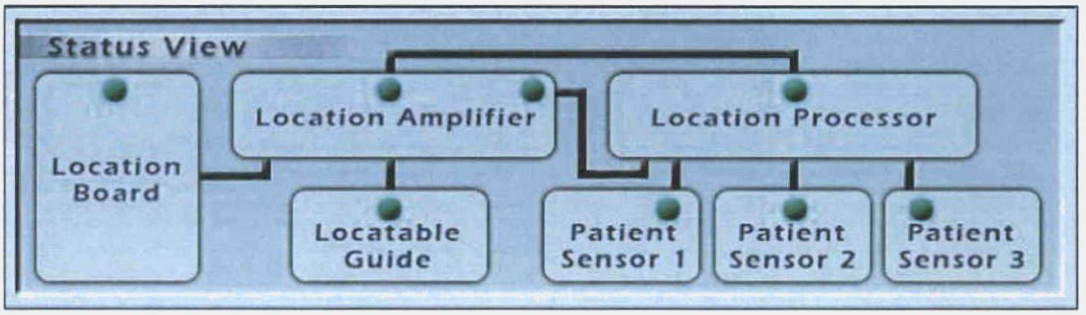


Figure 7-5: The Status View

The indicator lights display any of the following three colors:

- A green light indicates that the system component is working properly.
- A yellow light indicates that a system component is not ready.
- A black light indicates that there is something wrong with the connections of the system components, or the components themselves. See *Log and Status Views*, on page 7-92 for further details.

➢ **To load a Planning File:**

1. To select a Planning File, select one of the Load From options.
2. If you choose to load from a CD-ROM, insert a CD-ROM with the Planning File to the PC.
3. If you choose to load from a removable disk, connect a removable disk with the Planning File to the PC.
4. From the Select File section, select the required Patient's row.
5. Click Next.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

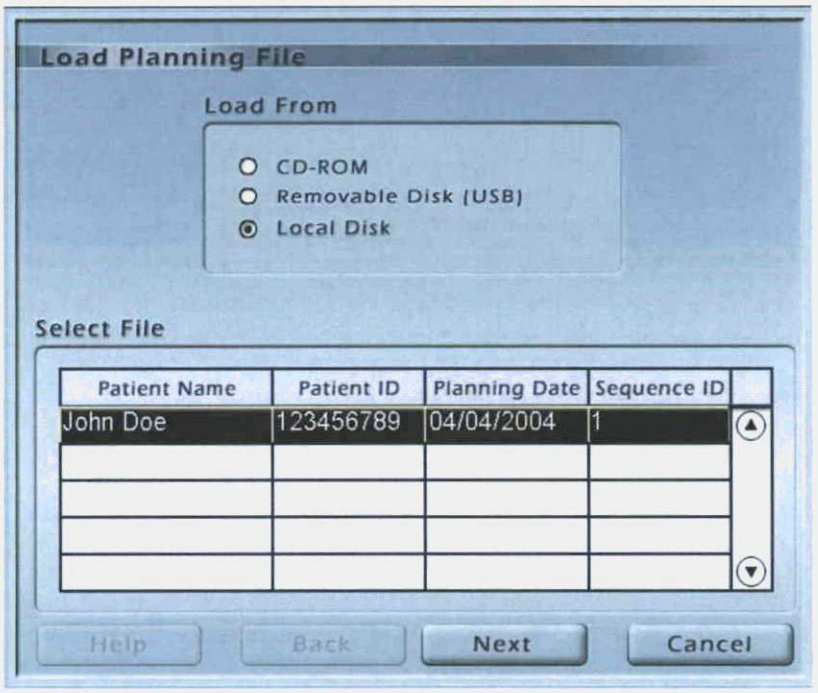


Figure 7-6: Loading Planning File *(updated)*

The patient's details from the Planning File are displayed in the Procedure Setup window.

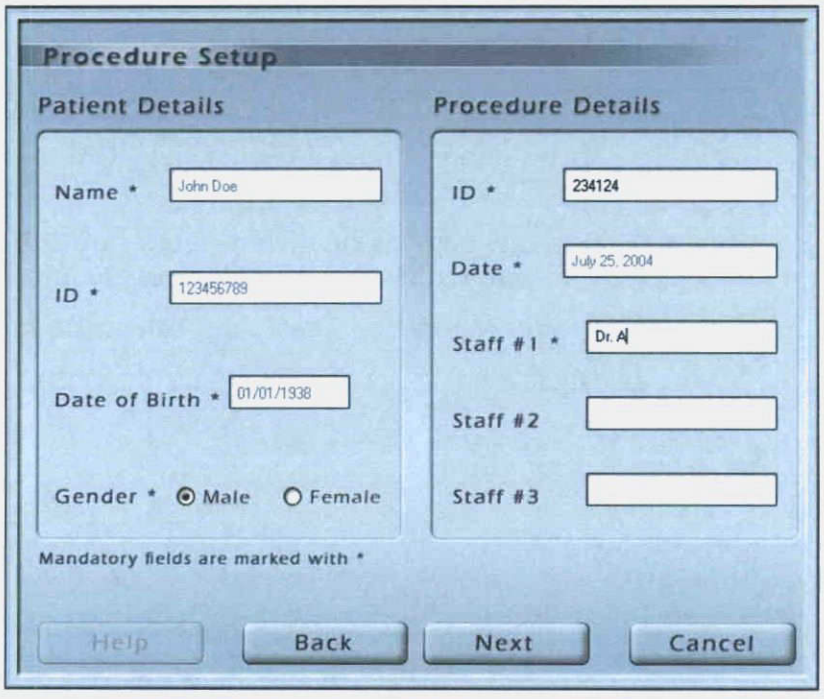


Figure 7-7: Patient Details window

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

6. Check the Patient and Procedure Details and edit if required.

   Note that fields marked with an asterisk are mandatory and must be completed in order to proceed.

7. Click Next to continue.

8. Using the PATIENT SENSOR PATCHES, attach the PATIENT SENSORS to the patient according to Figure 7-8.

Figure 7-8: Location of the Patient's Sensors

The PATIENT SENSORS, attached to the patient, are tracked by the system to compensate for changes in the position and orientation of the patient during the procedure.

9. Place the first sensor two fingers below the sternum notch.

10. Place the second sensor along the right midaxillar line on the eighth rib, and the third sensor along the left midaxillar line on the eighth rib.



Caution

In rare cases, sensitive individuals may have a mild transient skin rash after the use of the Patient Patches.

11. Connect the Patient Sensor Cables to the matching connectors located on the Sensor Connectors Panel, as shown in Figure 5-1.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

126

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The system will now check the location of the PATIENT SENSORS. The position of the PATIENT SENSORS is displayed in relation to the Location Board Sensing Volume Borders.

The following window, requesting that you adjust the Patient's position if necessary to align the patient sensors with the Location Board, will appear.

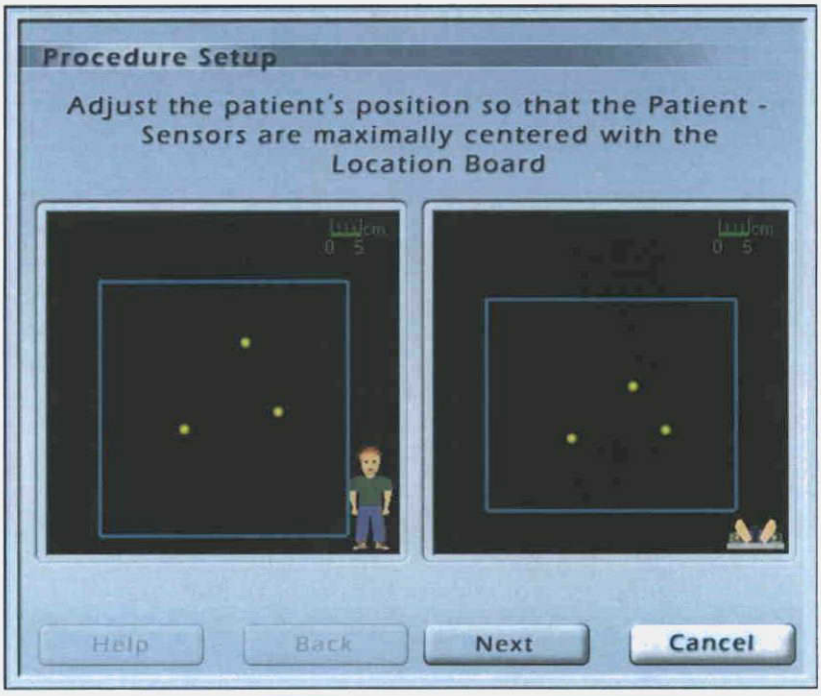


Figure 7-9: Adjusting the Patient Sensors' Location

If one or more of the PATIENT SENSORS are outside the Sensing Volume Borders, the Next button will be disabled.

12. Adjust the patient's position so that his/her chest area is centered over the Sensing Volume Area.
13. Once all the PATIENT SENSORS are correctly positioned within the Sensing Volume Borders, click Next. The following window will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

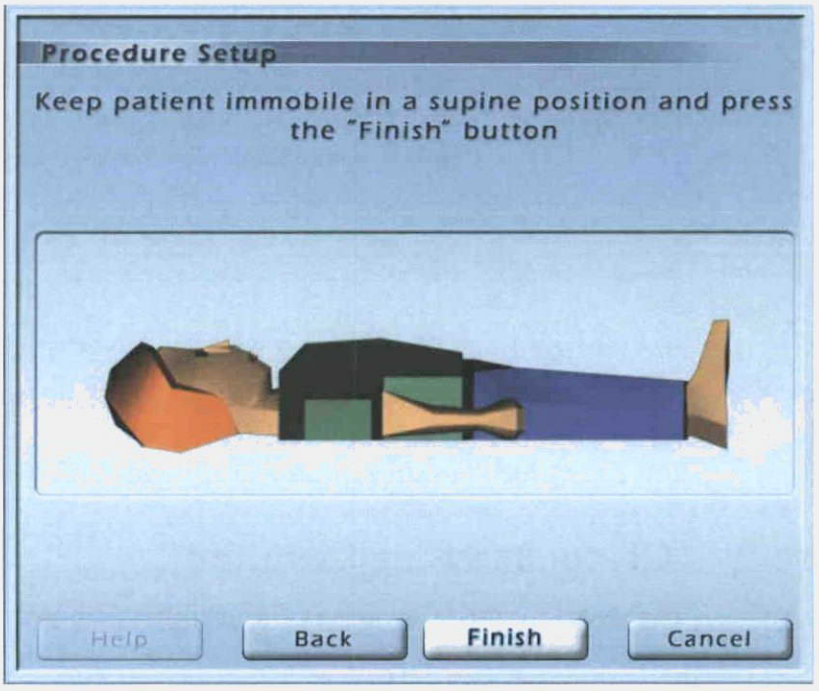


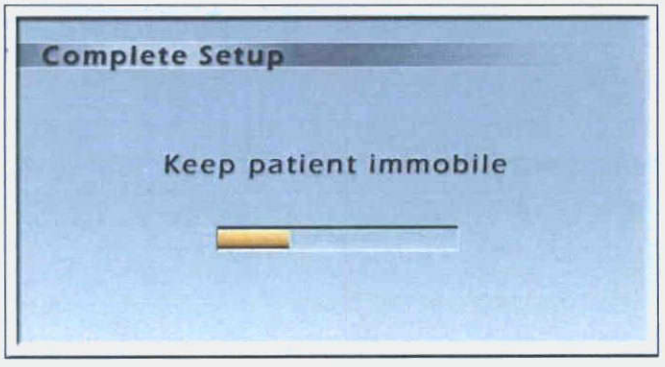
Figure 7-10: Keep patient immobile and press Finish

Warning

Excessive patient movement during use of the inReach™ System can affect the accuracy of the system potentially resulting in tissue irritation and possible injury to the bronchial airways.

The patient must be kept in a supine position.

14. Keep the patient immobilized in his/her current position and click Finish to complete the setup phase. The following message will appear:



178

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

The patient should be immobile for five seconds from the time that the Finish button is clicked.

The Setup phase is now complete. The next phase is Registration.

The LG can be attached at this stage and will be recognized by the system once it is correctly connected. See *Using the Locatable Guide and Extended Working Channel* on page 7-63 for further details.

Phase 2 - "CT-to-Body" Registration

Registration is the process of matching Registration Points, which were marked on the patient's CT images and saved in the Planning File, with actual locations in the patient's body. Once the listed Registration Points on the Planning File are matched to the correlating points in the patient's body, the marked Targets are also matched to the patient's body, so that you can view them during the Navigation phase, on top of the different CT cross-sections.

Registration Points are registered by physically placing the LG's tip on the exact location that correlates to the selected Registration Point. It is important to use care when performing the registration process. The more accurately the registration points are marked with the LG during this process, the more accurately the CT image is registered to the patient. A minimum of four Registration Points must be acquired before you can proceed with the navigation phase.

Once the setup has been completed, the following window will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

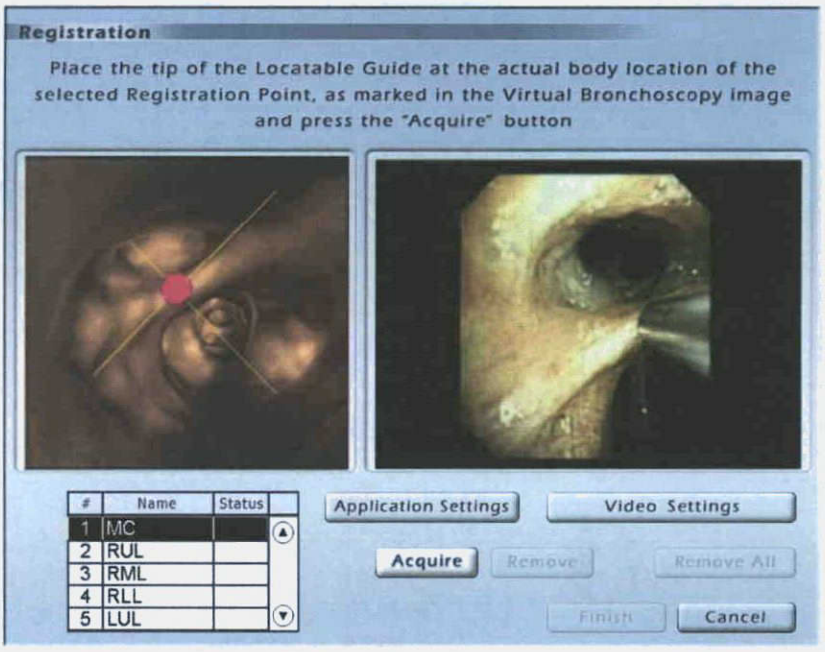


Figure 7-11: Registration Phase *(updated)*

➢ **To carry out Registration:**

1. A list of Registration Points is displayed in the table. A virtual image of the selected point is displayed, showing the exact location for marking the registration point. By default the first point is selected (highlighted). Use the remote control, touch-screen or mouse to scroll and select another point if required.
2. Position the tip of the LG on the exact location of the selected Registration Points in the patient's body and, using the REMOTE CONTROL, the FOOT SWITCH, touch-screen, or the mouse, click Acquire.

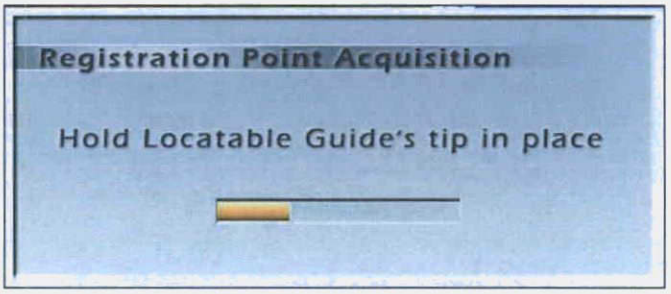
CAUTION READ DIRECTIONS BEFORE OPERATING	**Caution** Instruct the patient to hold his/her breath as long as possible during each Registration Point acquisition.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

180

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The following dialog box will appear:



Note

If you are working in "No Average" mode, the "Hold Tip in Place" message will not appear. (See *The Crosshairs and Average Mode* on page 7-41).

3. Hold the tip of the LG in place until the acquisition of the Registration Point is complete.

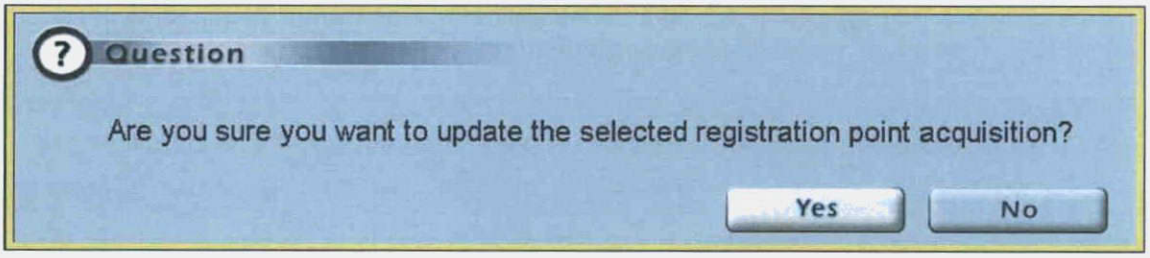
   Once the point has been acquired, the Status column will display the word Done to show that the Registration Point has been acquired. The next point in the list will be automatically selected.

4. Repeat steps 1-3, until at least four Registration Points have been acquired.

   You can also use the following options:

   Re-acquire a Point

   a. To re-acquire a point, select the point and perform the Registration process. Once the point is re-acquired the following confirmation message will appear:



   b. Click Yes to confirm.

181

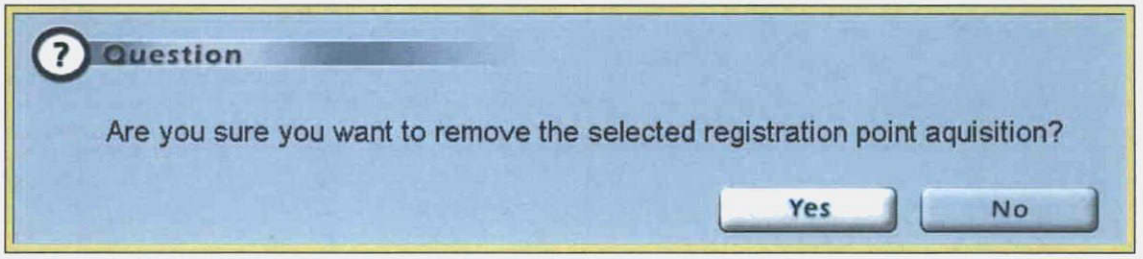
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Delete a Point

a. To delete a previously acquired point, select it from the list and click Delete.

The following confirmation message will appear:

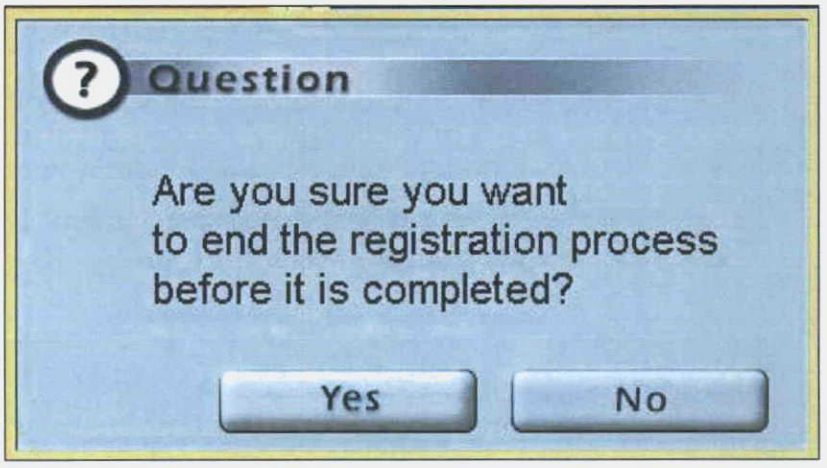


b. Click Yes to delete the point.

Exit Registration

a. To exit the CT Registration phase, without saving, click Cancel.

The following confirmation message will appear:



Note

Clicking Yes will exit the registration process without saving any of the acquired Registration Points and return back to the Setup phase.

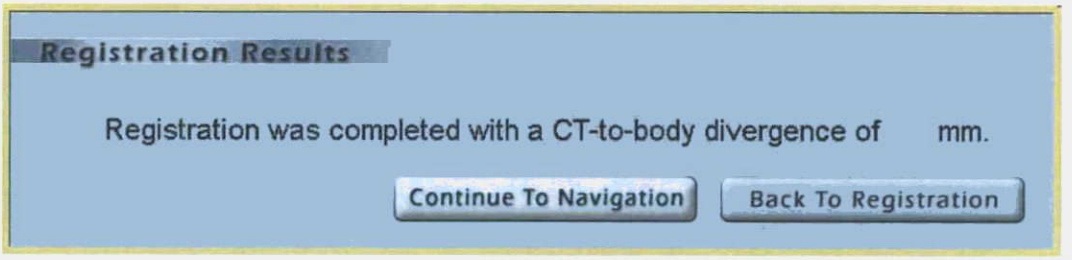
5. Once at least four points have been registered the Finish button is enabled and can be clicked at any time. Click Finish

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

182

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

once all the required points have been registered. The Registration results dialog box, seen below, will appear, indicating the CT-to-body divergence.



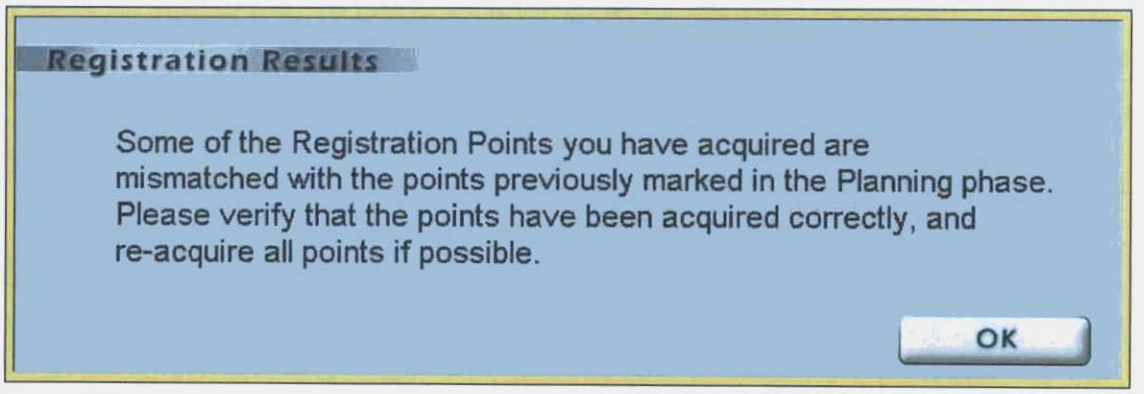
It may also be that the system will suggest re-acquiring a certain point in order to improve the registration results.

Warning

CT-to-Body divergence values in excess of 10mm can affect the accuracy of the system potentially resulting in tissue irritation and possible injury to the bronchial airways.

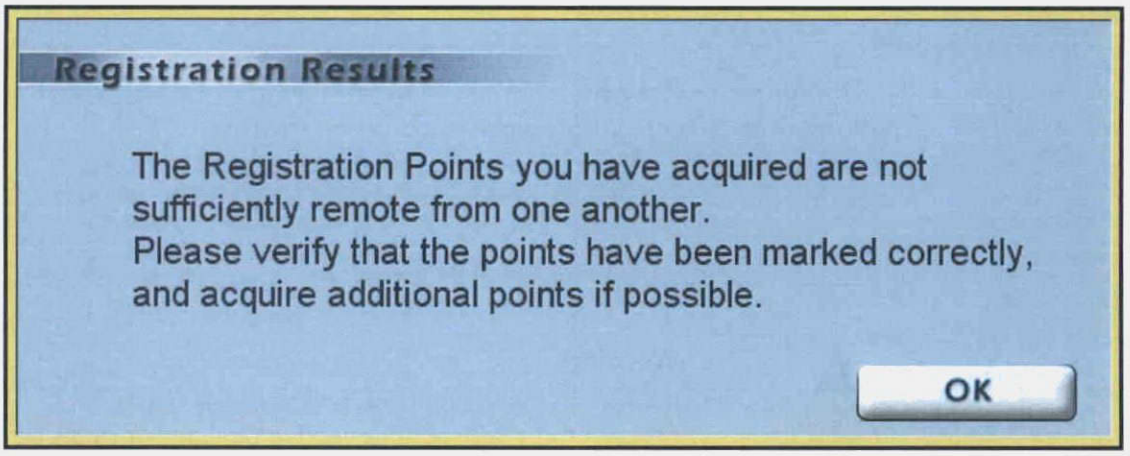
6. Click 'Continue to Navigation' to begin the navigation. Or click 'Back to Registration' to return to the registration screen if you would like to re-acquire a certain point.

   If the registration was unsuccessful, one of the following two windows will appear:



Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Click OK to repeat the Registration process.

Note

The Registration process can be repeated at any stage during navigation, by clicking the Tools>Registration.

Re-registration will delete all previously acquired data marked during the previous navigation, including lines, Targets and points. Re-registration will also delete all Registration Points, unless carried out within five minutes from registration completion.

Error Message Signal

A flashing Error Message Signal icon located on lower right side of the bronchoscope video screen indicates one of the following situations:

- LOCATABLE GUIDE tip is out of the sensing volume
- LOCATABLE GUIDE is disconnected

Refer to *Error Message Signal* on page 7-31 for further details.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

184

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Video Display

The image from the endoscopic video camera can be displayed in the Registration Screen, allowing you to position the LG's tip in the required location. The endoscopic video camera is connected to the video input port on the superDimension inReach™ System.

Warning
In order to avoid potential patient or use injury, an endoscopic video camera used in conjunction with superDimension inReach™ System must comply with the requirements of standard IEC/EN 60601-1 and IEC/EN 60601-2 or their equivalent.

Video Setup

You can set the parameters of the video image displayed on the Registration window by clicking Video Setting.

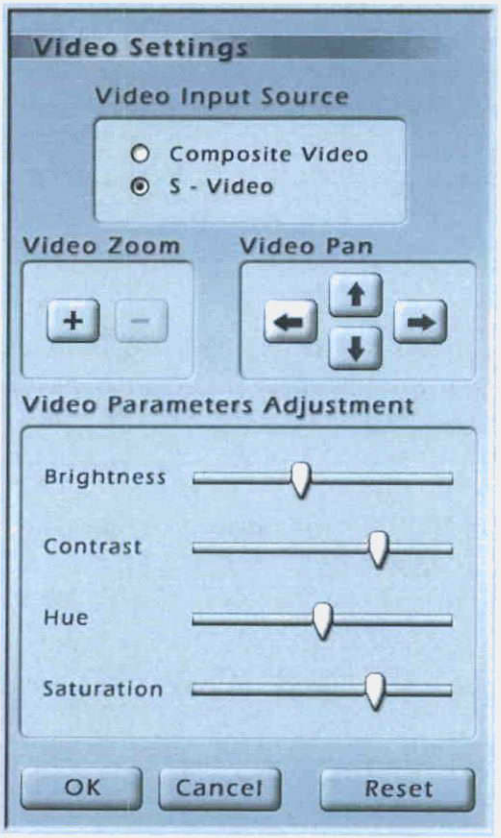


Figure 7-12: The Video Settings window *(updated)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To set the type of video input signal:**

1. Choose between Composite Video and S – Video option on Video Input Source on the Video Setting dialog box.
2. Set the switch on the video panel 

accordingly.
3. The Video Setup also enables the following settings during the CT to Body Registration Phase:
   - Video Zoom: Zoom In /Zoom Out feature for the Bronchoscope Video image.
   - Video Pan: Moving the Bronchoscope Video image.
   - Video Parameter: visual settings of the bronchoscope video image.

   For additional configurations for the Registration phase refer to *Procedure Module Settings* on page 7-82.

Visual Registration Verification

The following visual verification procedure should be performed after completing the registration process, to ensure that the Registration Points were accurately registered.

➢ **To visually verify registration:**

1. Using the bronchoscope's vision, position the LG's tip at a specific Registration Point that you recognize and hold it in place.

   Suggested Registration Points are the Carina, RML, or LUL.
2. Confirm that the position of the LG's tip, as indicated by the crosshairs in on all viewports on the superDimension screen, matches the position of the LG's tip as visualized with the bronchoscope.
3. Repeat steps 1 and 2 for at least two additional spatially-separated Registration Points, preferably the remaining two listed in step 1 above. If a notable discrepancy is detected, please repeat the entire Registration process.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

186

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Warning

To avoid potential accuracy problems, repeating visual registration verification is required after the LG is retrieved and reinserted to commence a new navigation, as well as after any replacement of the LG. The procedures may also be performed, at the physician's discretion, should the accuracy of the system be in doubt at any point in the course of the bronchoscopic procedure.

Phase 3 - Navigation

Once the Registration phase has been successfully completed, the Navigation phase will begin. The current Target is displayed in all four viewports, allowing you to navigate the LG towards it.

Refer to *Navigating to the Target* on page 7-22 for details.

Warning

To maintain accurate CT-to-Body registration during the procedure, it is recommend to retain the bronchial tree in its natural shape during the procedure, as it appears in the pre-operative CT images.

It is therefore recommended, during navigation of the LOCATABLE GUIDE towards the target, to position the distal tip of the bronchoscope so that it does not apply any pressure to the endobronchial walls.

Phase 4 - Arriving at the Target's Location

Once the tip is on the Target, perform the following steps to remove the LG and keep the EWC in place:

Caution

Fluoroscopy, performed on at least two perpendicular angles or other external position verification technique should be used to verify the location of the Locatable Guide at the target.

187

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To remove the Locatable Guide and keep the EWC in place:**

1. Once the LG has reached the Target, lock the BRONCHOSCOPE ADAPTER by turning it clockwise until the LG is fastened in place and cannot move.
2. Open the EWC LUER CONNECTION to detach it from the EXTENSION TUBE.
3. Gently pull the EWC to verify that it is firmly locked in place.
4. Remove the LG from the EWC. Be careful not to move the EWC out of its current position on the Target.
5. Store the LG in a sterile location in case it is needed again during this procedure.
6. Fasten the BRONCHOSCOPE ADAPTER by turning it clockwise until the EWC is securely locked in place and cannot move freely. A compatible tool can now be inserted through the EWC. For a list of Compatible Endoscopic Tool see page 3-18.



Caution

Any movement of the bronchoscope at this stage will affect the position of the EWC, which may cause it to move off target.

If the Bronchoscope was unintentionally moved, insert the LG and re-navigate to the Target.



Warning

Use the chosen compatible tool as specified in the User Manual supplied with the tool.

For a list of Compatible Endoscopic Tool see page 3-18.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

188

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

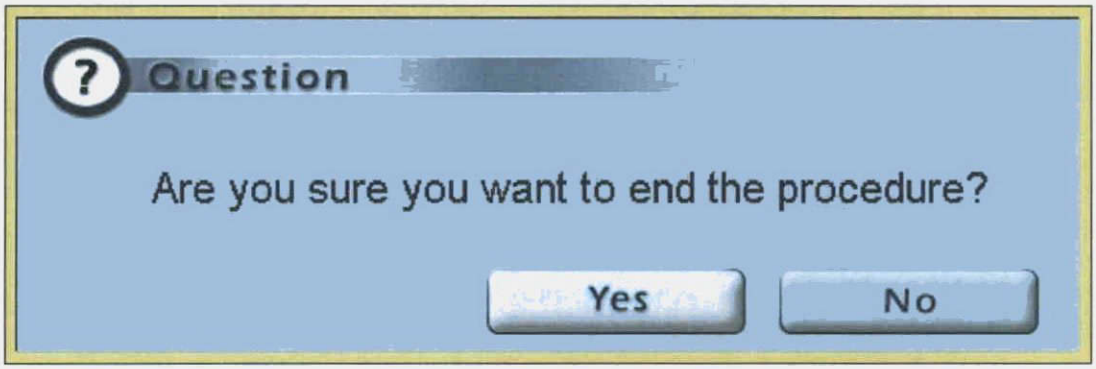
Phase 5 – Ending the Current Procedure

You can end the current procedure but stay in the current module.

➢ **To close the current procedure:**

1. Once you have completed the current procedure, select File>Close Procedure.

   The following message will appear:



2. Click No to return to the Navigation phase screen.

   Click Yes to end the procedure.

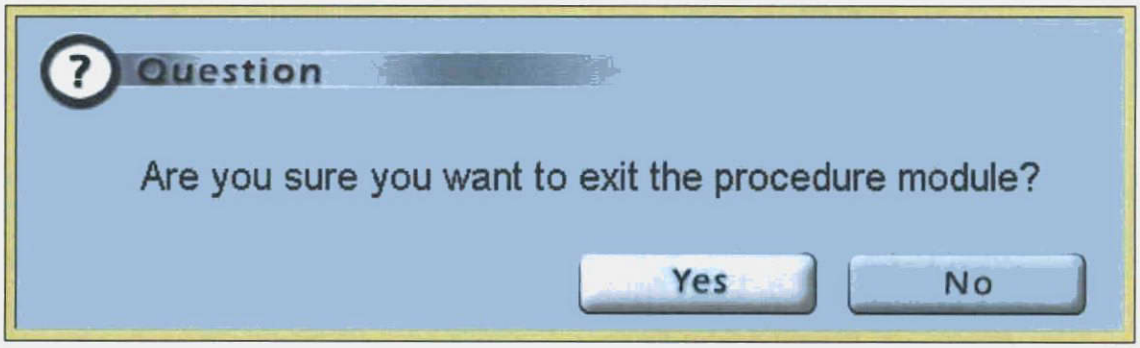
Exiting the module

If there is no error message on the screen, use the following procedure:

➢ **To exit the current module (with no error message):**

1. Select File>Exit.

   The following message will appear:



2. Click No to return to the Navigation procedure screen.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

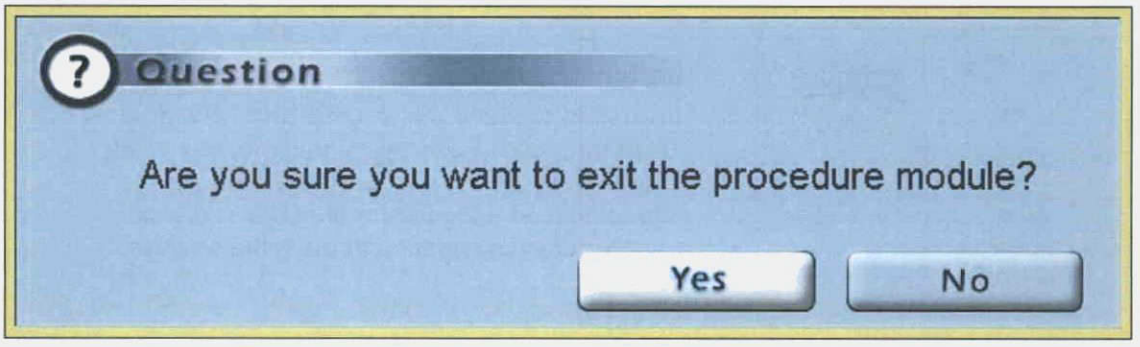
Click Yes to exit the current module.

If there is an error message on the screen, you should exit the current module.

➢ **To exit the current module (with an error message):**

1. Click Abort on the error message window.

   The following message will appear:



2. Click Yes to exit the current module.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Navigating to the Target

Once the registration process has been successfully completed, the Navigation phase will begin. You can now use the different viewports to navigate the LG to the Target. Looking in at least two of the cross-section perpendicular viewports, you can see the spatial location of the LG.



Caution

Navigation of the bronchoscope and Locatable Guide through the airways should not rely solely on data from the viewports. Rather, the viewport data should be used to augment the traditional bronchoscopic navigation through the airways.

Navigation Screen Layout

You can set the Navigation screen layout to the required layout by clicking View > Viewing Presets, from the menu bar.

CT-Guided Navigation modes

The CT Guided Navigation is the default viewing layout.

The Navigation mode button  toggles between the 'CT Guided Navigation' and the 'CT and Video Guided Navigation' layouts. Optionally, click the View > Viewing Presets on the menu bar.

The 'CT-Guided Navigation' can be operated in either Direct-to-Target mode or Pathway Navigation mode.

➢ **To use the Direct to Target mode:**

Click the 'Direct to Target' button  located on the left panel toolbar.

The Direct to Target mode enables navigation to the Target without the use of the planned Pathways. In this mode, the Pathway's Waypoints are hidden in all the viewports. The Tip view displays the steering directions needed in order to deflect the tip directly towards the Target.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

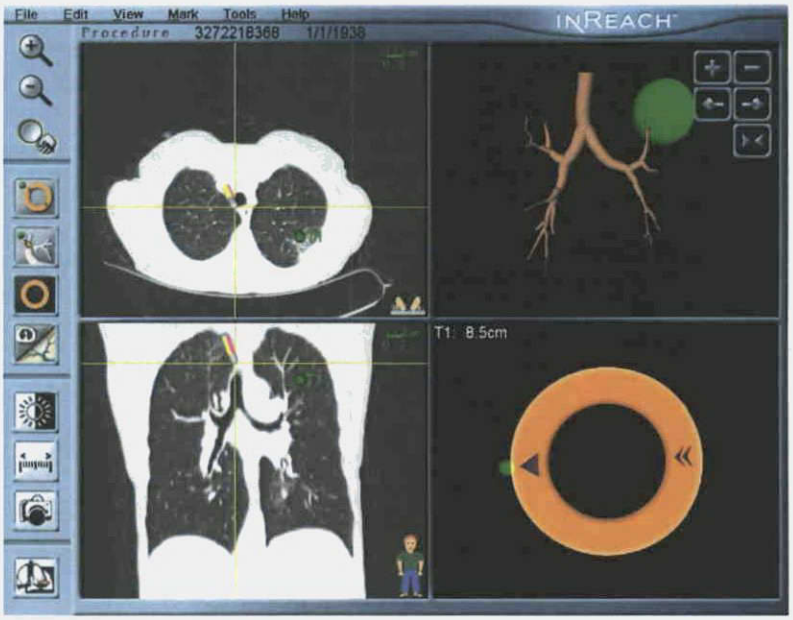


Figure 7-13: Direct to Target mode *(new)*

➢ **To use the Pathway Navigation mode**

The Pathway Navigation mode enables navigation to the Target using the planned Pathway. In this mode the Pathway to the Target is displayed in the 3D-Map viewport. The waypoints to the target are displayed on the 3D-Map with the current waypoint highlighted in dark blue. In the CT cross-section viewports only the current waypoint is displayed.

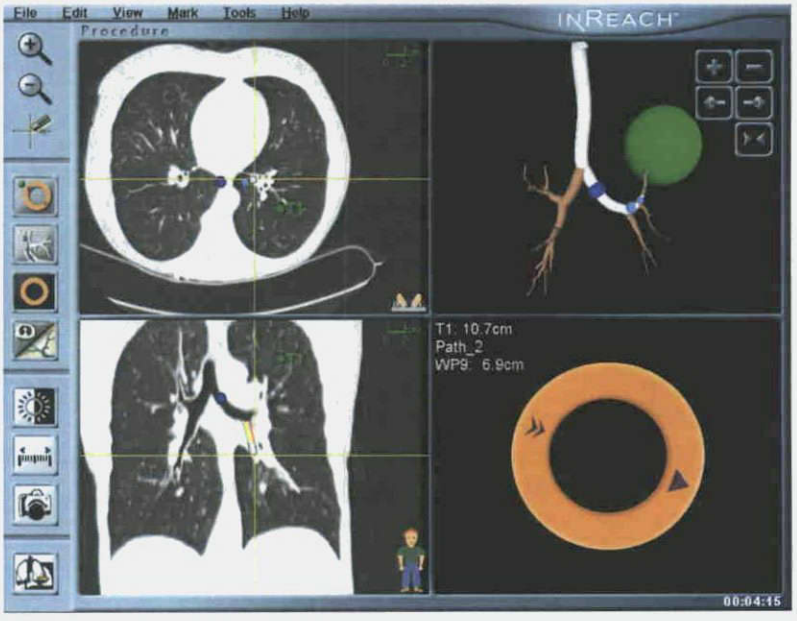


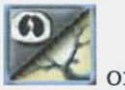
Figure 7-14: Pathway Navigation mode (new)

By default, the 3D-Map viewport replaces the Sagittal cross-section viewport. To toggle between the 3D-Map and the Sagittal

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

192

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

viewport, click the Show/Hide 3D-Map toggle button  on the left panel toolbar.

The default CT cross-section displaying the 3D-Map can be configured using the Application Settings. For more information refer to *Procedure Module Settings* on page 7-82.

'CT-Guided' Navigation screen layout preset

The CT-Guided Navigation can be configured to display three screen layout options.

➢ **To set the Steering Directions View:**

The Steering Directions view is the default Tip View

The Steering Directions button  toggles between the tip views. Optionally, click View > Tip View > Steering Directions on the menu bar.

The following navigation screen layout will appear.

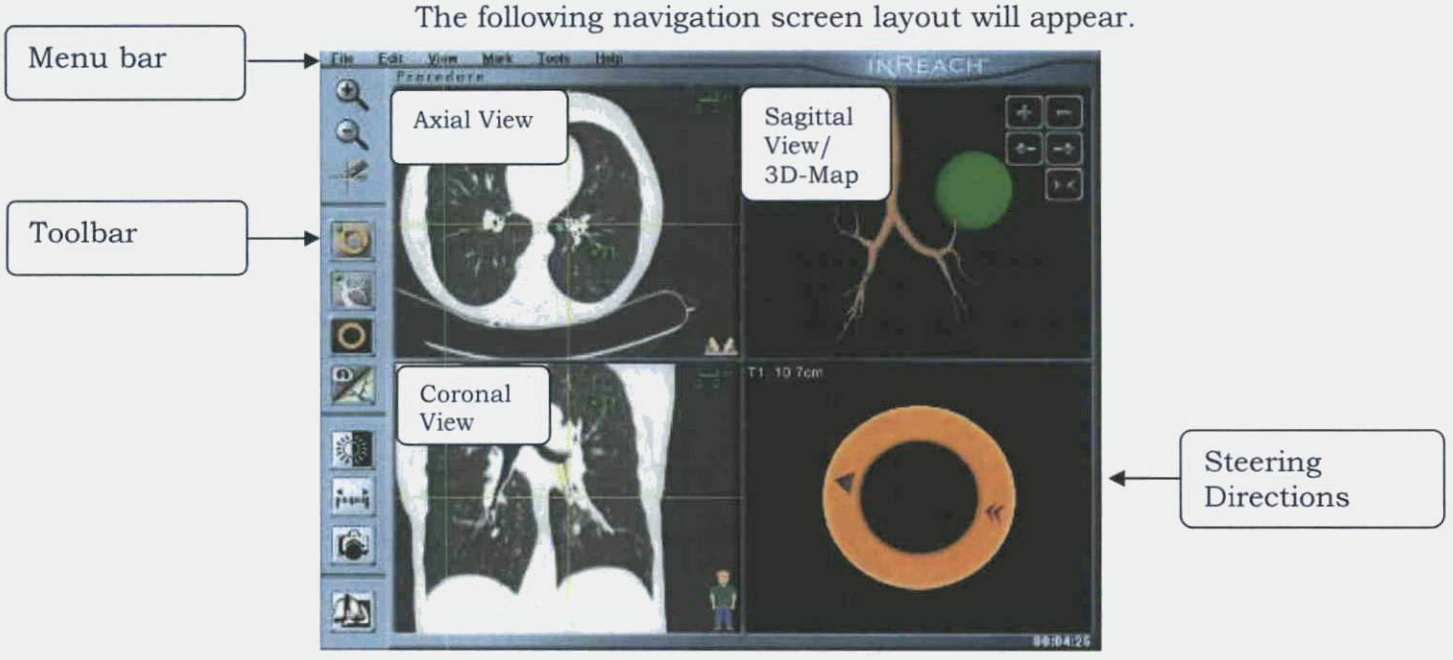
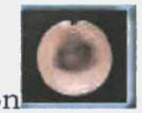


Figure 7-15: Steering Directions screen layout *(updated)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To add the Bronchoscope Video to the Tip View**

Click the Bronchoscope Video button  on the left panel toolbar. Optionally, click View > Tip View > Bronchoscope View Video on the menu bar.

The following navigation screen layout will appear.

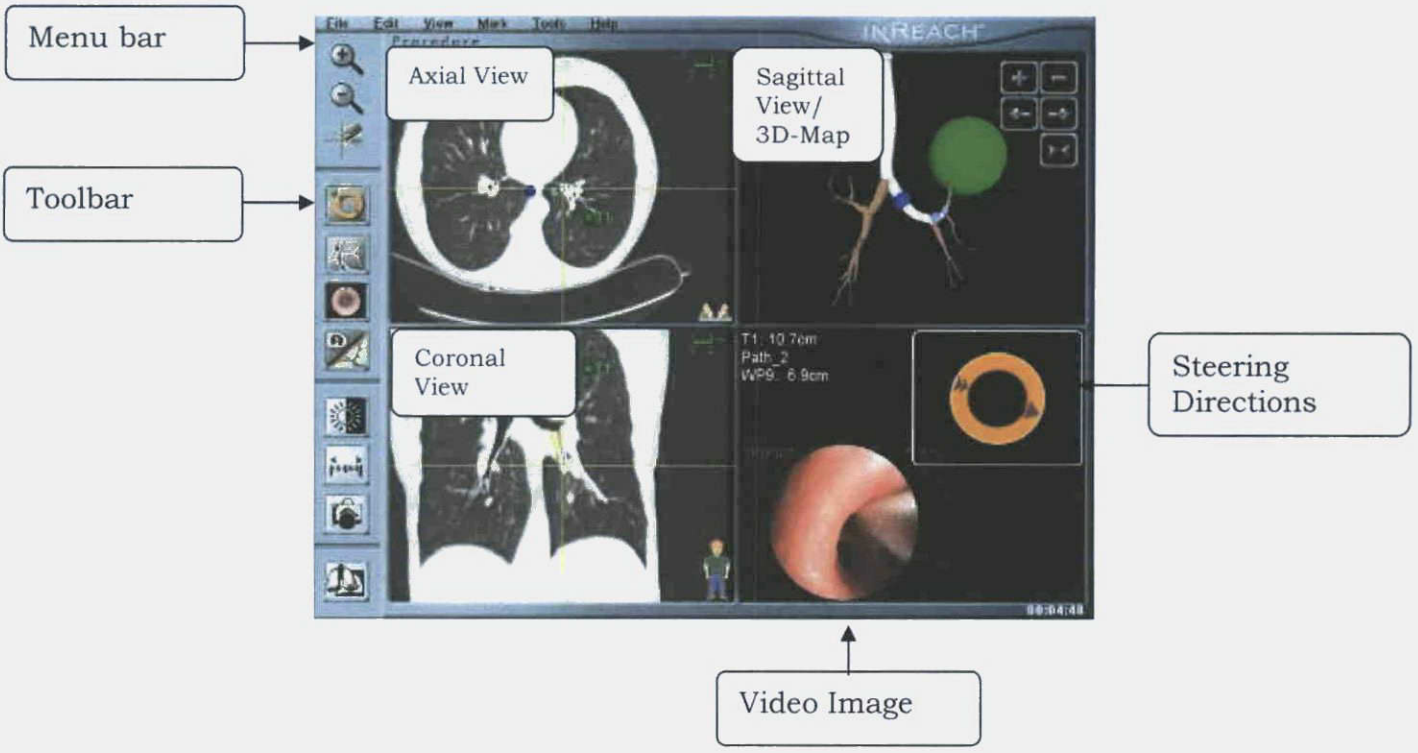


Figure 7-16: Bronchoscope Video screen layout *(updated)*

194

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To add the 3D CT View to the Tip View:**

The 3D CT view displays a combined view of the CT slices from the viewing direction of the tip of the LG.

The following steps apply to inReach™ System s with 3D CT capabilities.

Click the 3D CT View button  on the left panel toolbar.

Optionally, click View > Tip View > 3D CT on the menu bar.

The following navigation screen layout will appear.

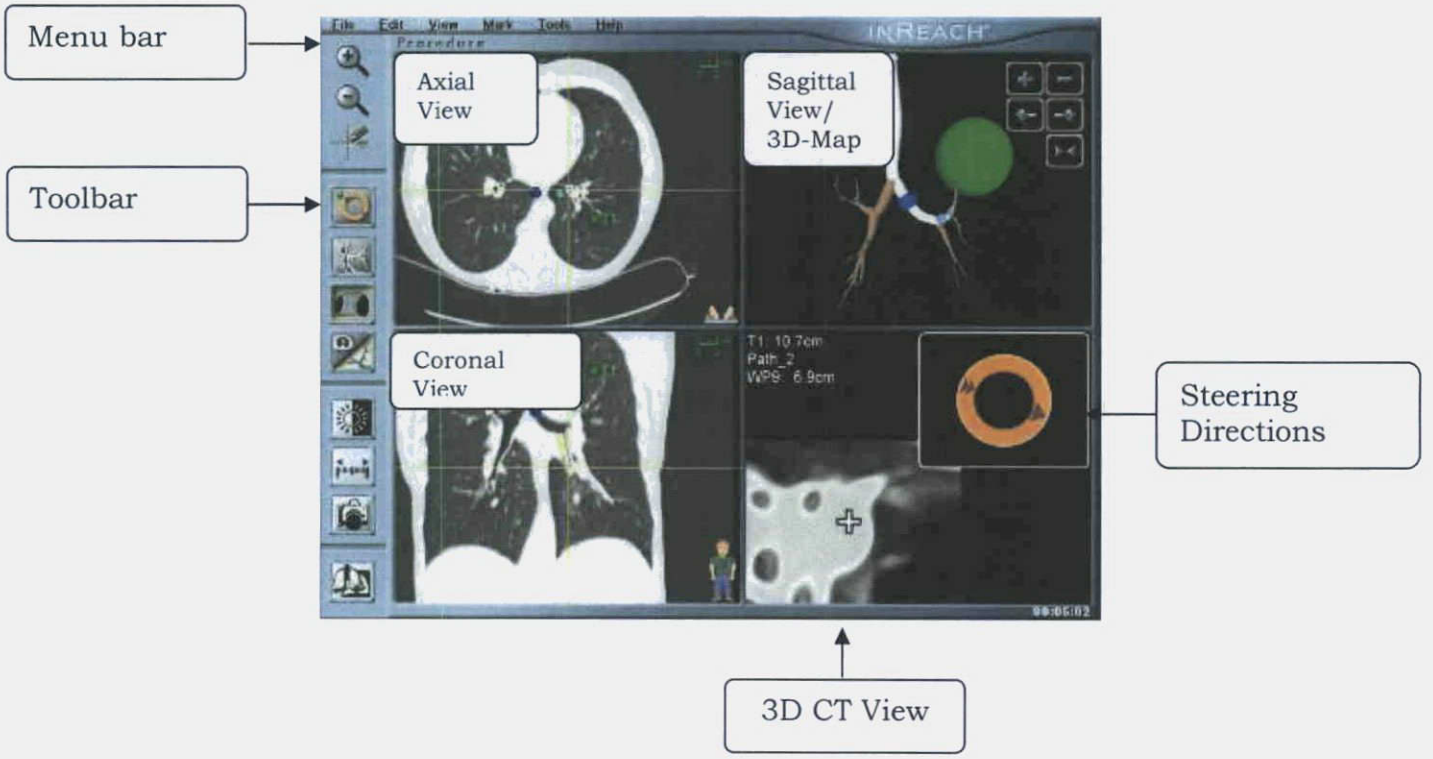


Figure 7-17: 3D CT screen layout *(updated)*

Optionally, use the F5 on your keyboard to toggle between 'Tip View' layouts.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

CT and Video Guided Navigation screen layout preset

The Navigation mode button  toggles between the CT Guided Navigation and the CT and Video Guided Navigation layout. Optionally, click the View > Viewing Presets on the menu bar.

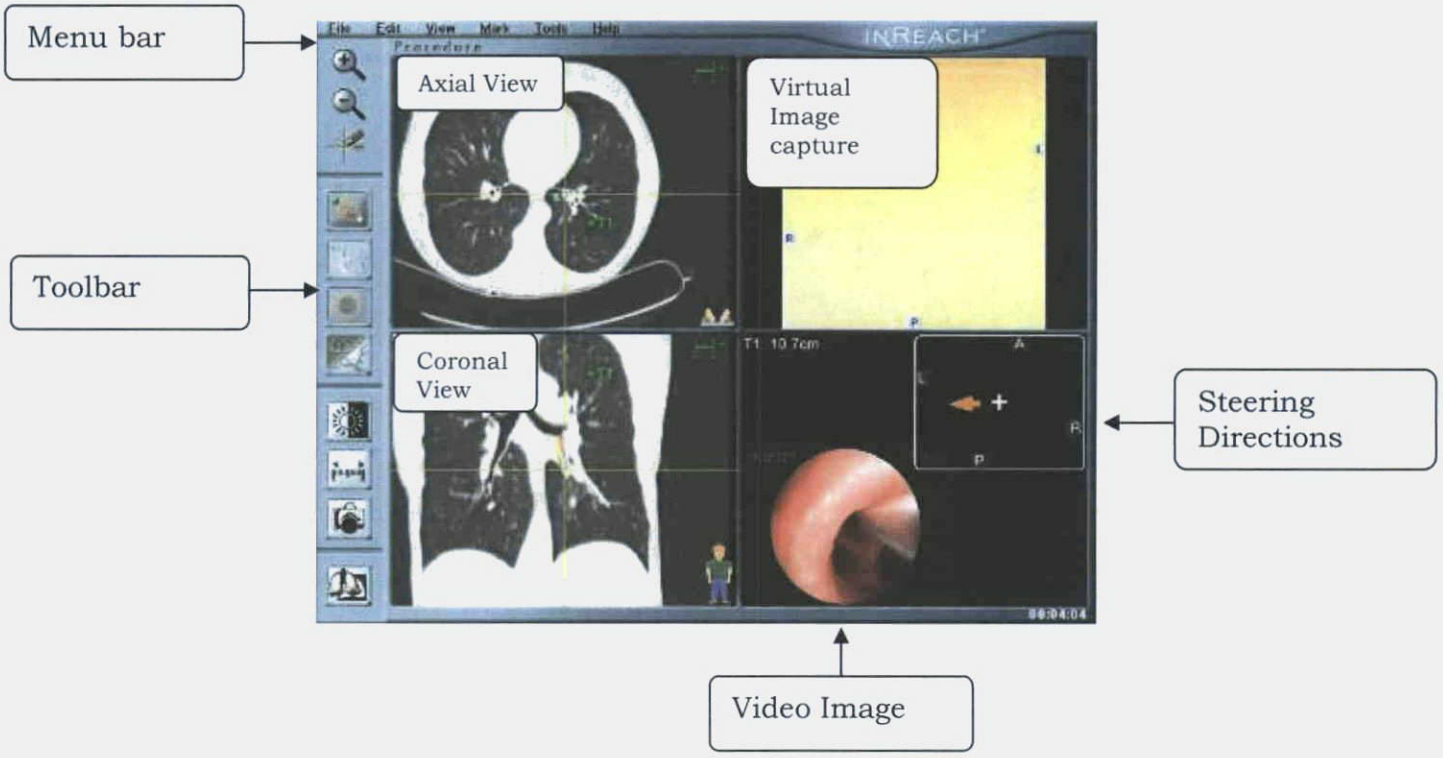


Figure 7-18: CT and Video Guided Navigation screen layout viewing preset *(updated)*

Customize preset viewing screen layout

The Procedure module navigation screen layout can also be customized according to your preferences.

➢ **To show/hide the defined Target size in the Tip View**

1. From the View menu select/unselect View>Target Size.

➢ **To activate the Freeze screen capture of the navigation screen during CT and Video Guided Navigation**

1. Press Enter on the REMOTE CONTROL, FOOT SWITCH or KEYBOARD to generate first freeze. Press another Enter to generate the second freeze.

196

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

2. Unfreeze navigation screens as needed by pressing Enter the third time.

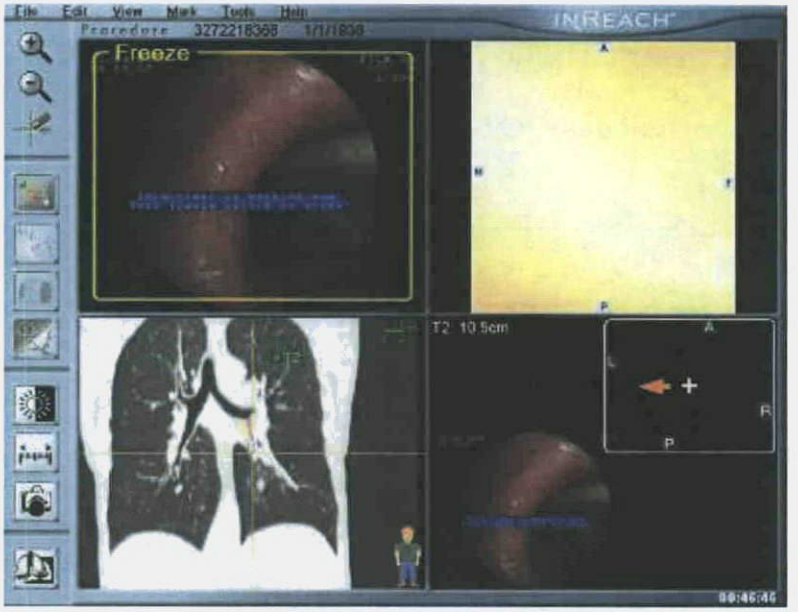


Figure 7-19: CT and Video Guided Navigation *(updated)*

➢ **To toggle between navigation screen layouts:**

To toggle between 'CT Guided' and 'CT and Video Guided' presets, use the Navigation mode button  or click View >Viewing Presets from the menu bar and select/deselect the desired preset. Optionally, use the F7 to select 'CT Guided' and F6 to select 'CT and Video Guided'.

Navigating to the Target using Waypoints

In 'CT Guided Navigation' mode, the Pathways created in the Planning Module are displayed on the 3D-Map and the CT cross-section viewports. The Pathways, which are made up of Waypoints, are used to guide the navigation to the Target.

By default the Waypoint furthest from the Target is displayed as the current Waypoint. The Waypoints of a Pathway are set in descending order from 'WPn' to the closest Waypoint to the Target 'WP1'.

197

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

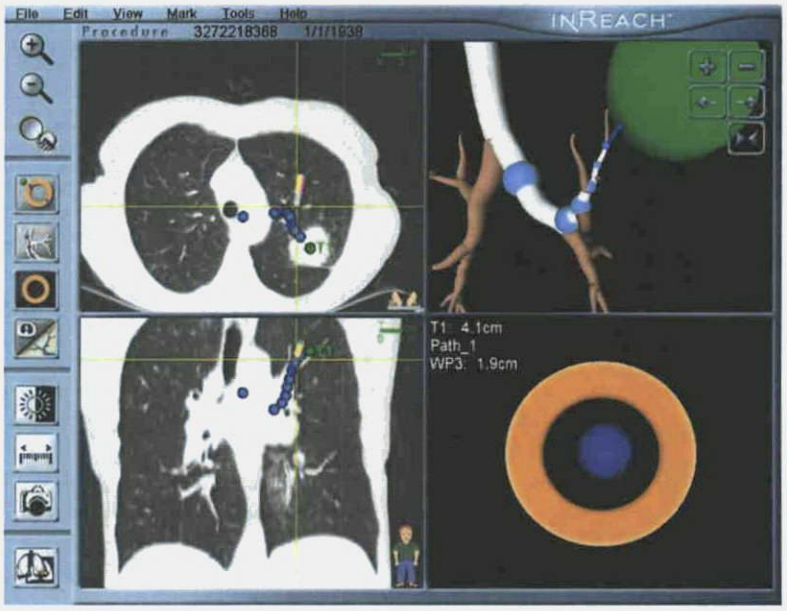


Figure 7-20: Navigating using Waypoints *(new)*

Toggling between Waypoints is done manually using the left and right arrows on the remote control and on the keyboard. The Foot Switch moves from the current Waypoint to the next Waypoint. Use the up and down arrow keys on the remote control and on the keyboard to toggle between Targets and Pathways.

Screen Layout Options

You can define the display direction of the three cross-section viewports as well as the position of the Tip viewport.

These layout options are set in the Application Settings window, which is opened by clicking Tools>Application Settings. See *Tools Menu* on page 10-12 for further details and also see Procedure Module Settings on page 7-82.

The display direction of the axial viewport can be set to either cranial or caudal; this will change the Coronal and Sagittal viewports respectively.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
198

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

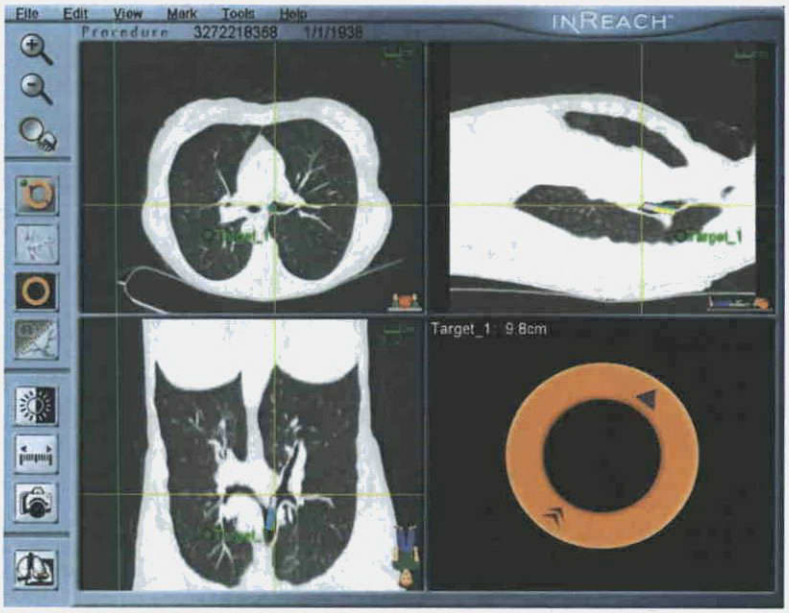


Figure 7-21: Cranial Perspective *(updated)*



Figure 7-22: Caudal Perspective *(updated)*

The location of the Tip viewport can be set to either the left upper quadrant or the right lower quadrant. The Tip and Axial viewports effectively change places.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 7-23: Tip viewport – Lower Right Quadrant *(updated)*

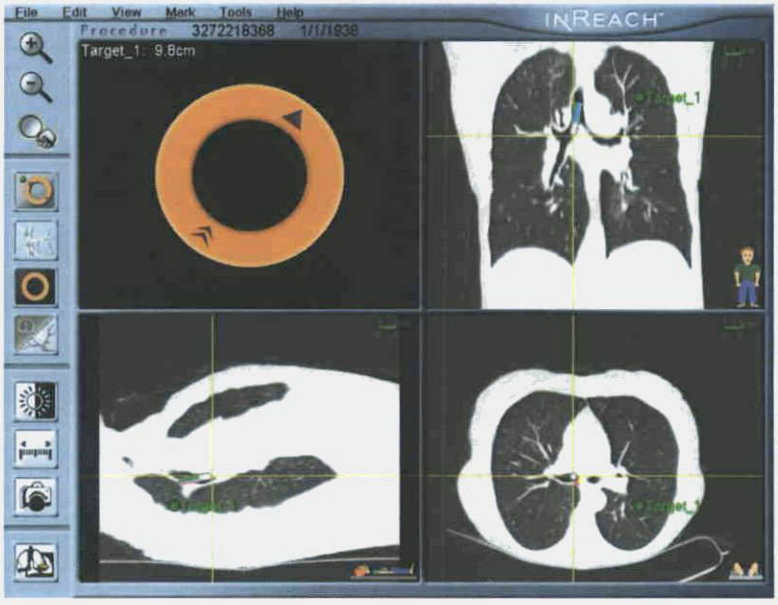


Figure 7-24: Tip viewport – Upper Left Quadrant *(updated)*

Error Message Signal

The flashing Error Message Signal icon in the lower right quadrant of the screen indicates one of the following situations:

- LOCATABLE GUIDE tip is out of the sensing volume
- LOCATABLE GUIDE is disconnected

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

200

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

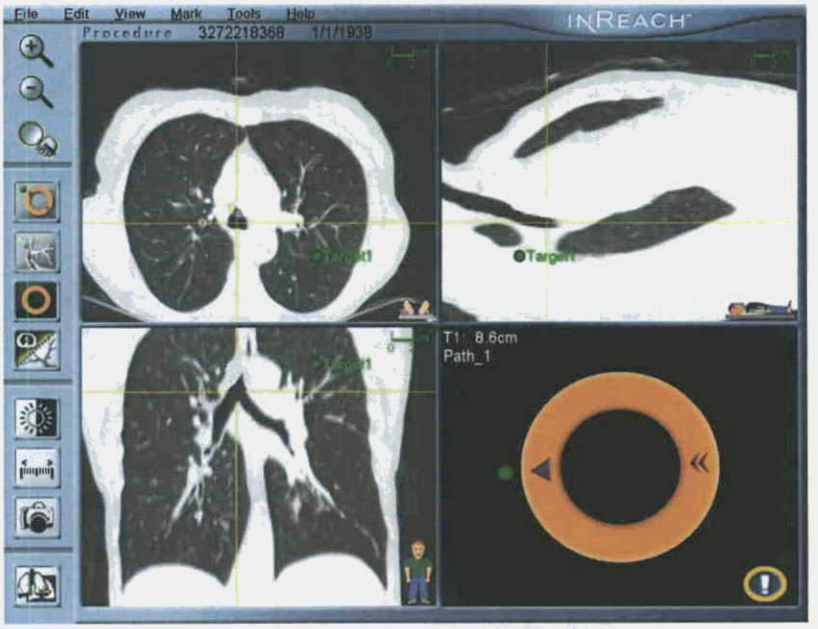


Figure 7-25: Error Message Signal during navigation *(updated)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

201

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Error Message Signal can also appear in the bronchoscope video screen during *Phase 2 – "CT-to-Body" Registration* as illustrated below:

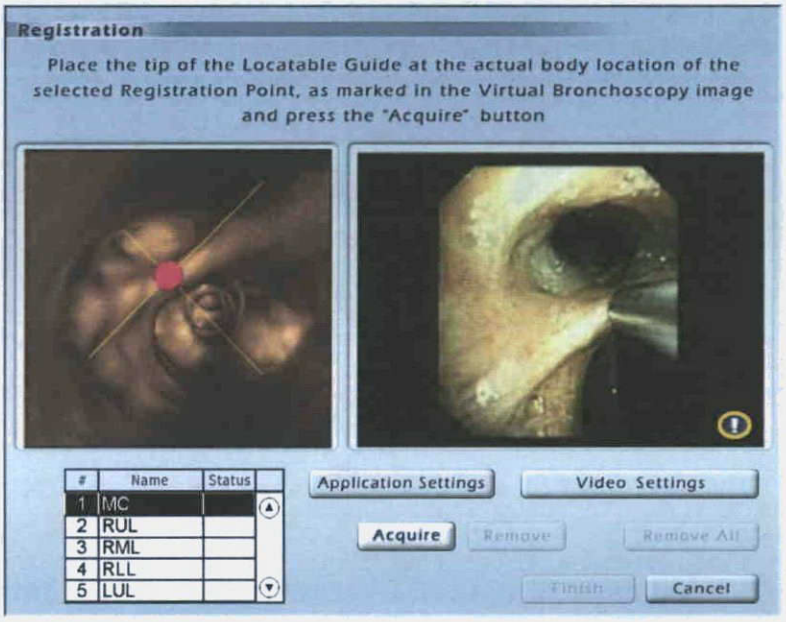
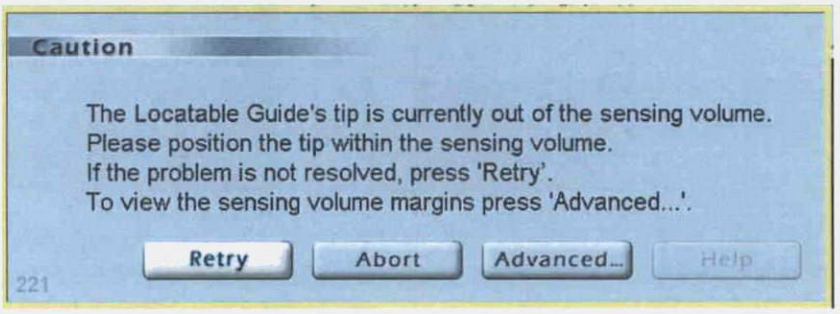


Figure 7-26: Error Message Signal during registration *(updated)*

Press the flashing notification icon on the touch screen or click the icon with the left mouse button. One of the following messages will appear:

Locatable Guide out of sensing volume

If the LOCATABLE GUIDE tip is out of sensing volume the following dialog box will appear:



Adjust the LOCATABLE GUIDE and click Retry.

Optionally, click the Advanced button to view the sensing volume margins. The following screen will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

202

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

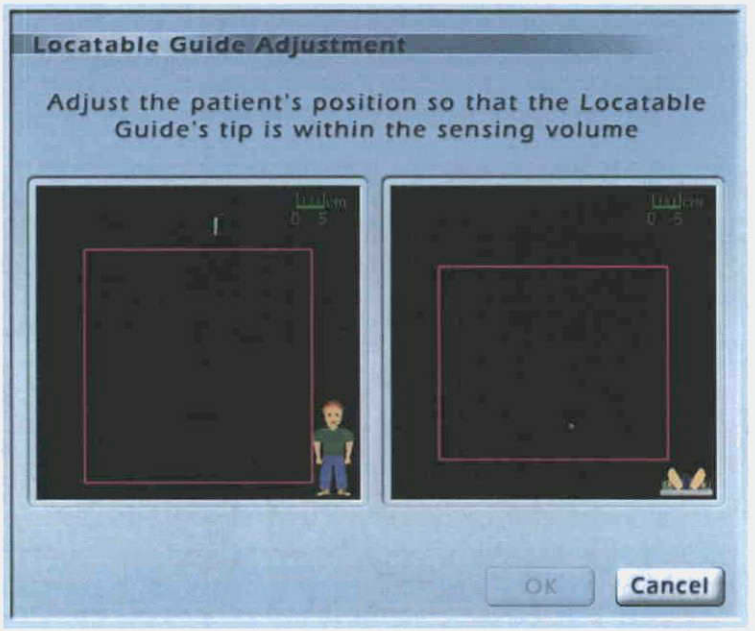


Figure 7-27: Locatable Guide out of sensing volume

Adjust LOCATABLE GUIDE tip so that is within the sensing volume as in the figure below and click OK to continue:

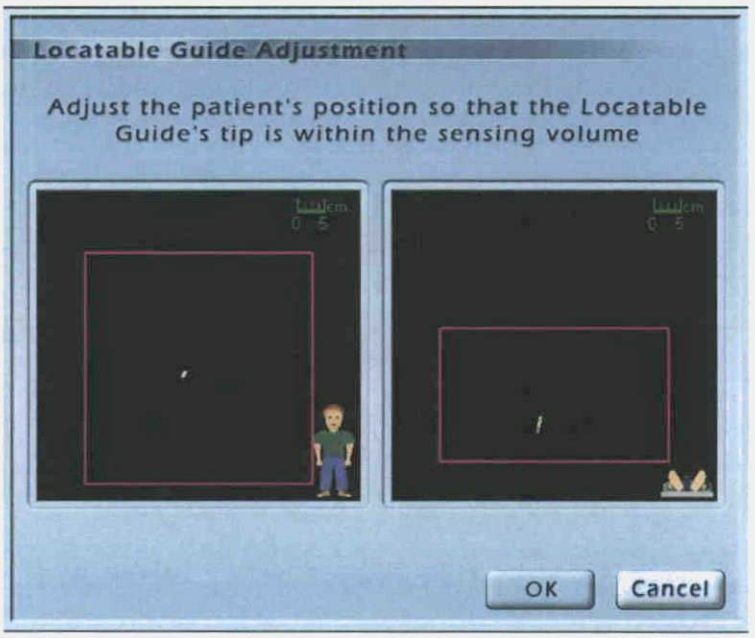


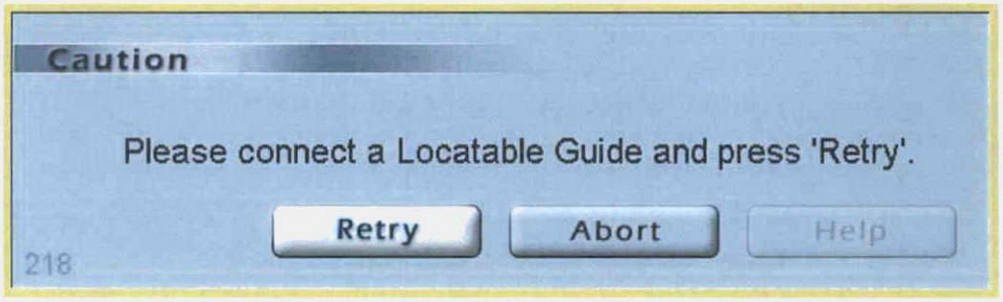
Figure 7-28: Adjusting the Locatable Guide

Locatable Guide disconnected

If the LOCATABLE GUIDE is disconnected the following dialog box will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Ensure that the LOCATABLE GUIDE is properly connected and click Retry, or click Abort to exit.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Viewports

The Navigation screen is divided into four viewports – three cross-section viewports and the Tip viewport.

The following cross-section viewports are available:

Axial – Displays the horizontal cutaway of the patient. This viewport can be displayed from a caudal or cranial perspective. This will automatically change the perspective in the Sagittal and Coronal viewports accordingly.



Figure 7-29: Axial viewport

Sagittal – Displays the vertical cutaway of the patient as seen from the patient's side. The direction of the Sagittal plane will automatically change if the Axial viewport is changed.

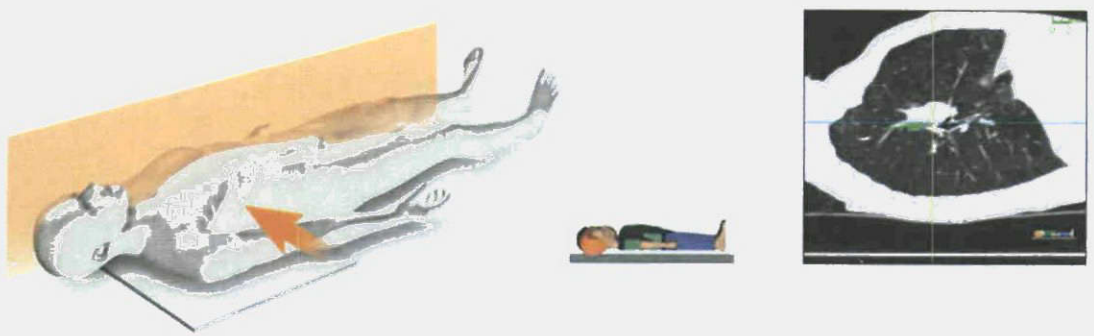


Figure 7-30: Sagittal viewport

205

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Coronal – Displays the vertical cutaway of the patient as seen from the patient's front. The direction of the coronal plane will automatically change if the Axial viewport is changed.

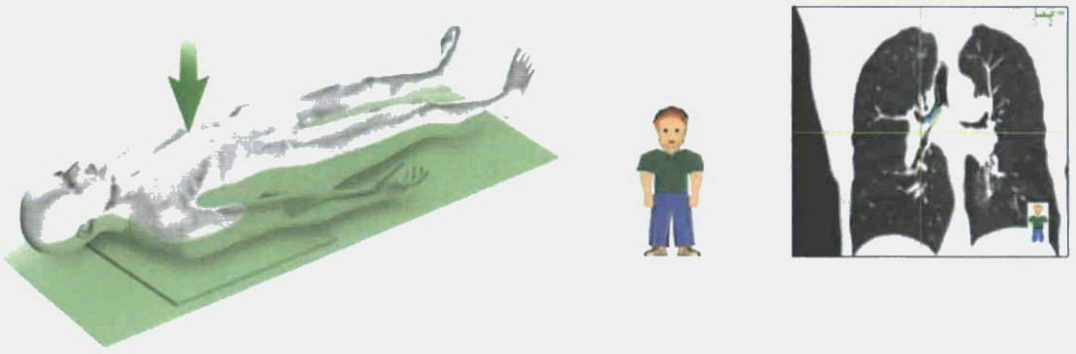


Figure 7-31: Coronal viewport

3D-Map Viewport

The 3D-Map viewport is a three-dimensional roadmap visualization of the patient bronchial tree. The 3D-Map viewport displays the pathway planning to the Target created in the Planning Module.

Note
The 3D-Map view provides a fixed representation of the bronchial airways. It does not provide real time representation of the tip sensor movement.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
206

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

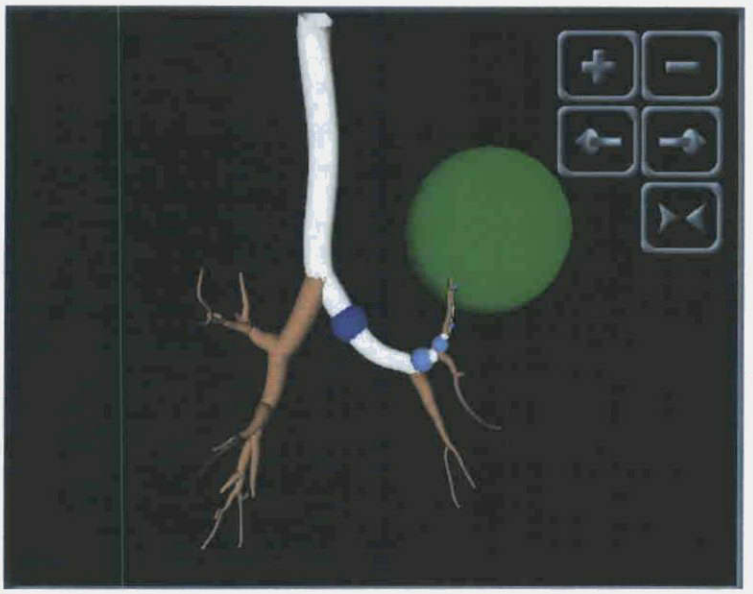


Figure 7-32: 3D-Map Viewport

➢ **To adjust the 3D-Map viewport**

The 3D-Map can be controlled in the following ways:

- Zoom: click  to zoom in on the 3D-Map and  to zoom out of the 3D-Map.
- Rotation: click the left rotation  and right rotation  buttons to rotate the 3D-Map on its axis.
- Panning: click and hold the left mouse button and move the mouse to the desired position.
- Reset Position: click the rest position button  to place the 3D-Map in the original position.

You can define the display location of the 3D-Map on any of the three cross-section viewports.

These layout options are set in the Application Settings window, which is opened by clicking Tools>Application Settings. See *Tools Menu* on page 10-12 for further details and also see Procedure Module Settings on page 7-82.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

207

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Tip Viewport for CT Guided Navigation

The Tip viewport displays, in real time, the graphical view from the LG's point of view. The tip's movement and orientation are reflected by the movement of the viewing angle, ensuring that the tip's position and orientation are kept fixed in the center of the viewport. It may appear to you as if the objects are moving in the graphical viewport, while the tip is fixed.

Only the current Target or current Waypoint is shown in the Tip viewport while all other points and pathways are not visible. The arrow on the circle in the Tip viewport indicates the steering direction that needs to be set accordingly, in order to deflect the tip towards the Target. Refer to *Using the Locatable Guide and Extended Working Channel* on page 7-63 for further details.

The zoom level and Viewing Angle are both fixed and cannot be changed.

The distance from the tip of the LG to the current Target and the current Waypoint is displayed in the top left-hand corner of the Tip viewport.

When available, the current Pathway name is displayed in the top left-hand corner of the Tip viewport.

The Target is displayed as a green point on the Tip viewport.

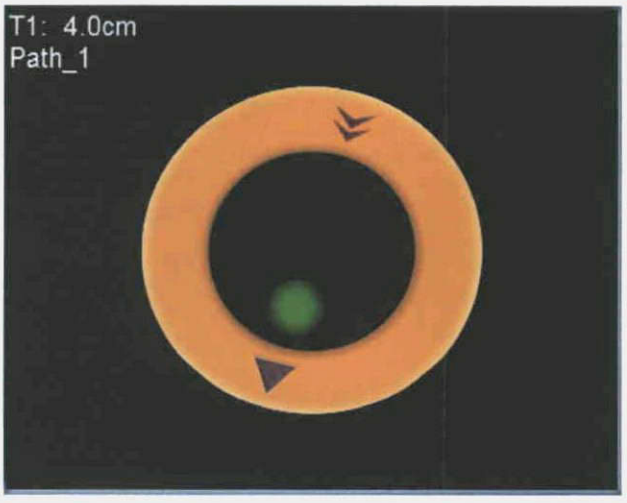


Figure 7-33: Locatable Guide Tip to Target *(updated)*

The Waypoint is displayed as a blue point on the Tip viewport.

208

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

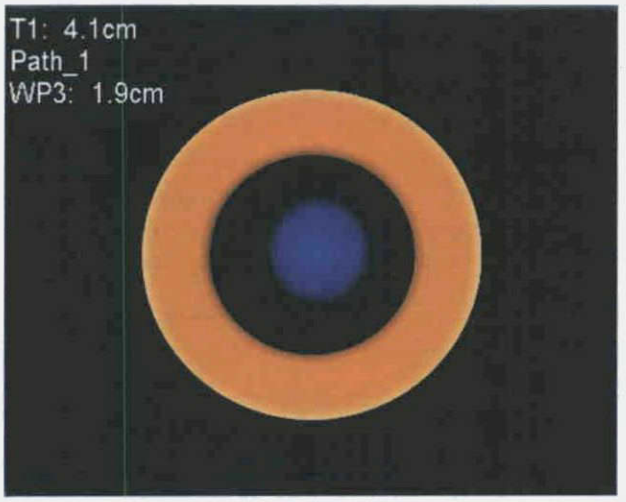


Figure 7-34: Locatable Guide Tip to Waypoint *(New)*

Tip Viewport for CT and Video Guided Navigation

The Tip viewport displays, in real time, the video image from the endoscopic camera and the graphical view from the LG's point of view. The tip's movement and orientation are reflected by the movement of the viewing angle, ensuring that the tip's position and orientation are kept fixed in the center of the viewport. It may appear to you as if the objects are moving in the graphical viewport, while the tip is fixed.

Only the current Target is shown in the Tip viewport while all other points and pathways are not visible. The arrow on the circle in the Tip viewport indicates the steering direction that needs to be set accordingly, in order to deflect the tip towards the Target. Refer to

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the CT and Video Guided Navigation together with the Locatable Guide on page 7-78 for further details.

The zoom level and Viewing Angle are both fixed and cannot be changed.

The distance from the tip to the selected Target is displayed in the top right-hand corner of the TIP viewport.

The roll orientation of the Tip viewport is kept fixed and it is indicated by the indication letters on the Tip viewport inner frame as described on the image below.

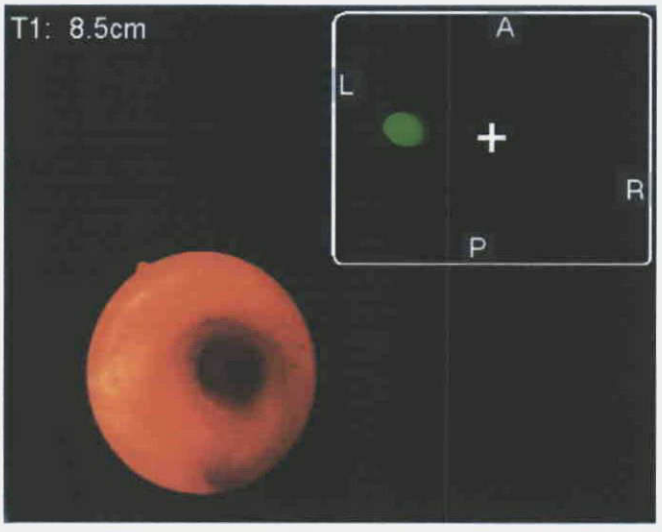


Figure 7-35: Tip viewport and video display *(updated)*

The Crosshairs and Average Mode

The position of the crosshairs represents the average location of the tip of the LG. The system can compensate for the movement of the patient's thoracic region during the normal cycles of respiration, by selecting one of the following Average Modes:

No Average

No compensatory time interval is set. The location of the crosshairs is set as the current location of the LG's tip.

By Sync

The system calculates the patient's vertical movement cycle and uses this time interval to continuously calculate the average location of the tip. If the system cannot establish the vertical movement cycle, a default time interval is used.

210

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

By Time

You can set the time interval, for example, three seconds, which is used as the cycle time of the vertical movement and is used to calculate the average location of the tip.



Caution

Under the Average by Time mode, the Averaging Time being used is recommended to be equal to the duration of a normal respiratory cycle. In such case, there is a higher accuracy in the displayed location of the crosshairs relative to the CT images in faster-than-normal and normal respiration. However, there may be a lower accuracy in case of slower-than-normal respiration.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

211

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

View Modes

Different VIEW modes can be selected to control the zoom levels and panning of the cross-section viewports. The different View modes can be accessed by selecting View>View Mode.

The following view modes can be selected:

- **Auto Zoom** – continuously updates the zoom level so that the LG's tip and the current Target are always both displayed on all three cross-section viewports.
- **Auto Center** – re-centers the viewport on the tip of the LG whenever the tip exceeds the borders of any of the cross-section viewports.
- **Full View** – zooms out to a predefined zoom level that displays the complete working area. This gives you an overall perspective of the LG'S tip's current position.
- **Manual Zoom** – enables you to manually set the zoom level.

Manual Center Viewports

This function enables you to center all the cross-section viewports on the tip of the LG, by selecting View>Center on LG.

Window/Level

You can adjust the window and level values of the CT images as needed during the Navigation phase.

➢ **To adjust the window and level:**

1. Click Tools>Window/Level or click the Window/Level button on the Toolbar.
2. To set the Window, move the left or right arrows.
3. To set the Level, move the up or down arrows.

The Window/Level is changed in all three CT cross-sections with the Window and Level values displayed on the screen.

Graphical Objects

You can create Reference Points during the navigation process and also draw lines to show the path of the LG.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Registration points

Reference Points that were marked during the Registration phase can be displayed over the CT cross-section images in all three cross-section viewports. The default setting is for all Registration Points to be hidden. See *Graphic Control* on page 7-49 for further details.

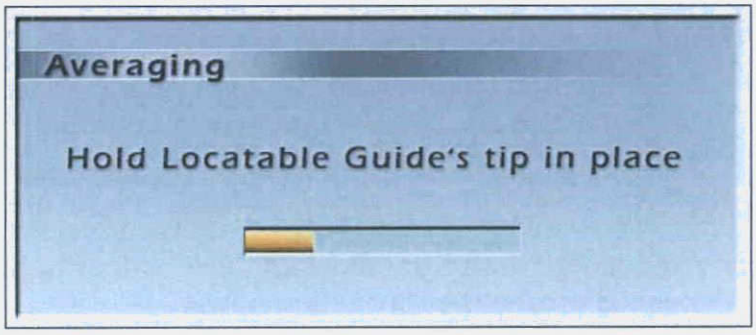
Reference Points

You can mark new Reference Points in addition to the existing ones that were marked in the planning file.

➢ **To mark a New Reference Point:**

1. Position the tip of the LG onto the required location.
2. Press the Add Point button , or select Mark >Mark Point.

   The following dialog box will appear:



Note
If you are working in No Average mode, the Hold Tip in Place message will not appear.

Note
Hold the tip of the Locatable Guide in position until the Hold Tip in Place dialog box closes. The point is acquired once the dialog box closes.

3. Hold the tip of the LG in place until the system has acquired the point. Once the point has been acquired the following window will appear:

213

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

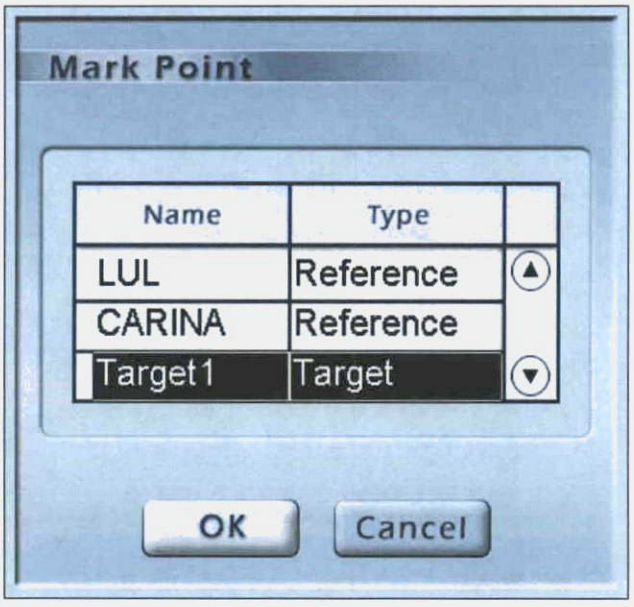


Figure 7-36: The Point Names List



Tip

- Select a name from the existing listed points. If a name that already exists is selected, an index number will be added. For example, if a second "Carina" point is created it will be named "Carina-1".
- Refer to *Editing Point Settings* on page 7-90 for further information on editing and adding the point names.

4. Select the relevant point name from the NAMES LIST and click OK to save the point. The point will be displayed in the three cross-section viewports as illustrated below.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

214

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 7-37: Creating Reference Points

Targets

The Target represents a point to which you navigate, with the LG. The location of the Target is based n the Planning File and calculated during the registration phase.

By default, the first target in the Planning File's target list is set to be the current target. The current target is the only target that is displayed in the Tip viewport. In the cross-section viewport the current target is displayed in bright orange, while all other targets are hidden by default. If a non-current target is also selected it is displayed in a faint orange. See *Set Current Target* on page 7-54 for further details.

You can choose to display or hide each of the other targets in the cross-section viewports. See *Graphic Control* on page 7-49 for further details. By default, only the selected target is displayed.

You can also add new targets in the same way that other points are added. See *Editing Point Settings* on page 7-90, for further details.

Waypoints

Waypoints are distinct points that make up a Pathway to a Target. The Waypoints are used as intermediate visual landmarks on the CT cross-section views, the Virtual Bronchoscopy view and on the 3D-Map view. A Pathway to Target is constructed in the Planning file to assist in navigating to the Target during the procedure.

During navigation to the Target, the current Waypoint is displayed in the Tip viewport. The distance from the LG Tip to the current

215

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Waypoint is also displayed. In the CT cross-section viewport the current waypoint is displayed in bright blue.

You can choose to display or hide the waypoints to the current target in the cross-section viewports. See *Show/Hide Waypoints* on page 7-48 for further details.

Measuring Distances



Caution

The superDimension inReach™ System is not a diagnostic device. The accuracy of the distance measurement function is dependent on many factors including registration, patient movement, and breathing and therefore should be used for purposes of general reference only.

You can measure the distance between two locations of the LG.

➢ **To measure the distance between two locations of the Locatable Guide:**

1. Position the tip of the LG in the first location and press the Distance Measurement button  on the Toolbar or select Tools>Measure Distance.

   As the LG is moved, a purple line is drawn along its path as displayed below:

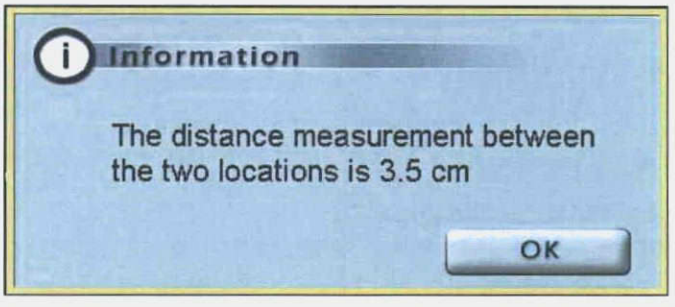


Figure 7-38: Distance Measurement

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

216

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

2. When the second location has been reached press the Distance Measurement button  on the Toolbar or select Tools>Measure Distance.

   The measurement, which is the distance between the locations of the crosshairs, appears as illustrated in Figure 7-38.

3. Click OK to close the window. When the window is closed, the purple distance line is deleted from the cross-section viewports.

Show or Hide Names

The names of graphical objects can be displayed next to the object in the cross-section viewports.

➢ **To show or hide names**

To show or hide object names, press the Names button on the Toolbar or check (or uncheck) Mark>Show Names.

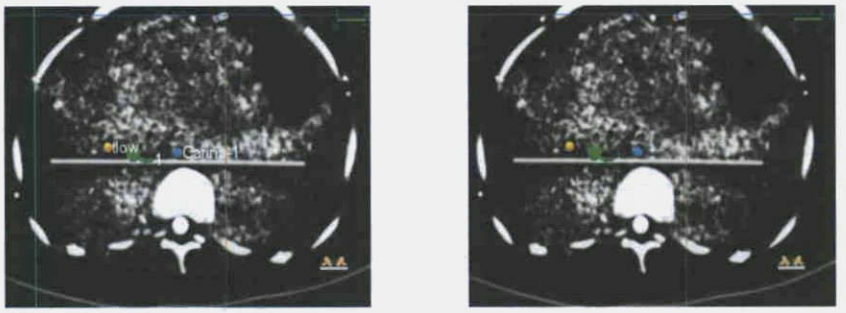


Figure 7-39: Show or Hide names

Show/Hide Waypoints

The Waypoints of a Pathway can be hidden in all the CT cross-section viewports.

➢ **To show or hide Waypoints**

To show or hide Waypoints click View > Show All Waypoints on the menu bar.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

217

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

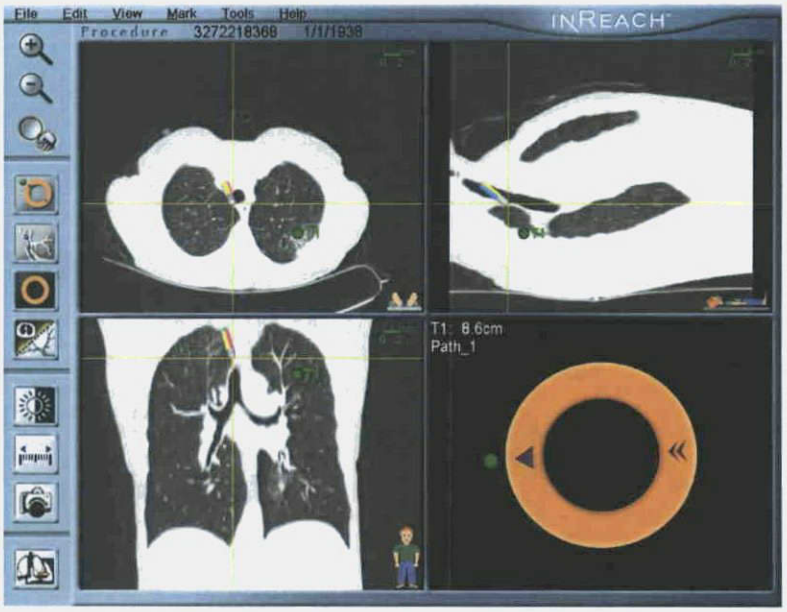


Figure 7-40: Show or Hide Waypoints *(new)*

When in 'Hide Waypoints' mode, newly added Waypoints will be shown on the viewports.

Graphic Control

You can control which graphical objects are displayed in the cross-section viewports and which are hidden. The status of each object can be set individually or generally, per object types. A target can also be set as the current target. The current target is the only graphical object that is displayed in the Tip viewport.

➢ **To display the Graphic Control menu:**

Select Mark>Graphic Control.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

218

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The menu options appear as follows:

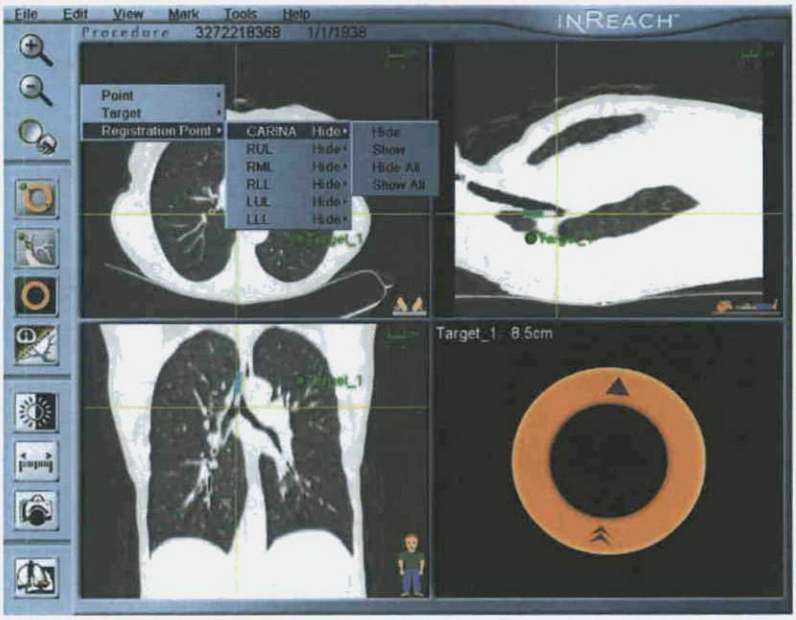


Figure 7-41: Graphic Control Menu *(updated)*

The following options can be set for any of the graphical object types:

- **Hide** – Hides a graphical object so that it will not be displayed in the cross-section viewports.
- **Show** – Shows a hidden graphical object so that it will be displayed in the cross-section viewports.
- **Hide All** – Hides all objects of the selected object type so that they will not be displayed in the cross-section viewports.
- **Show All** – Shows all objects of the selected object type so that they will be displayed in the cross-section viewports.

Hide

➢ **To hide a graphical object:**

1. Select Mark>Graphic Control.

   The following menu will appear:



(updated)

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

219

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

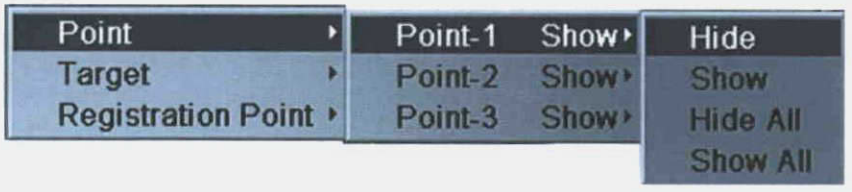
2. Select the required object type. The following menu will appear:



(updated)

The current status of the object appears next to the object's name.

3. Select the required object to set its display setting. The following options are displayed:



(updated)

4. Select Hide and press Enter.

The object will no longer be displayed in the cross-section viewports.

Show

➢ **To show a graphical object:**

1. Select Mark>Graphic Control.

The following menu will appear:



(updated)

2. Select the required object type.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
220

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The following menu will appear:



(updated)

The current status of the object appears alongside the object name.

3. Select the required object to set its display setting. The following options are displayed:



(updated)

4. Select Show and press Enter.

   The object is displayed in the cross-section viewports.

Hide All

➢ **To hide all graphical objects:**

1. Select Mark>Graphic Control.

   The following menu will appear:



(updated)

2. Select the required object type.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

221

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

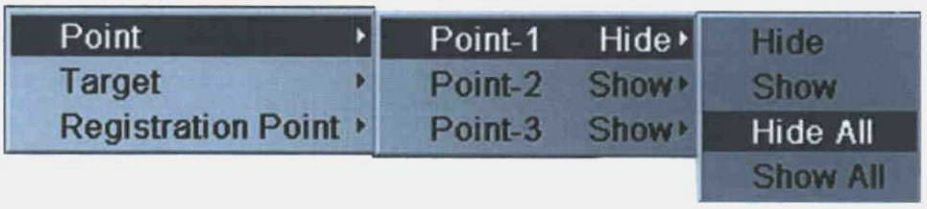
The following menu will appear:



(updated)

3. Select any object to set its display setting.

   The following options are displayed:



(updated)

4. Select Hide All and press Enter.

   All objects of the selected graphical object type will not be displayed in the cross-section viewports.

Show All

➢ **To show all graphical objects:**

1. Select Mark>Graphic Control.

   The following menu will appear:



(updated)

2. Select the required object type.

   The following menu will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



(update)

3. Select any object to set its display setting.

   The following options are displayed:



(updated)

4. Select Show All and press Enter.

   All objects of the selected graphical object type are displayed in the cross-section viewports.

Set Current Target

You can set the Current Target. The Current Target is the only target that will be displayed in the Tip viewport. The direction of the arrow in the Tip viewport will always point in the direction of the current target. The current target in the Tip and cross-section viewports is displayed in bright orange. All other targets are hidden by default and displayed in faint orange if you choose to show them.

➢ **To set a target as the current target:**

1. Select Mark>Graphic Control.

   The following menu will appear:



(updated)

2. Select Target from the menu options.

   The following menu will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



(updated)

3. Select the Target that you want to set as current.

   The following options are displayed:



(updated)

4. Select Current Target and press Enter.

   The selected Target will be set as the current Target and the previous current Target is hidden.

Refer to *Using the Remote Control* on page 7-79 for details on how to set Current Target using the REMOTE CONTROL.

Patient Sensors View

The Patient Sensors view, which is displayed during the setup phase, can be displayed at any stage on the procedure if you want to verify the position of the Sensors.

➢ **To display the Patient Sensors:**

1. Select Tools>Patient Sensors Adjustment.

   The following window will appear:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

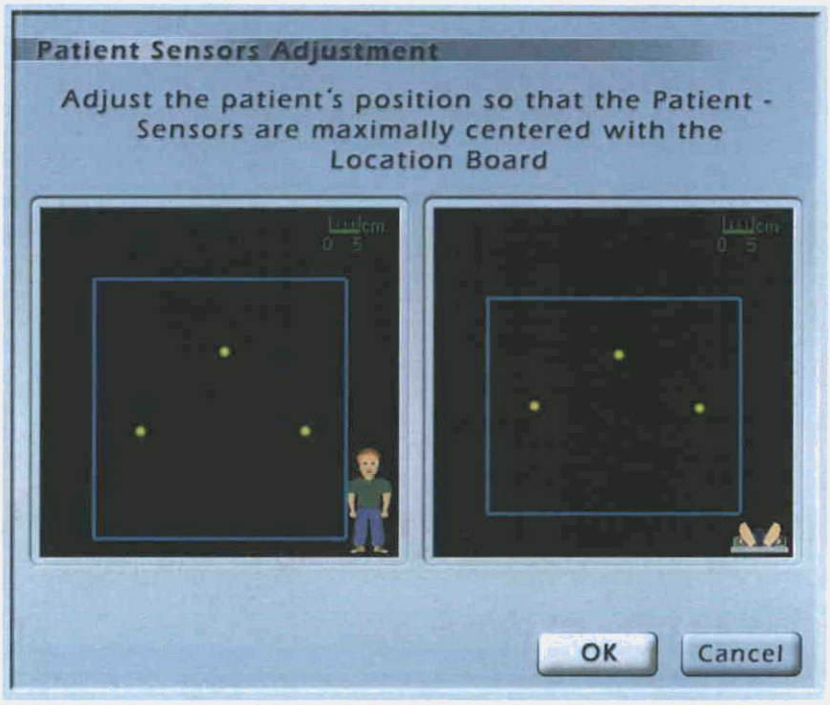


Figure 7-42: Patient Sensors Adjustment Window

2. Once you have checked the position of the Sensors, click OK to close the window.

Printing a Screen to File

A screen capture can be saved as a bitmap file for later reference.

➢ **To save a screen to file:**

1. Select File>Print to File, or press the Screen Capture button .

   The following dialog box opens:

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 7-43: Save Screen dialog box

2. Enter the required file name.
3. Choose one of the Save To options and click Save.

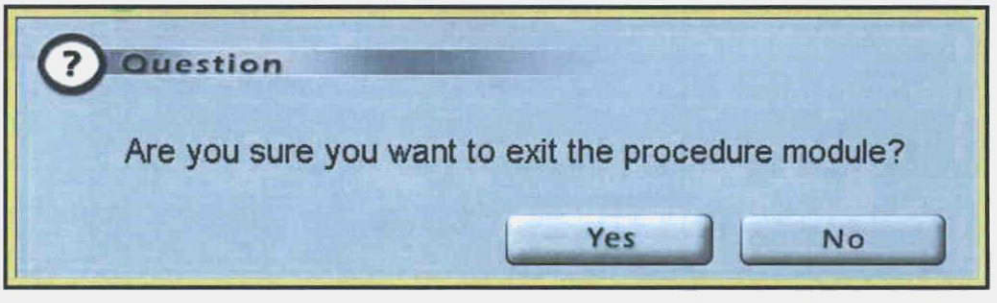
Shut-Down Process

Once the procedure has been completed and the system is no longer required, we recommend you to shut down the system.

➢ **To shut down the system:**

1. Select File>Exit.

   The following message will appear:



2. Click Yes to exit or No to stay in the Procedure module.

   If you click Yes, the module will close and return you to the Opening Screen.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 7-44: The Opening Screen *(updated)*

3. Click Exit.

   The following dialog box will appear:

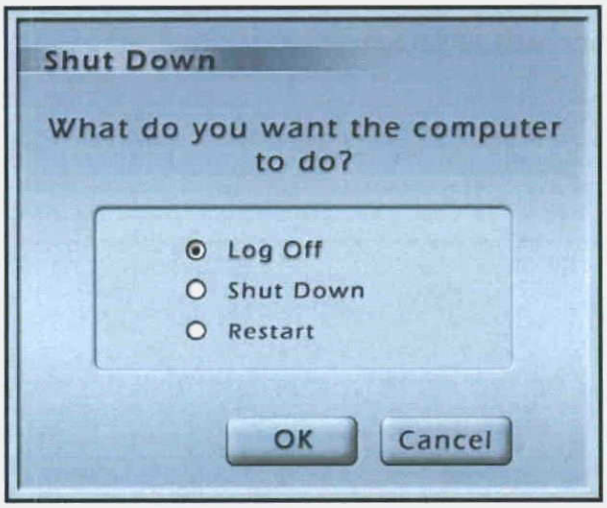


Figure 7-45: Shutting Down the system

4. Select Shut Down and click OK.
5. Once the operating system has shut down, switch off the system power supply switch located on the front of the power supply unit.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Figure 7-46: Switch off the Power Supply Switch

6. Switch off the main power supply switch located on the side of the cart.

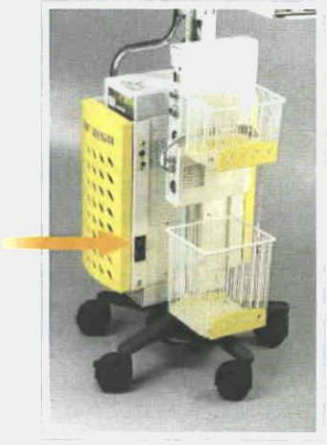


Figure 7-47: Switch off Main Power Supply Switch

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

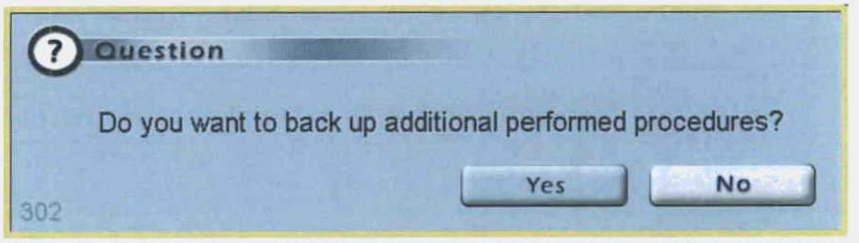
Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Backup

Procedure Backup is required in order to free up disk space on the system's hard drive and to provide supporting data for servicing. The data needs to be saved to an external media and stored.

➢ **To perform backup of procedures**

1. On the opening screen layout click the Backup button.
2. Insert a blank media into the CD/DVD drive and click OK.
3. When the burn process is complete the following dialog box will appear:



4. Click Yes to continue the backup or click No to return to the Opening screen.
5. Label the media in the following format and store in a safe place:
    - *Backup date*
    - *System Serial number*
    - *Site name.*

➢ **Performing backup after a procedure**

If there is sufficient data on the system's hard drive to fill an external media you will be prompted to perform a backup at the end of the procedure.



1. Click Yes to perform the backup or click No to return to the opening screen.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

- **Performing a necessary backup**

If there is no more space on the hard drive the Planning and Procedure buttons will be disabled and the following dialog box will appear:

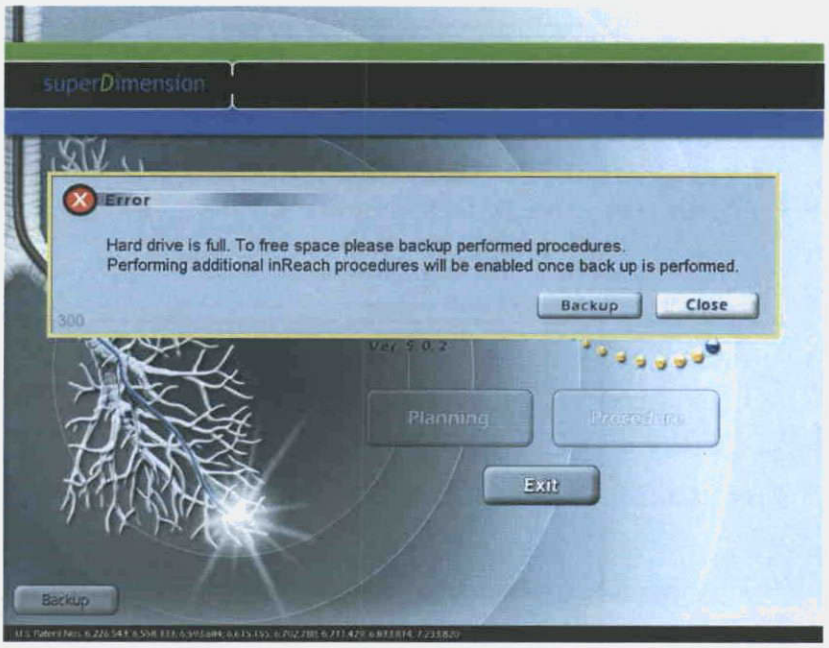


Figure 7-48: System's hard drive is full *(new)*

Once the backup is performed, the Planning and Procedure buttons will be enabled.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
230

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Data Recovery Procedure

In the event of a power failure or sudden system failure, the superDimension inReach™ System has a 30-minute window period during which the last procedure can be recovered. If the system failed during the Registration phase of the Procedure module, it will return to the beginning of that phase when the system is restarted. If the system failed after the Registration phase was successfully completed, it will return to the Navigation phase of the Procedure module when the system is restarted.

➢ **To initiate the Data Recovery procedure:**

1. The Load Planning File page will appear.

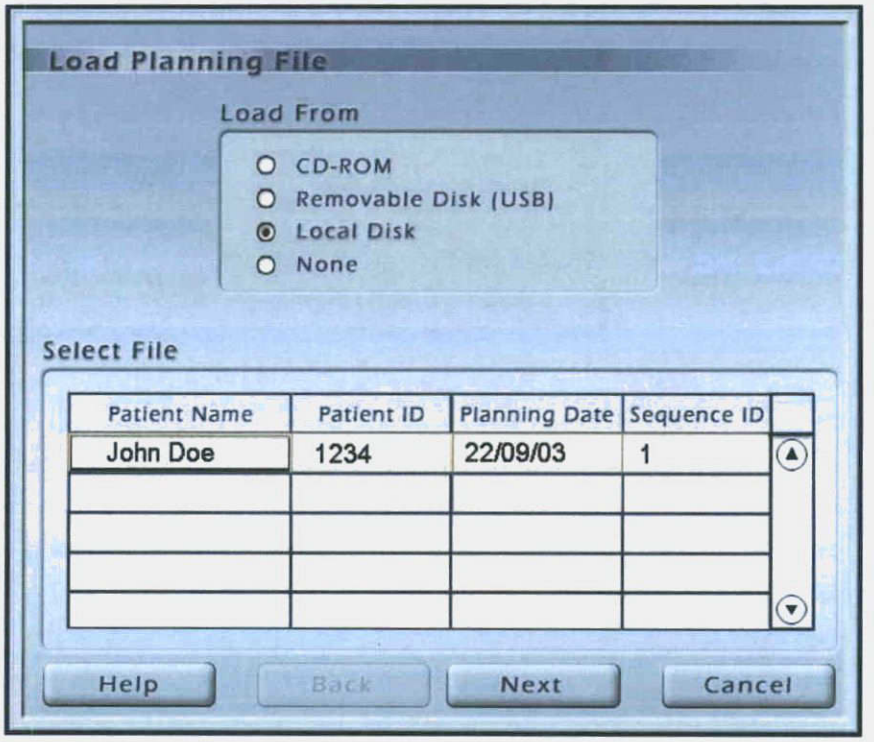


Figure 7-49: Load Planning File

2. Click Cancel.
3. The message "Are you sure you want to end the procedure?" appears. Click 'Yes'. The Load Planning File page is closed.
4. Select File>Continue Last Procedure.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the Locatable Guide and Extended Working Channel

Assembly



Warning

To avoid potential for infection, before opening any sterile packages containing system accessories, check that the packaging is intact, sealed, and is free from damage that could compromise the sterile barrier.



Warning

The Locatable Guide, Extended Working Channel, Bronchoscope Clip and Bronchoscope Adapter are all intended for single use only. To avoid potential for infection or cross contamination, do not reuse these accessories.



Warning

When handling the EXTENDED WORKING CHANNEL and the LOCATABLE GUIDE, be sure not to bend, twist, drop, or otherwise roughly handle these accessories as damage can result. Damage to the system accessories can cause tissue irritation and possible injury to the bronchial airways.

➢ **To connect the Locatable Guide to the EWC:**

1. Before use, perform a functional test of the LOCATABLE GUIDE and check that no components are damaged.
2. Insert the tip of the LG through the EWC Luer connector.

232

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

3. Push the LG shaft through the EWC in short stages, to prevent the LG from bending. If it does not move smoothly through the EWC, check the EWC for any obstruction.

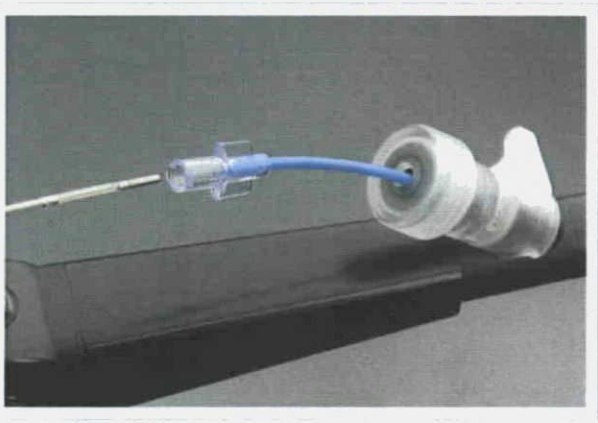


Figure 7-50: Inserting Locatable Guide into EWC

4. Once the tip of the LG protrudes from the EWC, fasten the LG to the EWC by turning it in a clockwise direction.



Caution

Check that the tip of the LOCATABLE GUIDE protrudes 5mm (± 3mm) from the end of the EWC. Perform the connection procedure described above only when the LG is in a straight position.

If the tip does not protrude or protrudes further than shown in the figure below, refer to *Troubleshooting* on page 9-1

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

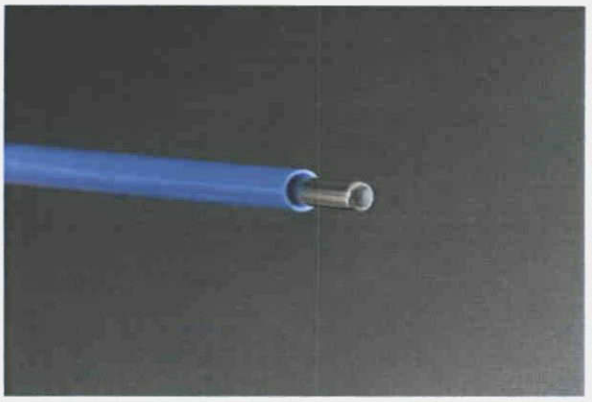


Figure 7-51: Recommended protrusion of the LG's Tip from the EWC

Inserting the Locatable Guide into a Bronchoscope

Warning

Never operate the LOCATABLE GUIDE without the EWC attached.

Before each use, check the outer surfaces of the LOCATABLE GUIDE and EWC, which are intended for insertion into a patient, to ensure there are no rough surfaces, sharp edges or protrusions. Sharp edges on these accessories can cause bleeding and/or pneumothorax.

When handling the EWC and the LOCATABLE GUIDE, be sure not to bend, twist, drop, or otherwise roughly handle these accessories as damage can result. Damage to the system accessories can cause tissue irritation and possible injury to the bronchial airways.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

➢ **To insert the Locatable Guide into a Bronchoscope:**

1. Ensure that you are using a compatible bronchoscope (see *Compatible Bronchoscopes*, page 3-15).
2. Remove the original working channel seal from the bronchoscope.
3. Attach the BRONCHOSCOPE ADAPTER onto the working channel of the bronchoscope.



Figure 7-52: Attaching the Bronchoscope Adapter

4. Attach the adapter clip so that the BRONCHOSCOPE ADAPTER is firmly attached to the bronchoscope's working channel.

235

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

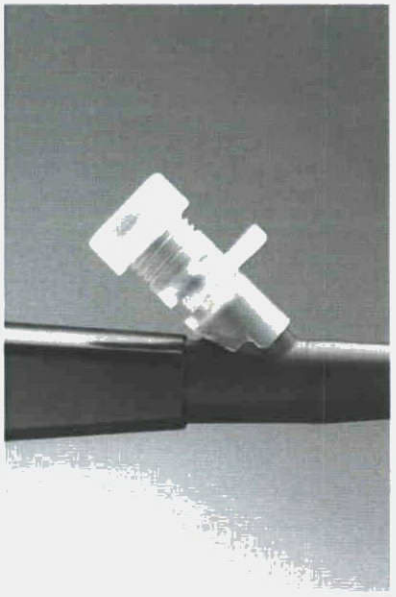


Figure 7-53: Bronchoscope Adapter attached

5. Open the BRONCHOSCOPE ADAPTER fully by turning the BA nut counter-clockwise.
6. Insert the tip of the LG into the bronchoscope's working channel through the BRONCHOSCOPE ADAPTER and push it through in short steps. Ensure that the LG protrudes 10 mm (± 1 mm) from the end of the bronchoscope as shown below.



Figure 7-54: Locatable Guide Tip Protruding from the Bronchoscope

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

231

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018



Caution

If the LOCATABLE GUIDE does not move smoothly through the working channel, there could be an obstruction. Check that the working channel is free of any obstruction and that the LOCATABLE GUIDE is free of any debris.

If problem persists, refer to *Locatable Guide, EWC, Bronchoscope Adapter, Bronchoscope Clip* and PC Troubleshooting on page 9-17.

7. Tighten the BRONCHOSCOPE ADAPTER by turning it clockwise until the LG is secured in place and cannot be moved.

   If the LG cannot be locked in place, refer to *Troubleshooting* on page 9-1.

237

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

8. Attach the BRONCHOSCOPE Clip to the bronchoscope as shown in Figure 7-55.

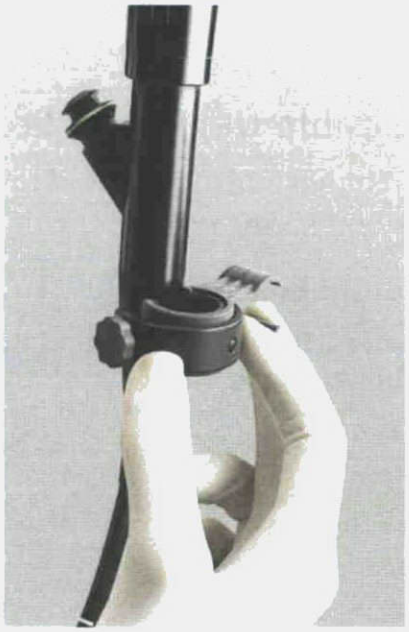


Figure 7-55: Attaching the Bronchoscope Clip

9. Tighten the BRONCHOSCOPE Clip to the bronchoscope as shown in Figure 7-56.



Figure 7-56: Tightening the Bronchoscope Clip

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the Bronchoscope Clip

The user may choose to anchor the LG using the BRONCHOSCOPE CLIP as described in Figure 7-57.

Holding Methods for the Locatable Guide and Bronchoscope

We recommend two different holding methods when using the LG during the Registration and Navigation phases.

The Registration Grip Using the Bronchoscope Clip

Hold the bronchoscope in your left hand and hold the LG using the BRONCHOSCOPE CLIP as shown below.

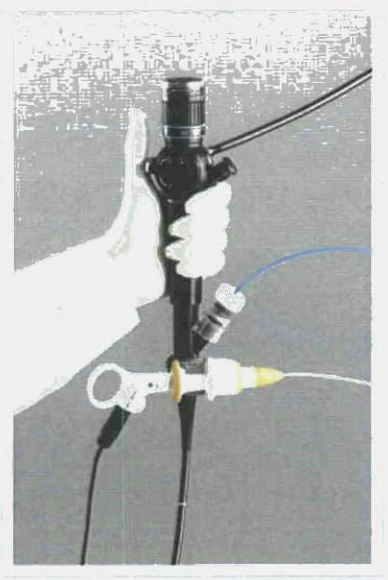


Figure 7-57: The Registration Grip

239

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Navigation Grip

Hold the bronchoscope in your left hand and grip the LG with your left hand by inserting your thumb in the handle and holding the PULLING DIAL between your index and middle fingers. The LG is held in a horizontal direction as shown below.

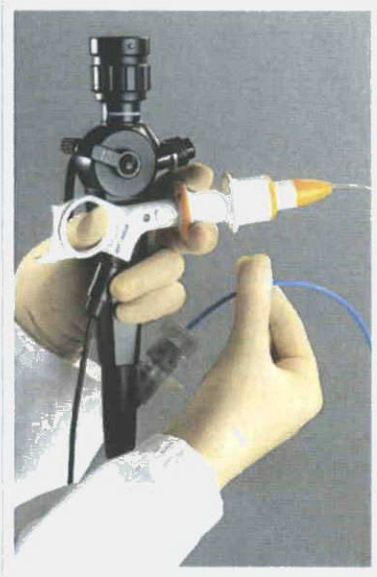


Figure 7-58: The Navigation Grip

Controlling the Locatable Guide's Tip

The LG's tip can be deflected in eight directions, evenly divided around the axis shaft of the LG. You can set the direction by turning the PULLING DIAL in the desired direction. The purple arrow on the PULLING DIAL indicates in which direction the tip deflects.

➢ **To change the direction of the Locatable Guide Tip:**

1. Release the PULLING DIAL to verify that it is fully returned to the distal side.
2. Turn the PULLING DIAL to the required direction.
3. Pull the PULLING DIAL as required.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

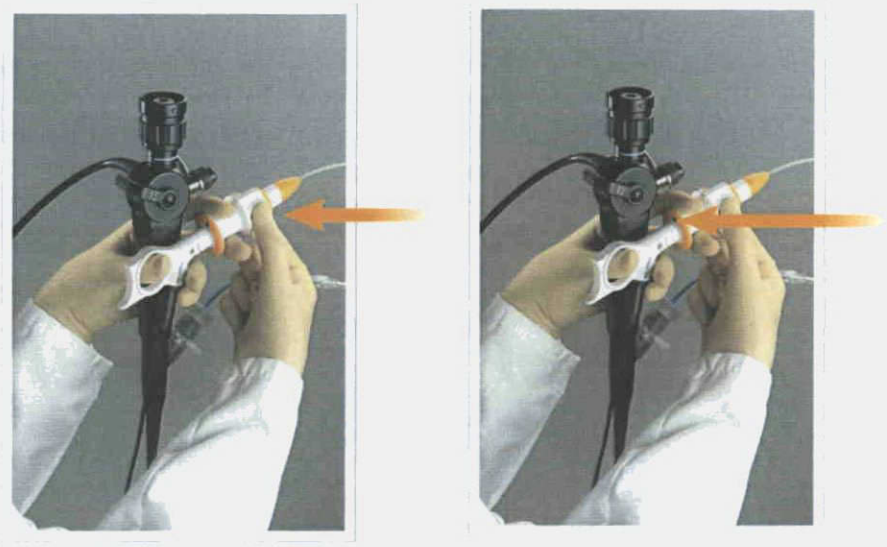


Figure 7-59: Turning the Locatable Guide's Tip

4. To change direction, first release the PULLING DIAL all the way, before attempting to turn it.

Notes

Never attempt to turn the PULLING DIAL while it is pulled back.

Always release the PULLING DIAL first before turning it when changing direction.

Operating the Locatable Guide

➢ **To operate the Locatable Guide During Registration:**

1. Attach and insert the LG into the bronchoscope's working channel as explained on page 7-65.
2. Hold the LG in a Registration grip as illustrated in Figure 7-57 and ensure that it is locked in place by the BRONCHOSCOPE ADAPTER.
3. Perform the Registration procedure.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Operating the Locatable Guide During Navigation



Warning

To avoid damage to the EWC and tissue irritation and possible injury to the bronchial airways, never use excessive force (1 Kg force (10N)) during the insertion or extraction of the Locatable Guide, endoscopic tools or marker delivery tools through the EWC.

In case of difficulties during the insertion or extraction of the Locatable Guide, endoscopic tools or marker delivery tools through the EWC, first straighten the bronchoscope distal tip, then un-lock the Locatable Guide and gently pull out the Locatable Guide, or maker delivery tool together with the EWC. In case that is not possible, then pull the entire bronchoscope out together with whatever is inserted through its working channel.

Afterwards, replace EWC and/or Locatable Guide and/or endoscopic tool and/or marker delivery tool if damaged. Reinsert and navigate back towards the Target area as needed.

➢ **To operate the Locatable Guide During Navigation:**

1. Hold the LG in a Navigation grip and carefully open the BRONCHOSCOPE ADAPTER, by turning it counter-clockwise, until the LG can move freely.
2. Carefully push the LG slowly, in short steps, through the bronchoscope's working channel.
3. Navigate the LG along the correct airway until the Target is reached.
4. Once the LG's tip is on target, release the PULLING DIAL and fasten the BRONCHOSCOPE ADAPTER, by turning it clockwise until the LG is securely held in place and cannot move.
5. Open the EWC bayonet to detach it from the LG.
6. Remove the LG from the EWC while taking care that the EWC and bronchoscope were not moved from their current position on the Target.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

242

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

7. Leave the LG in a sterile location in case it is needed again during this procedure.
8. A tool can now be inserted via the EWC after marking its length (See *Marking the Endoscopic Tool Length*, on page 7-74 for details on how to mark the tool length).



Caution

Any movement of the bronchoscope at this stage will affect the position of the EWC, which could cause it to move off target.

If the bronchoscope was unintentionally moved, insert the LOCATABLE GUIDE again and re-navigate towards the Target.

Marking the Endoscopic Tool Length

Before using any tool with the EWC, its length must be marked so that you can see how much of the tool should be inserted into the EWC. The tool must be marked before starting any procedure.

➢ **To mark the Tool length:**

1. Insert the tool into the EWC or MEASURING TUBE, straighten the EWC or MEASURING TUBE and push the tool it until it protrudes from the end as much as needed for proper operation.
2. Using a marker, mark the proximal side of the tool, adjacent to the EWC or MEASURING TUBE proximal edge.
3. Remove the tool from the EWC or MEASURING TUBE.

   Keep the EWC or MEASURING TUBE in a sterile location for further possible marking of additional tools, for the same procedure.



Caution

The tool length marking process must be performed on all tools that will be used during the procedure and should be performed during procedure preparation.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

243

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Inserting a Endoscopic Tool into the EWC

Warning

To avoid potential injury to the bronchial airways always use the chosen compatible tool as specified in the User Manual supplied with the tool.

For a list of Compatible Endoscopic Tool see page 3-18.

Caution

Any tool, from the approved tool list, intended for insertion into the EWC, must undergo the tool length marking process beforehand.

Refer to Marking the Endoscopic Tool Length on page 7-74.

➢ **To insert a tool into the EWC:**

1. Gently insert the tip of the tool into the EWC.
2. Push the tool through the EWC until the tool limit mark is reached. Do not push the tool past the tool limit mark.
3. Once the procedure is complete, remove the tool and open the BRONCHOSCOPE ADAPTER by turning it counter-clockwise.
4. Remove the EWC and dispose of it.

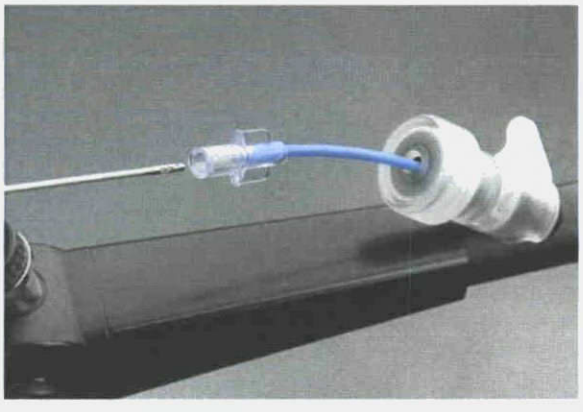


Figure 7-60: Inserting an Endoscopic Tool into the EWC

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Marker placement in soft lung tissue



Warning

To avoid potential injury to the lungs pleura, exercise caution when deploying markers near pleura target sites.

➢ **To insert a Radiosurgical Marker using the EWC:**

After reaching the desired target using the superDimension inReach™ System, the following method may be used to place sterile radiosurgical markers at the target location.

1. Pre-mark the guide catheter and guide wire or other radiosurgical marker delivery tool by inserting into the EWC and advancing until it protrudes from the end as much as needed for proper operation. Place a "tool limit mark" on the proximal side of the tool, adjacent to the proximal edge of the EWC hub (See *Marking the Endoscopic Tool Length*, on page 7-74 for details on how to mark the tool length).
2. Insert the guide catheter or radiosurgical marker delivery tool into the EWC.
3. Advance the guide catheter or radiosurgical marker delivery tool through the EWC until the tool limit mark has been reached and the tip is positioned at the desired marker implant location.
4. Load the sterile radiosurgical marker into the guide catheter.
5. Use a guide wire or other inner member to advance the radiosurgical marker, and using the tool limit mark as a guide, deploy the radiosurgical marker into the soft lung tissue.
6. Repeat steps 4-5 until the desired number of radiosurgical markers (typically 2-5) have been implanted in the target area.
7. Remove the guide catheter or radiosurgical marker delivery tool from the EWC.
8. Verify placement and position of the radiosurgical markers. Fluoroscopy can also be used to verify the location of the

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

radiosurgical markers, if performed on at least two perpendicular angles.

➢ **To insert a Dye Marker using the EWC:**

After reaching the desired target using the superDimension inReach™ System, the following method may be used to inject dye markers at the target location(s).

1. Load the syringe with the desired dye marker volume.
2. Pre-load the needle-catheter with desired volume of dye per standard procedure.
3. Pre-mark the needle-catheter or dye marker delivery tool by inserting into the EWC and advancing until it protrudes from the end as much as needed for proper operation. Place a "tool limit mark" on the proximal end of the marker delivery tool adjacent to the proximal edge of the EWC hub (See *Marking the Endoscopic Tool Length*, on page 7-74 for details on how to mark the tool length).
4. Insert the needle-catheter or dye marker delivery tool into the EWC.
5. Advance the needle-catheter or dye marker delivery tool through the EWC until the tool limit mark has been reached and the tip is positioned at the desired marker location.
6. Inject the dye marker into the soft lung tissue through the needle-catheter or dye marker delivery tool at target location(s).
7. Remove the needle-catheter or dye marker delivery tool from the EWC.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

246

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the CT and Video Guided Navigation together with the Locatable Guide



Warning

To avoid potential for infection, before opening any sterile package containing system accessories, check that the packaging is intact, sealed and is free from damage that could compromise the sterile barrier.

When using the CT and Video Guided Navigation, use the LOCATABLE GUIDE with the EWC as described below:

➢ **To operate the Locatable Guide using the CT and Video Guided Navigation:**

1. Insert the LOCATABLE GUIDE with the EWC to the bronchoscope and complete the Registration phase.
2. Set the Navigation screen layout to the CT and Video Guided viewing presets from the View → Viewing Preset menu. (See, Navigation Screen Layout on page 7-22 for details on how to set the Navigation screen layout).
3. Navigate and steer the bronchoscope together with the LOCATABLE GUIDE towards the designated Target and position the LG in the correct direction towards the designated Target.
4. Freeze video images and CT slices by pressing the FOOT PEDAL or the Enter button on the KEYBOARD or on the REMOTE CONTROL.
5. Retract the LG together with the EWC.
6. You may replace the BA used with a BA body with the 2 mm BA Valve to fixate the endoscopic tool to the bronchoscope.
7. Insert the endoscopic tool.
8. Compare live video with frozen images to verify the proper location of the inserted tool.

Use the endoscopic tool according to the instruction for use provided by the vendor of that specific tool.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the Remote Control

The REMOTE CONTROL provides you with a practical and convenient method of controlling certain phases of the procedure without having to use the mouse or keyboard. It is especially useful during the registration and navigation phases, when you have to work with the bronchoscope and the LG.

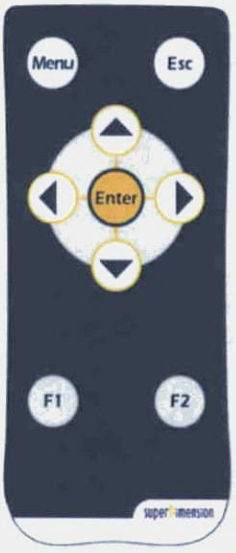


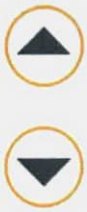
Figure 7-61: The Remote Control

The following sections detail the required buttons and button combinations needed to perform basic functions in the Registration and Navigation phases.

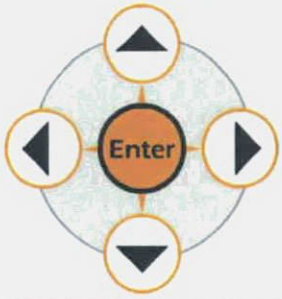
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Button Controls for the Registration Phase

Function	Button(s)	Process
Scroll List		Use the Up and Down arrows to scroll through a list.
Acquire/ OK/ Cancel/ Undo/ Yes/No Responses		Use the Left and Right arrows to move the focus onto the required option in a dialog box, e.g. Acquire.
		Press Enter to select the required option.

Button Controls for the Navigation Phase

Function	Button(s)	Process
Menu Activation	Menu	Press the Menu button to display the first menu on the menu bar.
		Use the Up and Down arrows to scroll through the menu options and the Left and Right arrows to move between menus.
Move to next Waypoint		Press the Enter button to start the pathway and press it again to stop the pathway.
Change Current Target/Change current Pathway to Target		Use the Up and Down arrows to toggle between current targets and pathways. These buttons will stay activated for toggle between current targets until needed for another action.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Function	Button(s)	Process
Change Current Waypoint		Use the Left and Right arrows to toggle between current waypoints. These buttons will stay activated for toggle between current waypoints until needed for another action.
Zoom Out	F1	Zooms out of the image.
Zoom In	F2	Zooms in on the image.
Esc	Esc	Close any open menu.

The F1 and F2 buttons can be configured using the Application Settings by clicking Tools > Application Settings. Refer to Procedure Module Settings on page 7-82.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

256

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Using the Foot Switch

The FOOT SWITCH operates as an Enter button and can be used in all instances where the Enter button on the REMOTE CONTROL or keyboard would be used.



Figure 7-62: The Foot Switch

Procedure Module Settings

The system comes with certain factory default settings. You can change these settings to suit your specific preferences and style of work. The default settings can always be restored by clicking RESET.

➢ **To access the Application Settings:**

- Select Tools>Application Settings.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

251

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The Application Settings window will appear.

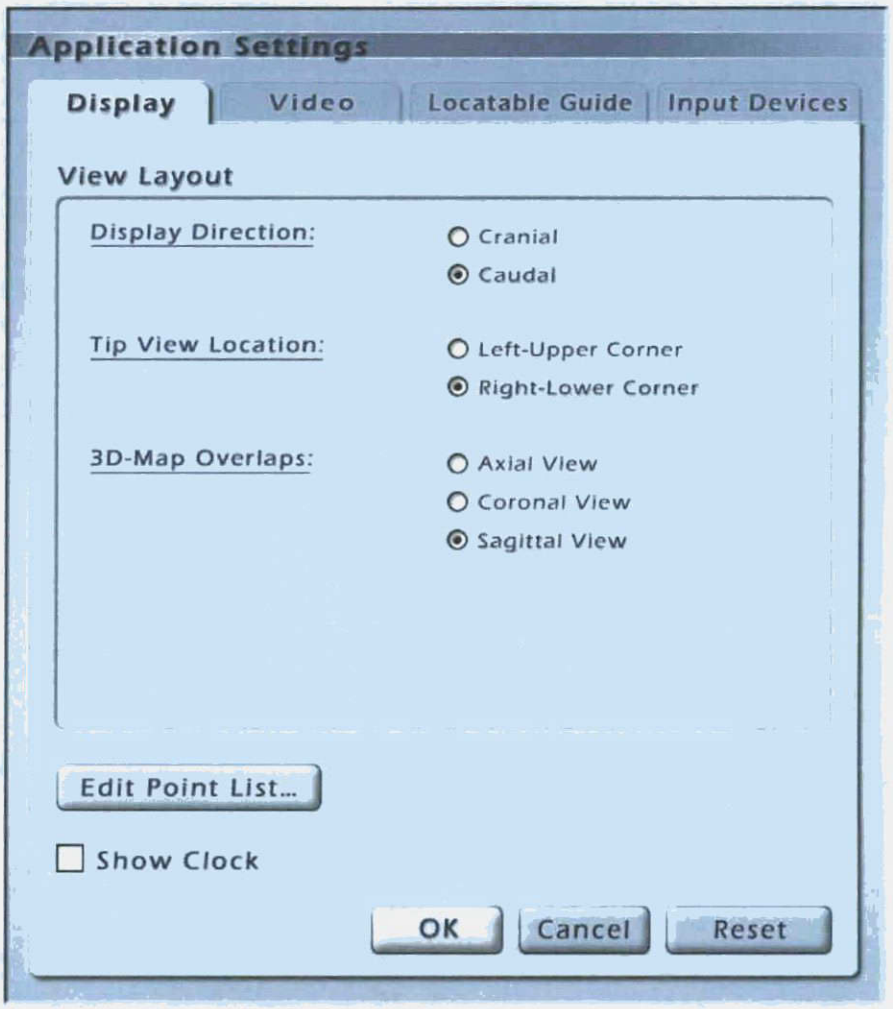


Figure 7-63: The Applications Settings window *(updated)*

You can define the following settings:

- Display
- Video
- Locatable Guide
- Video Preview
- Input Devices

252

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Display

View Layout

Option		Description
View Display Direction	Cranial	Sets the display direction as cranial.
	Caudal	Sets the display direction as caudal.
Tip View Location	Left Upper Corner	Displays the Tip viewport in the left upper quadrant.
	Right Lower Corner	Displays the Tip viewport in the right lower quadrant.
3D-Map Overlaps	Axial View	Displays the 3D-Map in the Axial viewport
	Coronal View	Displays the 3D-Map in the Coronal viewport
	Sagittal View	Displays the 3D-Map in the Sagittal viewport

Point Setting

Option	Description
Point Preset	By clicking Edit you can define other point names and types, which will be added to the name selection list that is displayed when adding a new point. See *Editing Point Settings* on page 7-90 for further details.

Show Clock

Option	Description
Show Clock	Checking this box will display the elapsed time of a procedure from the CT-to-Body Registration Phase. The elapsed time will be displayed in the bottom right of the Procedure module screen.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

253

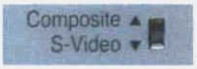
Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Video

Refer to *Video Display* on page 7-16 for more details regarding the Video Review function.

Option		Description
Video Review during registration	**None**	There is no Video Preview after acquiring a Registration Point.
	Auto Confirm	You can define the Review time (in seconds) after acquiring a Registration Point.
	Manual Confirm	The Video is paused until you confirm the acquisition of each Registration Point.
Video Output Source	**Composite Video**	Sets the video output port to Composite Video.
	S - Video	Sets the video output port to S - Video.

➢ **To set the type of video output signal:**

1. Choose between Composite Video and S – Video option on the Video tab in the Application Settings dialog box of the Procedure Module.
2. Set the switch on the video panel 

accordingly.

Locatable Guide

See *The Crosshairs and Average Mode* on page 7-41 for further details regarding the different AVERAGE MODES.

Option	Description
No Average	No compensation is set.
By Sync	Set in sync with chest movement cycle.
By Time	Set by a manually defined time interval.

254

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Input Devices

Remote Control Configuration

See *Using the Remote Control* on page 7-79 for more details on the Remote Control functions. You can define the control buttons F1 and F2 on the Remote Control by selecting the desired default function in the pull down menu.

Option	Description
Zoom In	Zooms in on the image.
Zoom Out	Zooms out of the image.
Viewing Presets toggle	Toggles between the CT Guided Navigation and the CT and Video Guided Navigation modes.
Screen Capture	Performs a screen capture of the screen layout.
3D-Map display toggle	Toggles between the 3D-Map and the respective CT cross-section viewport.
Tip view presets toggle	Toggles the Tip View in CT Guided navigation.
Re-registration	Return to the registration screen.

255

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

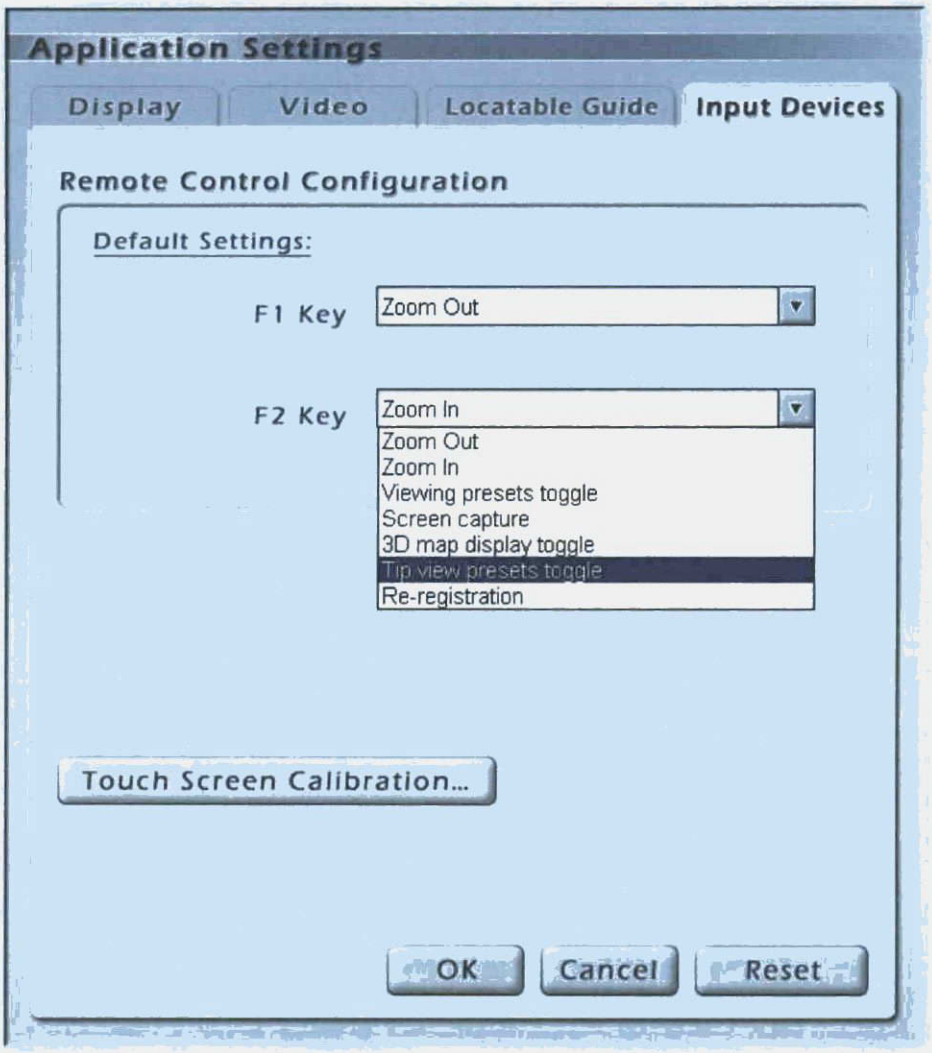


Figure 7-64: The Applications Settings window *(updated)*

Touch Screen Calibration

The Touch Screen Calibration can be performed when there seems to be an offset between the finger touch point and the cursor position (cursor or button click does not appear directly under finger).

➢ **To calibrate the touch screen:**

1. Click the Touch Screen Calibration button in the Application Settings window. The Touch Screen calibration window will appear.

256
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

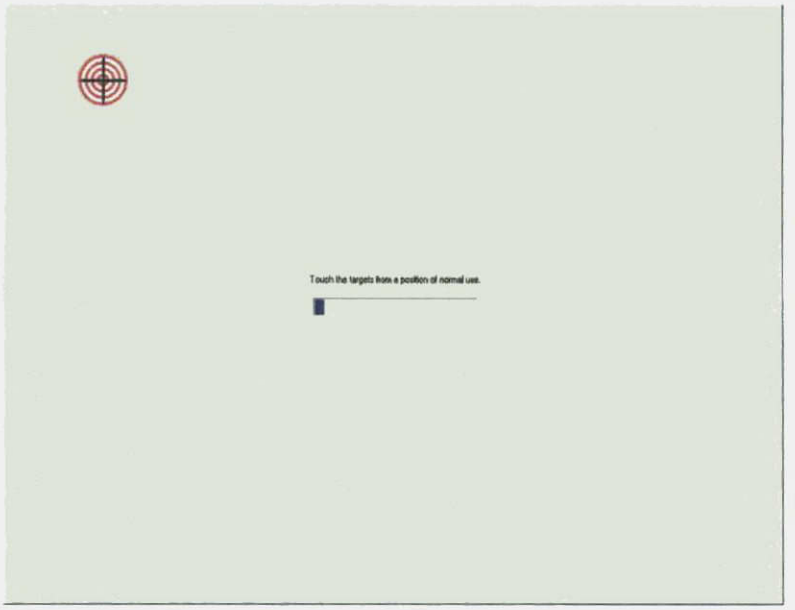


Figure 7-65: Touch Screen calibration *(new)*

2. Touch the center of the small target (+) in the upper left of the screen.
3. Touch the center of the small target (+) in the bottom right of the screen.
4. Touch the center of the small target (+) in the upper right of the screen.
5. Click the check mark button to approve the calibration or click the redo button to restart the calibration.



Figure 7-66: Calibration confirmation *(new)*

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The calibration must be performed within 30 seconds or the calibration window will close and return to the Application Settings window.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Editing Point Settings

When you create a new point, a list of predefined named points from which you must make a selection is displayed. New points can be added to this list and existing points can be edited by clicking the Edit button in the Application Settings window. The following dialog box will appear:

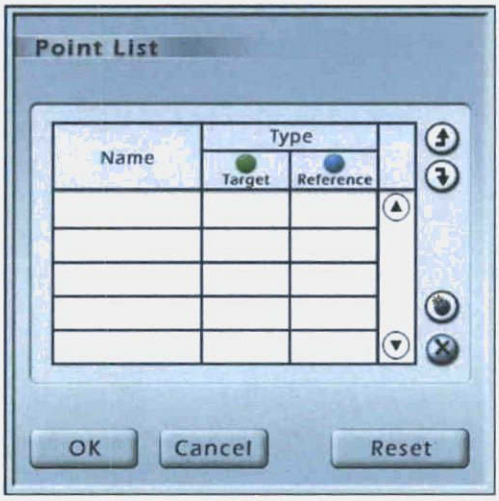


Figure 7-67: Preset Points Settings dialog box

➢ **To create a New Preset Point**

1. Click .

   A new row will appear at the end of the list.

2. Indicate the Type of the new point, as either a Reference Point or a Target. A Reference Point can be displayed in all cross-section viewports. The current target is displayed in all viewports including the Tip viewport, while all other targets are only displayed in the cross-section viewports.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

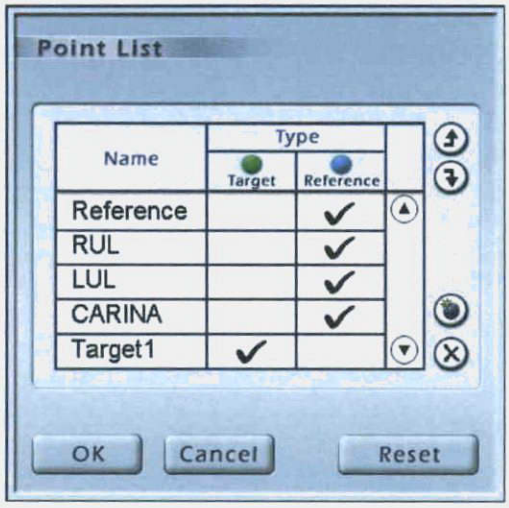


Figure 7-68: Set Point Type

3. Click in the Name field and enter a name for the point.
4. Click OK to save the changes and close the dialog box.

Changing a Preset Point

An existing point can have its type and name changed by selecting the point and making the changes. Once all the required changes have been made, click OK to save them and close the dialog box.

Changing the Preset Point Order

You might want to customize the order in which the points are listed. To change the order, select the required point and click  to move the point up the list or  to move the point down.

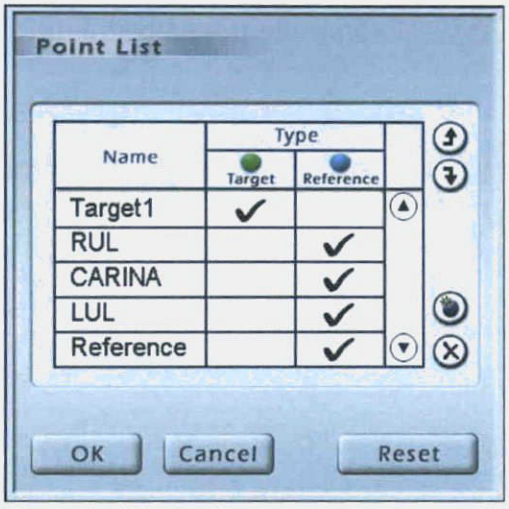


Figure 7-69: Change Point Order

260

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Removing a Point

➢ **To remove a point:**

1. Click the required point.
2. Click .

   The selected point is removed.

Log and Status Views

Status View

The Status View displays the current status of the system components, allowing you to immediately identify the source of any technical problem. The Status View is displayed during the setup stage in the Navigation module and can also be displayed at any time during the procedure by selecting View>Status View.

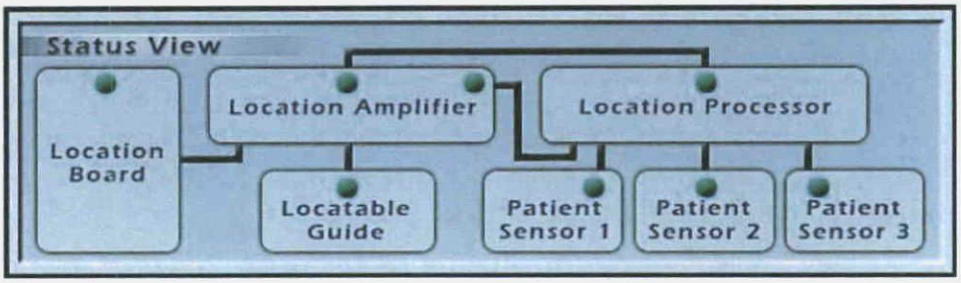


Figure 7-70: Status View

Each block represents a component. The black lines represent the connections between the components. Within each component block is an indicator light, which indicates the current status of that component. Note that the LOCATION AMPLIFIER has two indicator lights, one for each internal component within the LOCATION AMPLIFIER.

The following indicator light colors are being displayed:

Color	Status	Description
● Green	Ready	Component is ready for use.

261

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Color		Status	Description
○	Yellow	Not ready	Component is correctly connected but not ready for use. For example, the yellow light would appear if the LOCATABLE GUIDE were out of the sensing volume.
●	Black	Not connected/detected	Component is not connected correctly or is not being detected by the system. Check the connection and refer to *Troubleshooting* on page 9-1 if the problem persists.

262

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Log View

The Log View displays a chronological list of events that were registered by the system. Select View>Log View, to display the Log View at any time during the procedure.

The following window will appear:



Figure 7-71: Log View

Each log displays the time of the event and a description of the action that occurred.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

The following table lists the event types that are logged:

Procedural Phase Events

Event Type	Log Text Description
Start Procedure	Procedure started at <system time and date>
Procedure Details	Procedure No.: <procedure no.>
Patient Details	Patient ID: <patient ID> Patient Name: <Patient Name> Gender: < Gender>.
Setup Complete	Setup completed
Registration Complete	Registration was completed with a CT-to-Body divergence of X.Y mm.
End Procedure	Procedure ended at <system time and date>
Continue Procedure	Procedure continued at <system time and date>
Elapsed Time Reset/Change	Procedure elapsed time changed at <system time and date> to <elapsed time >

System Component Events

Event Type	Log Text Description	
System Component Connection		<*System component name and ID no.* connected>.
	For PATIENT SENSORS include also port no.:	<*System component name and ID no.* connected on port < *port no.*>.
System Component Not Detected/ Disconnection		<*System component name* not detected.
	For PATIENT SENSORS include also port no.:	<*System component name*> not detected on port <*port no.*>.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Navigation Command Events

Event Type	Log Text Description
Mark point	Point "<name>" marking
Mark Target	Target "<name>" marking
Start/ End pathway	Pathway "<no.>" Started/Ended
Undo/Redo	Undo/Redo <marking command>
Set Target as current	"<target name>" set as current Target

Exporting the Log File

The Log file can be exported and saved in a predefined location.

➢ **To export a Log File:**

1. Select File>Export Log

   The following dialog box will appear:



Figure 7-72: Export Log

2. Enter a name for the file
3. Choose one of the Export To options and click Save.

   Note that the storage location cannot be changed. The file can be saved as a *.dat file and can be opened by using a default text editor, such as Microsoft Notepad.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 8: Cleaning

Cleaning Components Located on the Cart

The system components located on the cart should be cleaned by wiping with a clean gauze pad.



Warning

To avoid electrical shock, always disconnect the system from the wall outlet prior to cleaning the system and replacing fuses.

To avoid health hazards, comply with the detergent manufacturer's instructions.



Caution

To avoid the possibility of static shock and damage to the system, do not use aerosol spray cleaners on the monitor.

Do not clean the system with chlorinated or aromatic solvents, acidic or basic solutions, isopropyl alcohol, or strong cleaners such as ammoniated products, as these may damage the surface of the system. Use the cleaning procedure recommended below.

Do not use spray cleaners on the system as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.

The following components should be cleaned by wiping with a clean gauze pad dipped in 70% ethyl alcohol:

- Patient Sensor
- Touch screen
- Location Board and Cable
- Locatable Guide Cable
- Remote Control

266

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

- FOOT SWITCH
- KEYBOARD AND MOUSE



Warning

To avoid electrical shock and system damage, replace fuses only with fuses that have the same ratings for blow characteristics, current, and voltage as the fuses supplied with the device.

267

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 9: Troubleshooting

This chapter explains how to respond to system error messages and provides solutions to general technical problems that may be encountered during operation.

If the problem is not covered here or the recommended corrective action does not rectify the problem, contact your superDimension customer service representative for assistance.

Error Handling

If an error message appears, search for it in the following tables and perform the corrective action as described.

Planning Module Error Messages

Loading DICOM

Error Message or Symptom	Problem and Corrective Action
Message: "CD or CD drive is defective. Please insert correct CD and try again." **Message No.: (100)**	Ensure that the CD is inserted in the CD drive and that the drive is closed. If problem persists contact your customer service representative.
Message: "CD drive is not ready. Please insert correct CD and try again." **Message No.: (101)**	Ensure that the CD is inserted in the CD drive and that the drive is closed. If problem persists contact your customer service representative.
Message: "Could not open the CT data. Please call service" **Message No.: (102)**	Ensure that the CD is in standard DICOM 3.0 format. If problem persists contact your customer service representative.
Message: "Could not open the CT data." **Message No.: (103)**	The CD does not contain DICOM files.
CT images do not load properly or are corrupt.	Can occur if the Planning file was not properly transferred to the Removable Disk (USB). Export the Planning file to the USB again, ensuring not to remove the USB until the LED stops blinking.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
Message: **"Connection to <DICOM System> Failed** **Message No.: (202)**	Can occur during query/retrieve of studies, where the <*DICOM System*> designates the system used. Ensure that the Ethernet cable is connected to the wall plug and that connection to the network is established. Contact your administrator for further assistance.
Message: **"Search Action Failed** **Message No.: (200)**	Appears if no matching criteria were found in the query process. Refine you search definitions and try again.
Message: **"Retrieve Action Failed** **Message No.: (201)**	The retrieval of studies failed possibly due to a bad connection or lack of available data for this study.

269

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning File Status

Error Message or Symptom	Problem and Corrective Action
Message: "The Planning file is not ready for use in a procedure. Please make sure that: ▪ You have marked at least four registration points. (Five or more points are advised.) ▪ You have marked at least one Target. ▪ The registration points you have marked are sufficiently remote from one another. Specifically, please mark the Main Carina as well as two points in each lung, one in the upper lobe and one in the middle/lower lobe, for a total of five points." Do you want to exit/export anyway?" **Message No.: (110-128)**	Can occur while exiting or exporting a planning file that is not ready for use in a procedure. Verify the needed conditions according to the message displayed on screen. Complete the planning file before continuing to the procedure.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

270

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Registration Points/Targets

Error Message or Symptom	Problem and Corrective Action
Message: "Invalid name, please enter a new name." **Message No.: (130)**	Enter a valid name for the registration point. A valid name must include only alphanumeric characters, without any spaces.
Message: "There is already a registration point by that name. Please enter a new name." Or "There is already a Target by that name. Please enter a new name." **Message No.: (131-132)**	The entered name already exists. Enter in a different name for the registration/Target.

3D-Map generation

Message: "3D-Map generation cannot be completed. Please press 'OK' button to continue." **Message No.: (190)**	A 3D-Map cannot be generated for this CT scan. The Planning module will load without the 3D-Map.
Message: "The Pathway cannot be saved prior to 3D-Map exit point selection. Please click the 3D-Map to select exit point." **Message No.: (135)**	A pathway must be constructed with an exit point, either from the airways or from the target. Click on the location on the 3D-Map where you would like to place the exit point.

Print Screen

Error Message or Symptom	Problem and Corrective Action
Message: "An error occurred during the file	Ensure that the floppy medium is inserted in the CD drive and that the

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
export process. Please verify that the floppy medium is inserted and press 'Retry'. If problem repeats, please call service."	drive is closed. If problem persists contact your customer service representative.
Message No.: (140)	
Message: "An error occurred during the file export process. Please verify that the USB medium is inserted and press 'Retry'. If problem repeats, please call service."	Ensure that the USB medium is inserted in the USB port. If problem persists contact your customer service representative.
Message No.: (141)	
Message: "There is not enough memory space to complete the file export process. Please insert a new floppy medium or remove files from current floppy medium and press 'Retry'." **Message No.: (142)**	Please insert a new floppy medium or remove files from current floppy medium and press 'Retry'.
Message: "There is not enough memory space to complete the file export process. Please insert a new USB medium or remove files from current USB medium and press 'Retry'." **Message No.: (143)**	Please insert a new USB medium or remove files from current USB medium and press 'Retry'.

Export file

Message: "The removable disk is full. Press OK to erase the entire content of the disk"	The removable disk is full. Press OK to erase the entire content of the disk. Alternatively, you may also press Cancel and export to a CD or a

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

272

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Message No.: (182)	different removable disk.
Message: "There is not enough space on the removable disk. Please export the files to a higher capacity removable disk or alternatively export to a CD."	The capacity of the removable disk used is insufficient for exporting a Planning file. Please export the files to a higher capacity removable disk or alternatively export to a CD.
Message No.: (183)	

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Module Error Messages

Location Processor Errors

Error Message or Symptom	Problem and Corrective Action
Message: "The Location Processor was not detected. Please check that the power supply is connected and the switch is ON, check the connection to the PC and press 'Retry'." **Message No.: (200)**	The power supply unit of the LOCATION PROCESSOR may be turned off or there may be a connection malfunction: 1. Make sure the LOCATION PROCESSOR is connected to the power supply unit and that the isolation transformer is connected to the main power supply. If the LOCATION PROCESSOR is disconnected from the power supply unit, turn OFF the power supply to the LOCATION PROCESSOR before reconnecting the LOCATION PROCESSOR to the power supply unit. 2. Reconnect the LOCATION PROCESSOR to the power supply unit if needed and turn ON the power supply unit. 3. Make sure that the switch of the power supply unit is turned ON. Make sure the LOCATION PROCESSOR is connected to the PC. Click Retry and the message will close if the LOCATION PROCESSOR is detected.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
Message: "Location Amplifier is connected to a wrong port of the Location Processor. Please remove, reconnect to the correct port and press 'Retry'." **Message No.: (201)** Or "Patient Sensor is connected to a wrong port of the Location Processor. Please remove, reconnect to the correct port and press 'Retry'." **Message No.: (202)** Or "Locatable Guide is connected to the Location Processor. Please remove the Locatable Guide, reconnect to the Location Amplifier and press 'Retry'." **Message No.: (203)**	The LOCATION AMPLIFIER, PATIENT SENSOR or LOCATABLE GUIDE may be connected to the incorrect port on the LOCATION PROCESSOR: 1. Remove the connector from the wrong port of the LOCATION PROCESSOR and reconnect to the correct port. 2. Click Retry. The message will close when the connector is detected through the correct port.
Message: "Connecting to the Location Processor..." **Message No.: (204)**	Occurs when the LOCATION PROCESSOR is turned on. Will disappear automatically once loading is completed.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Location Amplifier Errors

Error Message or Symptom	Problem and Corrective Action
For Location Amplifier Power port: **Message**: "The Location Amplifier was not detected. Please check connection to the Location Processor on the Location Amplifier Power port and press 'Retry'." **Message No.: (205)** Or For Location Amplifier port: **Message:** "The Location Amplifier was not detected. Please check connection to the Location Processor on the Location Amplifier port and press 'Retry'." **Message No.: (206)**	There may be a connection malfunction between the LOCATION AMPLIFIER and the LOCATION PROCESSOR: 1. Make sure the LOCATION AMPLIFIER is properly connected to the LOCATION PROCESSOR. 2. If the LOCATION AMPLIFIER is disconnected from the LOCATION PROCESSOR, turn off the power supply to the LOCATION PROCESSOR before reconnecting the LOCATION AMPLIFIER. 3. Reconnect the LOCATION AMPLIFIER to the LOCATION PROCESSOR if needed and turn ON the power supply to the LOCATION PROCESSOR. 4. Click RETRY.
Message: "The Location Amplifier is not functioning properly. Please call service." **Message No.: (207)**	There is an integral problem with the LOCATION AMPLIFIER unit. Contact your customer service representative for support.
Message: "Patient Sensor is connected to the port of the Locatable Guide. Please remove, reconnect to the correct port and press 'Retry'." **Message No.: (208)**	A PATIENT SENSOR is connected to the LOCATABLE GUIDE port. Remove the PATIENT SENSOR and connect it to the correct port and click RETRY. Refer to Figure 5-4 for further details.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Location Board Errors

Error Message or Symptom	Problem and Corrective Action
Message: "The Location Board was not detected. Please check connection to the Location Amplifier and press 'Retry'. If problem repeats, please call service." **Message No.: (209)**	1. Check the connection of the LOCATION BOARD to the LOCATION AMPLIFIER. 2. Click RETRY. 3. If the problem persists, disconnect and reconnect the Locatable Guide and Patient Sensor Triplets. 4. Click RETRY 5. Contact your customer service representative if problem continues.

Patient (Reference) Sensors Errors

Error Message or Symptom	Problem and Corrective Action
Message: "Patient Sensor No. <*no.*> is not responding. Please check the connection to the Location Processor and press Retry." **Message No.: (210)**	There may be a connection malfunction: 1. Make sure the PATIENT SENSOR is connected to the LOCATION PROCESSOR. 2. Click RETRY.
Message: "Patient Sensor No. < *no.*> is not working properly. Please remove, reconnect a new sensor and press Retry." **Message No.: (211)**	The sensor may be defective: 1. Disconnect the PATIENT SENSOR and replace with a new sensor. 2. Click RETRY. A message about the Patient Sensor change will appear.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
Message: "Patient Sensor No. <*no.*> is not functioning properly. Please confirm that the Sensor is in the correct sensing volume and press 'Retry'. If the problem repeats, change Sensor and repeat setup procedure." **Message No.: (212)**	There may be a bad signal from the sensor: 1. Make sure the sensor is within the PATIENT SENSOR sensing volume. 2. Click RETRY. If the problem continues, replace the sensor.
Message: "Patient Sensor(s) is out of the sensing volume. Please adjust the patient's position according to the User Manual and press 'Retry'. To view the sensing volume margins press 'Advanced'." **Message No.: (213)**	1. Click ADVANCE to display the ADJUSTMENT window. 2. Make sure the sensor is within the PATIENT SENSOR sensing volume. Adjust the patient's position if necessary. 3. Click OK. The PATIENT SENSOR adjustment window closes. If the problem continues, replace the sensor.
Message: "System inaccuracy was detected. Please adjust the patient's position and press 'Retry'. If problem persists, press 'Reset'." **Message No.: (214)** After pressing 'Reset' the following messages will appear: Message: "Are you sure you want to restart the procedure? Click No to return to the Procedure, or click Yes to return to the Setup phase." **Message No.: (215)**	This error message may be displayed during or after the registration phase. 1. Keep patient in supine position. 2. Make sure there is no metal mass nearby (close to the sensing volume), for example, a fluoroscope. 3. Click RETRY. If the problem persists press RESET. The registration process will have to be repeated after confirming that all previously collected data will be deleted.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
"Patient Sensor No. <*no.*> was replaced. You will not be able to continue using previously collected data. Please press 'OK' to repeat the registration process and start collecting new data." **Message No.: (216)**	Occurs during or after registration phase. Repeat the registration process.
"Interference in process. Please keep patient in a supine position and press OK to repeat." **Message No.: (217)**	Occurs after clicking FINISH in the setup phase due to patient movements. Keep patient in supine position and press 'OK' to repeat.

Locatable Guide Errors

Error Message or Symptom	Problem and Corrective Action
Message: "Please connect a Locatable Guide and press 'Retry'." **Message No.: (218)**	Check the connection between the LOCATABLE GUIDE and the LOCATION AMPLIFIER.
Message: "The Locatable Guide is not working properly. Please remove the Locatable Guide and reconnect a new one." **Message No.: (219)**	The LOCATABLE GUIDE may be defective. Replace the LOCATABLE GUIDE and press RETRY. Contact your customer service representative if problem persists.
Message: "The Locatable Guide is not functioning properly. Please confirm that the Locatable Guide's tip is within the sensing volume and press 'Retry'. If the problem repeats, change Locatable Guide". **Message No.: (220)**	There may be a bad signal from the LOCATABLE GUIDE: 1. Make sure the LOCATABLE GUIDE'S tip is within the sensing volume. 2. Click RETRY. If the problem continues, replace the LOCATABLE GUIDE.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Error Message or Symptom	Problem and Corrective Action
Message: "The Locatable Guide's tip is currently out of the sensing volume. Please position the tip within the sensing volume. If the problem is not resolved, press 'Retry'." **Message No.: (221)**	Reposition the tip of the LOCATABLE GUIDE within the sensing volume. The message closes automatically. If the message is not closed, click RETRY. Replace the LOCATABLE GUIDE if problem persists.
Message: "The Locatable Guide has already been used. Please replace it with an unused one." **Message No.: (222)**	The Locatable Guide has already been used. Please replace it with a new Locatable Guide and press OK.

Backup Errors

Error Message or Symptom	Problem and Corrective Action
Message: "Hard drive is full. To free space please backup performed procedures. Performing additional inReach™ procedures will be enabled once backup is performed.." **Message No.: (300)**	The system's hard drive is full. No more procedures can be performed. Use the Backup feature to free up disk space.
Message: "An error occurred during the backup process. Please verify that media is inserted in the CD/DVD drive and try again. If the problem persists, please call service." **Message No.: (300)**	Occurs when backup is performed without media in the CD/DVD drive. If the problem persists then replace the media and try again.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

286

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Setup Errors

Error Message or Symptom	Problem and Corrective Action
Message: "The Planning file is not ready for use in a procedure. Please make sure that: ▪ You have marked at least four registration points. (Five or more points are advised.) ▪ You have marked at least one Target. ▪ The registration points you have marked are sufficiently remote from one another. Specifically, please mark the Main Carina as well as two points, one upper and one middle/lower, in each of the lungs, for a total of five points."	Can occur while loading a planning file that is not ready for use in a procedure. Verify the needed conditions according to the message displayed on screen. Complete the planning file in the Planning Module before continuing to the procedure.
Message No.: (250)	
Message: "Do not use ', /, \ in procedure details fields."	The Procedure ID should not contains the characters ', / or \ in the Procedure ID field.
Message No.: (251)	
Message: "Procedure ID already exits! Please insert different procedure ID."	Procedure ID already exits. Please Enter a different Procedure ID.
Message No.: (252)	
Message: "Recovery is not possible due to excessive elapsed time."	Occurs while trying to continue last procedure when more then 30 minutes passed from last procedure ending time.
Message No.: (253)	

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Registration Errors

Error Message or Symptom	Problem and Corrective Action
Message: "Some of the Registration Points you have acquired are mismatched with the points previously marked in the Planning phase. Please verify that the points have been acquired correctly, and re-acquire all points if possible." **Message No.: (260)**	The REGISTRATION process was not performed accurately. Click OK, to repeat the REGISTRATION process.
Message: "The Registration Points you have acquired are not sufficiently remote from one another. Please verify that the points have been marked correctly, and acquire additional points if possible." **Message No.: (261)**	The REGISTRATION POINTS acquired are not sufficiently remote from one another. Click OK to repeat the REGISTRATION process.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

282

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

PC Errors

Error Message or Symptom	Problem and Corrective Action
Message: "The space on the hard disk is running low. Please call service." **Message No.: (280)** OR "Insufficient disk space for the software. The application will be closed. Please call service." **Message No.: (281)**	There is not enough space on the hard drive to perform a procedure. Click 'OK' and contact your customer service representative.
Message: "A system error occurred. The application will be closed. Please call service." **Message No.: (282)**	A fatal error has occurred. Click 'OK' and contact your customer service representative.
Message: System memory is low. Please exit the application before beginning the next procedure." **Message No.: (283)**	The system's virtual memory is low. Click 'OK' and close the application. Restart the application. If the problem persists contact your customer service representative.
Message: "A system error occurred. Press 'Ignore' to continue. If problem repeats, please call service." **Message No.: (284)**	Click 'Ignore' and continue working. If the problem persists contact your customer service representative.
Message: "The system's performance is insufficient. Please refer to the User Manual" **Message No.: (285)**	There may be too many displayed graphical objects on the screen. Click 'OK' and hide un-needed graphical objects and continue working. If the problem persists contact your customer service representative.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

General Troubleshooting

This section explains how to respond to general technical problems that may be encountered during normal operation.

Locatable Guide, EWC, Bronchoscope Adapter, Bronchoscope Clip and PC Troubleshooting

Problem/ Symptom	Corrective Action
Tip of Locatable Guide does not protrude from the EWC.	Check that the Bayonet lock is correctly fastened. If Bayonet lock cannot be fastened, replace the EWC. If problem persists, replace the LOCATABLE GUIDE. If problem still persists, contact your customer service representative.
The Locatable Guide cannot be inserted into the EWC.	Check that both the EWC and LOCATABLE GUIDE are clean and free of any debris. If problem persists, replace the EWC. If problem still persists, contact your customer service representative. Never use excessive force while inserting or extracting the LOCATABLE GUIDE into or from the EWC.
The Bronchoscope Adapter, on the bronchoscope, does not function correctly.	Replace the current Bronchoscope Adapter. If problem persists, contact your customer service representative.
The Bronchoscope Clip, on the bronchoscope, does not function correctly.	Replace the current Bronchoscope Clip. If problem persists, contact your customer service representative.
The superDimension software freezes up during the procedure.	Reboot the computer and continue with the procedure. If this does not solve the problem, turn off the system and then restart it. If the problem persists, contact your customer service representative.
Video Setup cannot Zoom Out with the Keyboard or Remote Control	Press the Zoom Out button on the monitor using the mouse or touch screen.
Foot Switch does not function	Ensure that the Foot Switch is properly

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Problem/ Symptom	Corrective Action
properly.	connected. If the problem persists, verify that the Locatable Guide and Patient Sensor Triplets are properly connected. If the problem persists, contact your customer service representative.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 10: Quick Reference

This chapter contains the description and function of all menu options and toolbar buttons found in both the PLANNING and PROCEDURE modules.

Planning Module

DICOM File Selection Menu Bar Options

Option		Description
File	**Scan CT data**	Scans the CT DICOM file directory.
	Load Planning	Starts a planning file using the selected CT or PET/CT DICOM sequence.
	Connect to DICOM System	Connects to network available DICOM System
	Export Study to DICOM	Opens the Export dialog, which enables to export the DICOM to a CD-ROM or to a Removable Disk.
	Print Screen	Saves the current procedure screen as a bitmap file.
	Exit	Closes the PLANNING Module and returns you to the OPENING SCREEN.
Help	**About**	Displays version information.

DICOM System Toolbar Buttons

Button	Function	Description
	**Connect to DICOM System**	Connects to network available DICOM System

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
287

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning Menu Bar Options

File Menu

Option	Description
Save Planning Data	Saves the current planning file.
Return to CT Data Browser	Returns to DICOM browser screen and allows the selection of a different CT sequence for planning.
Connect to DICOM System	Connects to network available DICOM System
Print Screen	Saves the current procedure screen as a bitmap file.
Export Planning File	Opens the Export dialog, which enables to export the Planning file to a CD-ROM or to a Removable Disk.
Export Study to DICOM	Opens the Export dialog, which enables to export the Study to DICOM to a CD-ROM or to a Removable Disk.
Exit	Closes the PLANNING MODULE and returns you to the OPENING SCREEN.

Actions Menu

Different options are available depending on which mode is currently selected.

Mode	Option	Description
All Modes	**Undo/Redo**	Allows Undo or Redo of the last crosshairs or camera movement.
	3D-Map	Initiates the 3D-Map generation.
Crosshairs	**Add Registration Point**	Adds a registration point in the selected location.
	Add Target	Adds a target in the selected location.
Virtual Camera	**Attach/Free Camera**	Toggles between 'Attached Camera' and 'Free Camera' methods. In 'Attached Camera' method the camera is directed on the location of the crosshairs while in 'Free Camera' method the camera can be moved freely without being always directed on the location of the crosshairs.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

	Camera On/Off	Hides/shows the camera symbol in the CT cross-section viewports.
Pan	**Reset Panning**	Centers the cross-section images after panning.
Select	**Go To Point**	Sets the crosshairs on the location of the selected point.
	Delete	Deletes the selected registration point or target.
	Rename	Allows editing a selected point name.
Window/Level	**Window Level Presets**	Sets the window and level values to the predefined values.
Distance Measurement	**Reset Distance Measurement**	Clears all measured distances from CT cross-section.

View Menu

Option		Description
Zoom In		Zooms in on the image.
Zoom Out		Zooms out of the image.
Zoom Reset		Resets the zoom level to a predefined value.
Hide Registration Points		Hides/shows the Registration Points in the CT cross-section viewports.
Hide Targets		Hides/shows the Targets in the CT cross-section viewports.
Display Direction	**Caudal**	Displays direction of the three cross-section viewports.
	Cranial	Displays direction of the three cross-section viewports.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Mode Menu

Option	Description
Crosshairs Mode	Enables positioning of the crosshairs and marking of registration points and targets.
Camera Mode	Enables positioning of the camera and enables specific camera mode button.
Pan Mode	Enables image panning and enables the Reset Pan button.
Select Mode	Enables the selection of registration points and targets and also enables specific select mode buttons.
Window/Level Mode	Enables window/level (image) setting and enables the Window/Level Presets button.
Distance-Measurement Mode	Enables a point-to-point distance measurement over the CT cross-sections.

Help Menu

Option	Description
About	Displays program version information.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning Toolbar Buttons

Button	Function	Description
	**Save File**	Saves the current planning file.
	**Zoom In**	Zooms in on the image.
	**Zoom Out**	Zooms out of the image.
	**Undo/Redo**	Allow Undo or Redo of the last crosshairs or camera movement.
	**Crosshairs Mode**	Enables positioning of the crosshairs for marking of registration points and targets.
	**Camera Mode**	Enables positioning of the camera and enables specific camera mode buttons.
	**Pan Mode**	Enables image panning and also enables the Reset Pan button.
	**Select Mode**	Enables the selection of registration points and targets and also enables specific select mode buttons.
	**Window/Level Mode**	Enables window/level (image) setting and enables the WINDOW/LEVEL PRESETS button.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

291

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Button	Function	Description
	**Distance Measurement**	Enables a point-to-point distance measurement over the CT cross-sections.

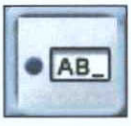
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

292

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Control Mode Toolbar Buttons

Each control mode displays specific buttons when activated.

Mode	Button	Function	Description
Crosshairs		**Add Registration point**	Adds a registration point in the selected location.
		**Add Target**	Adds a target in the selected location.
Camera		**Attach/Free Camera**	Toggles between 'Attached Camera' and 'Free Camera' methods. In 'Attached Camera' method the camera is directed on the location of the crosshairs while in 'Free Camera' method the camera can be moved freely without being always directed on the location of the crosshairs.
		**Camera On/Off**	Hides/shows the camera icon in the CT cross-section viewports.
Pan		**Panning Reset**	Centers the cross-section images after panning.
Select		**Go To Selected Point**	Sets the crosshairs on the location of the selected point.
		**Rename Selected Point**	Opens a dialog that enables renaming of the selected point.
		**Delete Selected Point**	Deletes the selected registration point or target.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Mode	Button	Function	Description
Window/ Level		**Window/Level Presets**	Sets the Window and Level values to the predefined values.
Distance Measurement		**Reset Distance Measurement**	Hides the Distance Measurement markings from the CT cross-sections.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

3D Camera Control Buttons

Button	Description
	Moves the virtual view upwards.
	Moves the virtual view downwards.
	Moves the virtual view left.
	Moves the virtual view right.
	Moves camera backwards.
	Moves camera forwards.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Planning Module keyboard Shortcuts

Keyboard Shortcut	Description
F1	Displays the software version
F3	Toggles between CT and PET/CT display (when PET/CT scan is available)
F4	Toggles the ColorMap options during PET/CT display.
F5	Displays Cranial directional view
F6	Displays Caudal directional view
CTRL+R	Opens the Add Registration Point window
CTRL+T	Opens the Add Target window
CTRL + SHIFT +R	Hides or displays the Registration Points
CTRL + SHIFT +T	Hides or displays the Target
Delete	Deletes selected Registration Point or Target
Print Screen, CTRL+P	Saves a screen capture in bitmap file
Spacebar	Toggles between 'Camera' mode and 'Crosshairs' mode
+/ -	Zoom in / Zoom out

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Module

Navigation Menu Bar Options

File Menu

Option	Description
Print to File	Saves the current procedure screen as a bitmap.
Export Log	Exports the log file to a specified location.
End Procedure	Closes the current procedure.
Exit	Closes the procedure module and returns you to the Opening Screen.

Edit Menu

Option	Description
Undo (last action)	Undoes the last action that was done or redoes the last action that was undone. This applies only to the last marking action that was undone/redone.

View Menu

Option		Description
View Mode	**Auto Zoom**	Continuously updates the zoom level so that the LOCATABLE GUIDE's tip and the selected target are always displayed in the cross-section viewports.
	Auto Center	Centers the viewports on the tip of the LOCATABLE GUIDE whenever the tip exceeds the borders of any of the cross-section viewports.
	Full View	Zooms out to a predefined zoom level that displays the complete working area. This gives you an overall perspective of his/her current position.
	Manual View	Allows you to manually set the zoom level.
Center on Locatable Guide		Centers all viewports on the tip of the LOCATABLE GUIDE.
Zoom In		Zooms in on the image in all cross-section viewports.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Option		Description
Zoom Out		Zooms away from the image in all cross-section viewports.
Status View		Displays the system status window in which the operational status of all system components can be viewed.
Log View		Displays the log window in which system actions are recorded.
Viewing Presets	**CT-Guided**	Sets the screen layout to CT-Guided Navigation preset.
	CT and Video Guided	Sets the screen layout to CT and Video Guided Navigation preset.
Target Size		Displays the Target size dimensions, as set during the Planning phase in the Tip view.
Tip View (in CT Guided navigation)	**Steering Directions**	Displays the Steering directions in the Tip View
	Bronchoscope Video	Displays the Bronchoscope Video in the Tip View
	3D CT	Displays the 3D CT view in the Tip
Pathway Navigation		Enables navigation to Target using constructed pathways.
Show all Waypoints		Enables Show/Hide of Waypoints to the Target (when Pathway Navigation is enabled).

Mark Menu

Option	Description
Mark Point	Marks the location of the LOCATABLE GUIDE as a reference point or target.
Graphic Control	Allows you to control which graphical objects are displayed in the cross-section viewports and which are hidden. Refer to *Graphic Control* on page 7-48 for further details.
Show Names	Displays or hides the names of all points and targets that appear next to each point or target.

Tools Menu

Option	Description

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Measure Distance	Measures the distance between two locations of the LOCATABLE GUIDE.
Registration	Repeats the registration process. Note that all previously registered points will be lost.
Patient Sensors Adjustment	Displays the sensor adjustment screen to adjust the patient's position to be within the sensing volume borders.
Window / Level Presets	Sets the Window and Level values to the predefined values.
Application Settings	Opens the application settings window in which certain system defaults can be changed according to user preferences.
Procedure Room Configuration	Opens the Procedure Room Configuration page to confirm the procedure room configuration according to the installation images.

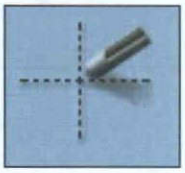
Help Menu

Option	Description
About	Displays program version information.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Navigation Toolbar Buttons

Button	Function	Description
	**Zoom In**	Zooms in on the image in all cross-section viewports.
	**Zoom Out**	Zooms away from the image in all cross-section viewports.
	**Auto Zoom Mode**	Continuously updates the zoom level so that the LOCATABLE GUIDE's tip and the selected target are always displayed in the cross-section viewports.
	**Auto Center Mode**	Centers the viewport on the tip of the LOCATABLE GUIDE whenever the tip exceeds the borders of any of the cross-section viewports.
	**Full Zoom Mode**	Zooms out to a predefined zoom level that displays the complete working area. This gives you an overall perspective of his/her current position.
	**Manual Zoom Mode**	Allow you to manually set the zoom level.
 	**CT Guided/ CT and Video Guided Navigation modes**	Toggles between the CT Guided Navigation and the CT and Video Guided Navigation modes.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

304

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Button	Function	Description
 	**Pathway Navigation/ Direct to Target**	Toggles between the Pathway Navigation and the Direct to Target modes.
	**Show/Hide 3D-Map**	Toggles between the respective CT cross-section viewport and the 3D-Map.
	**Steering Directions**	Displays the Steering directions in the Tip View.
	**Bronchoscope Video**	Displays the image from the Bronchoscope in the Tip View.
	**3D CT**	Displays the 3D CT in the Tip view.
	**Measure Distance**	Measures the distance between two locations of the LOCATABLE GUIDE.
	**Window/Level**	Controls the Window and Level values of the CT cross-sections.
	**Screen Capture**	Saves the current procedure screen as a bitmap to the removable disk (USB)

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

301

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Button	Function	Description
	**Registration**	Repeats the registration process. Note that all previously registered points will be lost.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Procedure Module keyboard Shortcuts

Keyboard Shortcut	Description
F1	Displays the software version
F2	Mark Point
F5	Toggles between 'Tip View' layouts
F6	Selects the 'CT and Video Guided' navigation screen layout
F7	Selects the 'CT Guided' navigation screen layout
F8	Selects the CT and Video Guided' Navigation layout with the 'Direct to Target' preset.
CTRL+N	Start a new procedure
CTRL+C	Continue from last procedure
CTRL+F	Centers on the LG tip
CTRL+D	Measure Distance
CTRL+G	Returns to Registration phase
CTRL+R	Returns to Procedure Room Configuration
CTRL+Z	Undo/Redo
↓↑	Toggles Previous/Next Target or Pathway
← →	Toggles Previous/Next Waypoint
← →	Adjusts the Window values when in Window/Level Mode
↓↑	Adjusts the Level values when in Window/Level Mode
↓↑ , **+ -**	Zoom in / Zoom out
Return	Generates Freeze capture in CT and Video Guided preset / Mark Line
Print Screen	Saves a screen capture in bitmap file

302

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 11: Ordering Accessories

The following table provides a list of all superDimension inReach™ System accessories. Contact your superDimension customer service representative for ordering information.

Accessory Name	Catalogue Number
Locatable Guide	AKI00017-01
EWC	AKI00072-01
Bronchoscope Adapter for Pentax	AKI00075-01
Bronchoscope Adapter for Olympus	AKI00074-01
Bronchoscope Adapter for Fujinon	AKI00073-01
Bronchoscope Clip	AKI00076-01
Patient Sensor Triplet	AAS00060-01
Patient Sensor Patch	AKI00024-01
Removable Disk (USB)	AED00039-01

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 12: Customer Service

If you need assistance in any of the following areas:

- Technical support
- Maintenance
- Upgrade information
- Article reprints
- Product literature
- Information about training activities
- Educational materials

Please contact your superDimension Ltd. customer service representative in your area:

United States Office	**Europe Office**
superDimension, Inc.	superDimension (Europe) GmbH
161 Cheshire Lane, Suite 100 Plymouth, MN 55441-5433, U.S.A. Office: 1-800-387-9016	Grossenbaumer Weg 10 D-40472 Düsseldorf Germany
Customer Service: 1-888-586-4767 Fax: 1-866-706-9639	Telephone: +49-(0)211-436-156-0 Fax: +49-(0)211-436-156-29
Info.us@superdimension.com	Info.de@superdimension.com
www.superdimension.com	www.superdimension.com

If you have questions or if you discover an error in this manual, please contact your superDimension Ltd. customer service representative.

305

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Chapter 13: Glossary

3D-Map	A three-dimensional virtual representation of the patient's bronchial airways' geometrical layout.
AP	Anterior/Posterior view.
Bronchoscope	A slender tubular instrument with a small light on the end for inspection of the interior of the bronchi.
Bronchoscopy	An examination used for inspection of the interior of the tracheo-bronchial tree.
Bronchus	Either of two main branches of the trachea, leading directly to the lungs.
Carina	The ridge separating the openings of the right and left main bronchi at their main junction with the trachea.
Caudal View	View from the inferior end of the body.
Cranial View	View from the superior end of the body.
CT	Computed Tomography – A special radiographic technique that uses a computer to assimilate multiple X-ray images into a two dimensional cross-sectional image.
DICOM	Digital Imaging and Communications in Medicine. The DICOM standard specifies protocols and formats for the exchange of medical images, between imaging equipment and medical applications.
DICOM System	Any modality or picture archive network entity that supports DICOM network protocol (e.g. PACS).
Endoscope	A highly flexible viewing instrument with capabilities of diagnostic (biopsy) through special channels. Used to examine the interior of a hollow organ
LLL	Left Lower Lobe of lung.
LUL	Left upper lobe of the lung.
PACS	Picture Archiving And Communications System (a type of DICOM System)

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

307

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

PET/CT	PET/CT scanner combines two scanners into one: PET (Positron Emission Tomography) which shows metabolism and the function of cells, and a CT (Computed Tomography) which shows detailed anatomy.
RLL	Right Lower Lobe of lung.
RML	Right Middle Lobe of lung.
RUL	Right Upper Lobe of the lung.
Trachea	The windpipe that consists of a fibrocartilaginous tube lined with mucous membrane and passes from the larynx to the bronchi.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

308

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

This page has been intentionally left blank.

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Design Control Activities

superDimension, Ltd.
Special 510(k) Submission
Proposed Minor Modifications to inReach™ Planning Laptop

This section is not applicable for the following reasons:

- Only minor modifications are being proposed to the Instruction for Use (inReach User Manual) to reflect the proposal that the inReach™ Planning Laptop be used as a stand-alone for bronchoscopy planning or CT-Viewing, or with the other system components.

- No changes are being made to the intended use or technological characteristics of the current marketed device.

- There are no modifications proposed to the software, hardware, firmware, product design or specifications, or manufacturing processes as currently approved (K081379, June 11, 2008). The currently approved design/process validations/verifications that were conducted in accordance with superDimension Design Control requirements as outlined in DOP00006, Design and Development Planning continue to remain valid as currently approved.

- There are no new, increased, altered, or eliminated risks associated with this minor modification as currently approved (K081379, June 11, 2008). The currently approved Risk Analysis that was conducted in accordance with superDimension procedures #DOP00009 continues to remain valid as currently approved.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

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

COVER SHEET MEMORANDUM

From: Reviewer Name _Ewa Czerska_____

Subject: 510(k) Number _K082386_____

To: The Record

Please list CTS decision code _SE_____

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

☐ Hold (Additional Information or Telephone Hold).

√ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	√	
510(k) Summary /510(k) Statement	*Attach Summary*	√	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	√	
Is the device Class III?			√
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			√
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			√
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			√
Is this device intended for pediatric use only?			√
Is this a prescription device? (If both prescription & OTC, check both boxes.)		√	
Is clinical data necessary to support the review of this 510(k)?			√
Does this device include an Animal Tissue Source?			√
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		√
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**
__21CFR 892.2050_____	II_____	LLZ_____

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

Additional Product Codes: _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 9/16/08
(Division Director) (Date)

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K__082386_____

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for modifications to the device description and the labeling_____.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and _____
   The company applied minor modifications to the instruction for use to reflect the proposal that the planning laptop be used as a standalone for bronchoscopy planning or CT-Viewing, or with other system components._____.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Ewa Czerska

(Reviewer's Signature)Ewa Czerska 9/10/2008 (Date)

Comments:
Since the original device was just cleared on 06/11/2008 I asked the reviewer of the original 510K to look it over to make sure that the changes were acceptable., see attached consulting review._____

revised:8/1/03

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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/eRoomReg/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:

Records Processed under FOI request 2016-10204; Released by CDRH on 05/23/2018

Czerska, Ewa M.

From: Rajan, Sunder
Sent: Wednesday, September 10, 2008 2:52 PM
To: Czerska, Ewa M.
Subject: K 082386

Hi Ewa:
In my opinion this 510(k) submission uses exactly the same software as the predicate, installed on a stand-alone laptop for viewing and planning purposes. The Intended use is essentially a subset of that of the predicate so that should be acceptable for a special submission. Let me know if you have further questions.
Sunder

This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at sunder.rajan@fda.hhs.gov

---

Sunder S. Rajan, Ph.D.
Radiological Devices Branch
Division of Abdominal, Reproductive and Radiological Devices (DRARD)
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

9200 Corporate Blvd., HFZ-470
Rockville, Maryland 20850

[redacted]l: (240) 276-3968
[redacted]x: (240) 276-3644

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

7