U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K133853 - 523 pages
COMPANY:	IRVINE BIOMEDICAL, INC. A ST.JUDE MEDICAL COMPANY (IRVIBIOMAST)
PRODUCT:	CATHETER, ULTRASOUND, INTRAVASCULAR (OBJ)
SUMMARY:	Product: VIEWFLEX XTRA ICE CATHETER
DATE REQUESTED:	Apr 20, 2016
DATE PRINTED:	Apr 21, 2016
Note:	Printed

510(K) SUMMARY

1. Administrative Information

Name:	Irvine Biomedical, Inc. a St. Jude Medical Company
Address:	2375 Morse Avenue Irvine, CA 92614
Phone:	949-769-5053
Fax:	877-482-7739
Contact Person:	Jennifer Correa Regulatory Affairs Specialist II
Date:	December 18, 2013

2. Device Information

Trade Name of Device:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Regulation Name:	870.1200, Diagnostic Intravascular Catheter
Product Codes:	OBJ

3. Predicate Device Information

1) ViewFlex Xtra ICE Catheter (Irvine Biomedical, Inc. a St. Jude Medical Company) – K121381 cleared June 7, 2012
2) AcuNav Diagnostic Ultrasound Catheter (Siemens Medical Solutions USA, Inc.) – K071234 cleared June 29, 2007

4. Device Description

The ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The ViewFlex Xtra is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles.

5. Intended Use

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.

6. Technological Characteristics

The design, technological characteristics and materials of the proposed ViewFlex Xtra ICE Catheter are identical to the predicate, cleared ViewFlex Xtra ICE Catheter. There have been no device changes.

7. Summary of Non-clinical Testing

There have been no device changes and no changes to the visualization location. This submission is to expand the current indications for use to include visualizing other devices within the heart. Demonstration of the ability of the ViewFlex Xtra ICE catheter to image devices in the heart was provided by referencing image quality testing and data for the cleared ViewFlex Xtra ICE catheter (K121381) and images collected during the use of the predicates for visualizing other devices within the heart. The Instructions for Use was updated to include examples of types of devices which could be imaged using the ViewFlex Xtra ICE catheter and that the use of the images is limited to visualization with no direct or indirect diagnostic use.

8. Substantial Equivalence Conclusion

The proposed ViewFlex Xtra ICE Catheter in this submission is substantially equivalent to previously cleared St. Jude Medical's ViewFlex Xtra ICE Catheter (K121381, June 7, 2012) and Siemen's AcuNav Diagnostic Ultrasound Catheter (K071234, June 29, 2007). Differences between the devices do not raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 19, 2014

Irvine Biomedical, Inc. A St. Jude Medical Company
Jennifer Correa
2375 Morse Avenue
Irvine, CA 92614 US

Re: K133853
Trade/Device Name: VIEWFLEX XTRA ICE CATHETER
Regulation Number: 21 CFR 870.1200
Regulation Name: Ice Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: April 11, 2014
Received: April 14, 2014

Dear Jennifer Correa:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

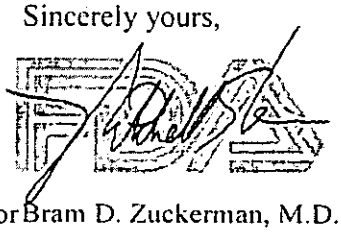
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ViewFlex Xtra ICE Catheter

Premarket Notification 510(k)

ST. JUDE MEDICAL

Indications for Use

510(k) Number (if known): K133853

Device Name: ViewFlex Xtra ICE Catheter

Indications for Use:

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.05.19 15:28:33 -04'00'

ST. JUDE MEDICAL

K123853

December 18, 2013

FDA CDRH DMC
DEC 19 2013
Received

Food and Drug Administration
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Traditional 510(k) for the ViewFlex Xtra ICE Catheter

To Whom It May Concern:
Irvine Biomedical, Inc., a St. Jude Medical Company, is submitting this Traditional 510(k) for the ViewFlex Xtra ICE Catheter.

Trade Name of Device:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Classification Name:	Catheter, Ultrasound, Intravascular
Device Classification:	II
Product Code & Regulation:	OBJ (870.1200)
Device Panels:	Cardiovascular

The purpose of this submission is to expand the indications for use of the currently cleared ViewFlex Xtra ICE Catheter (K121381, cleared on June 7, 2012). The ViewFlex Xtra ICE Catheter is indicated to visualize cardiac structures and blood flow within the heart; this submission proposes to expand the indications for use to include visualization of other devices within the heart. There are no previous FDA submissions or communications to expand the ViewFlex Xtra ICE Catheter indications for use.

The ViewFlex Xtra ICE Catheter in this submission is substantially equivalent to the cleared ViewFlex Xtra ICE Catheter and the AcuNav Diagnostic Ultrasound Catheter (K071234, cleared June 29, 2007). The proposed ViewFlex Xtra ICE Catheter is identical in materials, principles of operation and technological characteristics as the currently cleared ViewFlex Xtra ICE Catheter. The differences between the ViewFlex Xtra ICE Catheter and the predicate devices do not raise new questions of safety or effectiveness.

This premarket notification has been formatted in accordance with the FDA's August 12, 2005 guidance document titled *Guidance for Industry and Staff: Format for Traditional and Abbreviated 510(k)s*.

ST. JUDE MEDICAL

Principal Factors about the Design and Use of the ViewFlex Xtra ICE Catheter

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

(b)(4)

[redacted]

Sincerely,

Jennifer Correa
Regulatory Affairs Specialist II
St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

ViewFlex Xtra™ ICE Catheter

Traditional 510(k)

Submitted by:
Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Avenue
Irvine, CA 92614

December 18, 2013

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LIST OF ATTACHMENTS

Attachment Number	Attachment Description	First Page # of Attachment	eCopy File Name
1	Medical Device User Fee Cover Sheet	Page 57	002_Medical Device User Fee_Attachment 1
2	CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	Page 60	003_FDA Form 3514_Attachment 2
3	ViewFlex Xtra ICE Catheter Proposed Labels	Page 66	004_Proposed Labels_Attachment 3
4	ViewFlex Xtra ICE Catheter Proposed Instructions for Use	Page 69	005_Proposed IFU_Attachment 4

TRADITIONAL 510(K) ACCEPTANCE CHECKLIST

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
A. ADMINISTRATIVE				
1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			All content is written in English
2. Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			Section 2, page 16 Section 3, page 17
2a. Device trade name or proprietary name	X			Section 3, page 17
2b. Device common name	X			Section 3, page 17
2c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			Section 2, page 16 Section 3, page 17
3. Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109).	X			Section 4, page 19
4. Submission contains 510(k) Summary or 510(k) Statement Either a) or b) must be answered "Yes" to be considered complete.	X			Section 5, page 21 510(k) Summary Provided
4a. Summary contains all elements per 21 CFR 807.92 See also 510(k) Summary Checklist	X			
4b. Statement contains all elements per 21 CFR 807.93		X		
5. Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	X			Section 6, page 24
6. Submission contains Class III Summary and Certification See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k)		X		Not a Class III 510(k) , page 25

(b)(4)

[redacted]

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
9a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. "N/A" if the submitter states there were no prior submissions in criterion above.		X		No prior submissions in criterion above
B. DEVICE DESCRIPTION				
10a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. Select "N/A" if there are no applicable requirements in a device specific regulation.		X		There are no applicable requirements in a device specific regulation.
10b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. Select "N/A" if there is no applicable device-specific guidance.		X		There is no applicable device-specific guidance
11. Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	X			Section 11, page 33
11a. A description of the principle of operation and mechanism of action for achieving the intended effect.	X			Section 11, page 33
11b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			Section 11, page 33
11c. A list and description of each device for which clearance is requested. Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.		X		There is only one device or model
12. Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			Section 11, page 33
13. If device is intended to be marketed with multiple components, accessories, and/or as part of a system, Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.		X		Device is not intended to be marketed with multiple components, accessories, and/or as part of a system
13a. Submission includes a list of all components and accessories to be marketed with the subject device.		X		
13b. Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory.		X		
13c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.		X		
C. SUBSTANTIAL EQUIVALENCE DISCUSSION				
14. Submitter has identified a predicate(s) device	X			Section 12

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
14a. Predicate's 510(k) number, trade name, and model number (if applicable) provided.	X			Section 12, page 35
14b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			Section 5, page 22 Section 12, page 35
15. Submission includes a comparison of the following for the predicate(s) and subject device	X			Section 12, page 36
15a. Indications for use	X			Section 12, page 36
15b. Technology, including features, materials, and principles of operation	X			Section 12, page 36
16. Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			Section 12, page 35
D. PROPOSED LABELING				
17. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	X			Section 13, page 48
17a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	X			Section 13, page 48
17b. Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			Section 13, page 48 Section 3, page 18
18. If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol	X			Section 13, page 48
19. General labeling provisions	X			Section 13, page 48
19a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X			Section 13, page 48
19b. Labeling includes device common or usual name (21 CFR 801.61) Select "N/A" if device is for prescription use only.		X		Device is for prescription use only

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
(b)(4) [redacted]				
21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		X		Not an in vitro diagnostic device
E. STERILIZATION				
Submission states that the device and/or accessories are: (*one of the below must be checked*) ☑ Provided sterile ☐ Provided non-sterile but sterilized by the end user ☐ Non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	X			Section 14, page 49
22. Assessment of the need for sterilization information	X			Section 14, page 49
22a. Identification of device, and/or accessories, and/or components that are provided sterile.	X			Section 14, page 49
22b. Identification of device, and/or accessories, and/or components that are end user sterilized		X		Device is not end user sterilized
22c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.		X		Device does not have reusable and cleaning/ disinfection instructions
23. If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*	X			Section 14, page 49
23a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X			Section 14, page 49

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
23b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			Section 14, page 49
23c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	X			Section 14, page 49
23d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			Section 14, page 49
23e. Sterility Assurance Level (SAL) stated	X			Section 14, page 49
24. If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*		X		No part of the device, accessories, or components are end user sterilized
25a. If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation.*		X		No applicable requirements in a device-specific regulation.
25b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance.*		X		No applicable device-specific guidance
25c. If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.*		X		No applicable special controls document
F. SHELF LIFE				
26. Proposed shelf life/ expiration date stated	X			Section 14, page 49
27. For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.	X			Section 14, page 49
28. Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			Section 14, page 49

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
G. BIOCOMPATIBILITY				
Submission states that there: (*one of the below must be checked*) ☑ are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	X			Section 11, page 34
29. Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			Section 11, page 34
30. Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X			Section 11, page 34
31. Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			Section 15, page 50
H. SOFTWARE				
Submission states that the device: (*one of the below must be checked*) ☐ does ☑ does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*	X			Section 16, page 51 The software-related criterion is omitted from the checklist
I. EMC AND ELECTRICAL SAFETY				
Submission states that the device: (*one of the below must be checked*) ☑ does ☐ does not require EMC and Electrical Safety evaluation.	X			Section 17, page 52
34. Submission includes evaluation of electrical safety (e.g., per IEC 60601- 1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	Y			Section 17, page 52

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
35. Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			Section 17, page 52
J PERFORMANCE DATA – GENERAL				

(b)(4)

[redacted]

ACCEPTANCE CHECKLIST FOR A TRADITIONAL 510(K) REQUIREMENTS	YES	N/A	NO	LOCATION / COMMENT
38. If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature.*		X		The submission does not reference literature.
(b)(4) [redacted]		[redacted]		[redacted] d.
K. PERFORMANCE CHARACTERISTICS – IN VITRO DIAGNOSTIC DEVICES ONLY (SEE ALSO 21 CFR 809.10(B)(12))				
Submission indicates that device: (*one of the below must be checked*) ☐ is ☑ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*	X			Section 5, page 21

1. MEDICAL DEVICE USER FEE COVER SHEET

The Medical Device User Fee Cover Sheet is provided in **Attachment 1**.

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

The CDRH Premarket Review Submission Cover Sheet (FDA Form 3514) is provided in **Attachment 2**.

3. 510(K) COVER LETTER

December 18, 2013

Food and Drug Administration
Office of Device Evaluation
Document Mail Center - WO66-G609
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Traditional 510(k) for the ViewFlex Xtra ICE Catheter

To Whom It May Concern:
Irvine Biomedical, Inc., a St. Jude Medical Company, is submitting this Traditional 510(k) for the ViewFlex Xtra ICE Catheter.

Trade Name of Device:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Classification Name:	Catheter, Ultrasound, Intravascular
Device Classification:	II
Product Code & Regulation:	OBJ (870.1200)
***Device Panels*:**	Cardiovascular

The purpose of this submission is to expand the indications for use of the currently cleared ViewFlex Xtra ICE Catheter (K121381, cleared on June 7, 2012). The ViewFlex Xtra ICE Catheter is indicated to visualize cardiac structures and blood flow within the heart; this submission proposes to expand the indications for use to include visualization of other devices within the heart. There are no previous FDA submissions or communications to expand the ViewFlex Xtra ICE Catheter indications for use.

The ViewFlex Xtra ICE Catheter in this submission is substantially equivalent to the cleared ViewFlex Xtra ICE Catheter and the AcuNav Diagnostic Ultrasound Catheter (K071234, cleared June 29, 2007). The proposed ViewFlex Xtra ICE Catheter is identical in materials, principles of operation and technological characteristics as the currently cleared ViewFlex Xtra ICE Catheter. The differences between the ViewFlex Xtra ICE Catheter and the predicate devices do not raise new questions of safety or effectiveness.

This premarket notification has been formatted in accordance with the FDA's August 12, 2005 guidance document titled *Guidance for Industry and Staff: Format for Traditional and Abbreviated 510(k)s*.

Principal Factors about the Design and Use of the ViewFlex Xtra ICE Catheter

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

(b)(4)

[redacted]

Sincerely,

Jennifer Correa
Regulatory Affairs Specialist II
St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

4. INDICATIONS FOR USE STATEMENT

The indications for use statement is included on the following page.

Indications for Use

510(k) Number (if known):

Device Name: ViewFlex Xtra ICE Catheter

Indications for Use:

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

The 510(k) Summary of the ViewFlex Xtra ICE Catheter, per 21 CFR 807.92, is provided on the following pages.

510(K) SUMMARY

1. Administrative Information

Name:	Irvine Biomedical, Inc. a St. Jude Medical Company
Address:	2375 Morse Avenue Irvine, CA 92614
Phone:	949-769-5053
Fax:	877-482-7739
Contact Person:	Jennifer Correa Regulatory Affairs Specialist II
Date:	December 18, 2013

2. Device Information

Trade Name of Device:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Regulation Name:	870.1200, Diagnostic Intravascular Catheter
Product Codes:	OBJ

3. Predicate Device Information

1) ViewFlex Xtra ICE Catheter (Irvine Biomedical, Inc. a St. Jude Medical Company) – K121381 cleared June 7, 2012
2) AcuNav Diagnostic Ultrasound Catheter (Siemens Medical Solutions USA, Inc.) – K071234 cleared June 29, 2007

4. Device Description

The ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The ViewFlex Xtra is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles.

5. Intended Use

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

6. Technological Characteristics

The design, technological characteristics and materials of the proposed ViewFlex Xtra ICE Catheter are identical to the predicate, cleared ViewFlex Xtra ICE Catheter. There have been no device changes.

7. Summary of Non-clinical Testing

(b)(4)

[redacted]

8. Substantial Equivalence Conclusion

The proposed ViewFlex Xtra ICE Catheter in this submission is substantially equivalent to previously cleared St. Jude Medical's ViewFlex Xtra ICE Catheter (K121381, June 7, 2012) and Siemen's AcuNav Diagnostic Ultrasound Catheter (K071234, June 29, 2007). Differences between the devices do not raise issues of safety or effectiveness.

6. TRUTHFUL AND ACCURACY STATEMENT

Premarket Notification

Truthful and Accurate Statement

[As required by 21 CFR § 807.87(k)]

I certify that, in my capacity as a Regulatory Affairs Specialist II of Irvine Biomedical, Inc., a St. Jude Medical Company, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification for the ViewFlex Xtra ICE Catheter are truthful and accurate and that no material fact has been omitted.

Jennifer Correa	Jennifer Correa	18 DEC 2013
Regulatory Affairs Specialist II	Signature	Date

7. CLASS III SUMMARY AND CERTIFICATION

The Class II Summary and Certification Section does not apply to this 510(k) submission because the ViewFlex Xtra ICE Catheter is a Class II device.

8. FINANCIAL DISCLOSURE

(b)(4) [redacted]

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

No changes were made to the device and there are no FDA recognized standards applied to the ViewFlex Xtra ICE Catheter as a result of the expanded indications for use.

10. EXECUTIVE SUMMARY

10.1. DEVICE DESCRIPTION

Trade Name:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Classification Name:	Catheter, Ultrasound, Intravascular
Product Code:	OBJ
CFR Section:	21 CFR 870.1200

The ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The ViewFlex Xtra is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles.

10.2. INDICATIONS FOR USE

This 510(k) is intended to expand the current ViewFlex Xtra ICE Cather indications for use. The proposed indications for use to include visualizing other devices is shown below (addition shown in *italics*).

> The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow *and other devices* within the heart.

10.3. PREDICATE DEVICE COMPARISON

The proposed ViewFlex Xtra ICE Catheter presented in this 510(k) is substantially equivalent to the following devices:

Table 10.1: Predicate Devices

	Predicate 1	Predicate 2
Device Name	ViewFlex Xtra ICE Catheter	AcuNav Diagnostic Ultrasound Catheter
510(k)	K121381	K071234
Common Name	ICE Catheter	Diagnostic Ultrasound System
Regulation Number	21 CFR 870.1200*	21 CFR 870.1200
Regulation Name	Diagnostic Intravascular Catheter*	Diagnostic Intravascular Catheter
Regulatory Class	Class II	Class II
Product Code	OBJ*	OBJ

*Note: Multiple product codes were submitted for the ViewFlex Xtra ICE Catheter (Predicate 1) in 510(k) K121381. To identify the device as a catheter, the regulation number, regulation name and product code for a catheter is listed.

The proposed ViewFlex Xtra ICE Catheter is identical to the already cleared ViewFlex Xtra ICE Catheter (Predicate 1). The proposed ViewFlex Xtra ICE Catheter has the same general indications for use and the same principles of operation as the AcuNav Diagnostic Ultrasound Catheter (Predicate 2).

A comparison of the ViewFlex Xtra ICE Catheter to the legally marketed predicate devices is outlined in **Table 10.2**.

Table 10.2: Predicate Device Comparison

Attribute	Proposed Device	Predicate 1	Predicate 2	Discussion
	ViewFlex Xtra ICE Catheter (this submission)	ViewFlex Xtra ICE Catheter (K121381)	AcuNav Diagnostic Ultrasound Catheter (K071234)	
Indications for Use	The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac, structures, blood flow and other devices within the heart.	The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.	The Acuson AcuNav Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.	Same as Predicate 2 This 510(k) is to expand the indications for use of the ViewFlex Xtra ICE Catheter to include visualizing other devices within the heart. The proposed ViewFlex Xtra ICE Catheter and the Predicate 2 (AcuNav Diagnostic Ultrasound Catheter) have substantially equivalent indications for use. Both of the devices are used for the visualizing heart anatomy and other devices within the heart.
Transducer Type	64 element phased array	64 element phased array	64 element phased array	Same as Predicate 1 and Predicate 2
Manufacturer of Compatible Consoles	Zonare Philips	Zonare Philips	Siemens GE	Same as Predicate 1
Maximum Field of Depth	18 cm	18 cm	15 cm	Same as Predicate 1
Steering	Anterior / Posterior, Left/Right	Anterior/Posterior, Left/Right	Anterior/Posterior, Left/Right	Same as Predicate 1 and Predicate 2
Catheter Dimension	9 F	9 F	8F, 10F	Same as Predicate 1
Usable Length	90 cm	90 cm	90 cm	Same as Predicate 1 and Predicate 2
Transducer Type	64 element phased array	64 element phased array	64 element phased array	Same as Predicate 1 and Predicate 2

The differences between the proposed ViewFlex Xtra ICE Catheter and the predicate devices do not raise new questions of safety or effectiveness. The proposed ViewFlex Xtra ICE Catheter can be considered substantially equivalent to the listed predicate devices.

10.4. SUMMARY OF PERFORMANCE TESTING

(b)(4)

11. DEVICE DESCRIPTION

11.1. DEVICE CONSTRUCTION & COMPONENTS

The device construction and components of the proposed ViewFlex Xtra ICE Catheter are identical to the cleared ViewFlex Xtra ICE Catheter. The following description provides a summary of the ViewFlex Xtra ICE Catheter device construction and components.

The ViewFlex Xtra ICE Catheter is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. An illustration of the ViewFlex ™ Xtra is provided in Figure 11.1. The catheter is inserted into the heart via intravascular access. The catheter shaft is a 9 French catheter constructed with radiopaque Pebax® tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection with an angle of at least 120 degrees in each direction. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles.

(b)(4)

11.2. PATIENT CONTACT MATERIALS

(b)(4)

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

The proposed ViewFlex Xtra ICE Catheter is substantially equivalent to the ViewFlex Xtra ICE Catheter cleared June 7, 2012 (Predicate 1, K121381) and the AcuNav Diagnostic Ultrasound Catheter cleared June 29, 2007 (Predicate 2, K071234).

The proposed ViewFlex Xtra ICE Catheter is identical in design, materials, technological characteristics and principles of operations as the ViewFlex Xtra ICE Catheter (Predicate 1). The proposed ViewFlex Xtra ICE Catheter has the same general indications for use and the same principles of operation as the AcuNav Diagnostic Ultrasound Catheter (Predicate 2).

Table 12.1 provides a comparison of the ViewFlex Xtra ICE device and the predicate devices to demonstrate similarities and differences. Though there are some minor differences, none of these differences raise new questions in safety or effectiveness.

Table 12.1: Comparison of the Proposed ViewFlex Xtra Catheter to the Predicate Devices

Attribute	Proposed Device	Predicate 1	Predicate 2	Discussion
	ViewFlex Xtra ICE Catheter (this submission)	ViewFlex Xtra ICE Catheter (K121381)	AcuNav Diagnostic Ultrasound Catheter (K071234)	
Indications for Use	The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac, structures, blood flow and other devices within the heart.	The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.	The Acuson AcuNav Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.	Same as Predicate 2 This 510(k) is to expand the indications for use of the ViewFlex Xtra ICE Catheter to include visualizing devices within the heart. The proposed ViewFlex Xtra ICE Catheter and the Predicate 2 (AcuNav Diagnostic Ultrasound Catheter) have substantially equivalent indications for use. Both of the devices are used for the visualizing heart anatomy and devices in the heart.
Transducer Type	64 element phased array	64 element phased array	64 element phased array	Same as Predicate 1 and Predicate 2
Manufacturer of Compatible Consoles	Zonare Philips	Zonare Philips	Siemens GE	Same as Predicate 1
Maximum Field of Depth	18 cm	18 cm	15 cm	Same as Predicate 1
Steering	Anterior / Posterior, Left/Right	Anterior/Posterior, Left/Right	Anterior/Posterior, Left/Right	Same as Predicate 1 and Predicate 2
Catheter Dimension	9 F	9 F	8F, 10F	Same as Predicate 1
Usable Length	90 cm	90 cm	90 cm	Same as Predicate 1 and Predicate 2
Transducer Type	64 element phased array	64 element phased array	64 element phased array	Same as Predicate 1 and Predicate 2

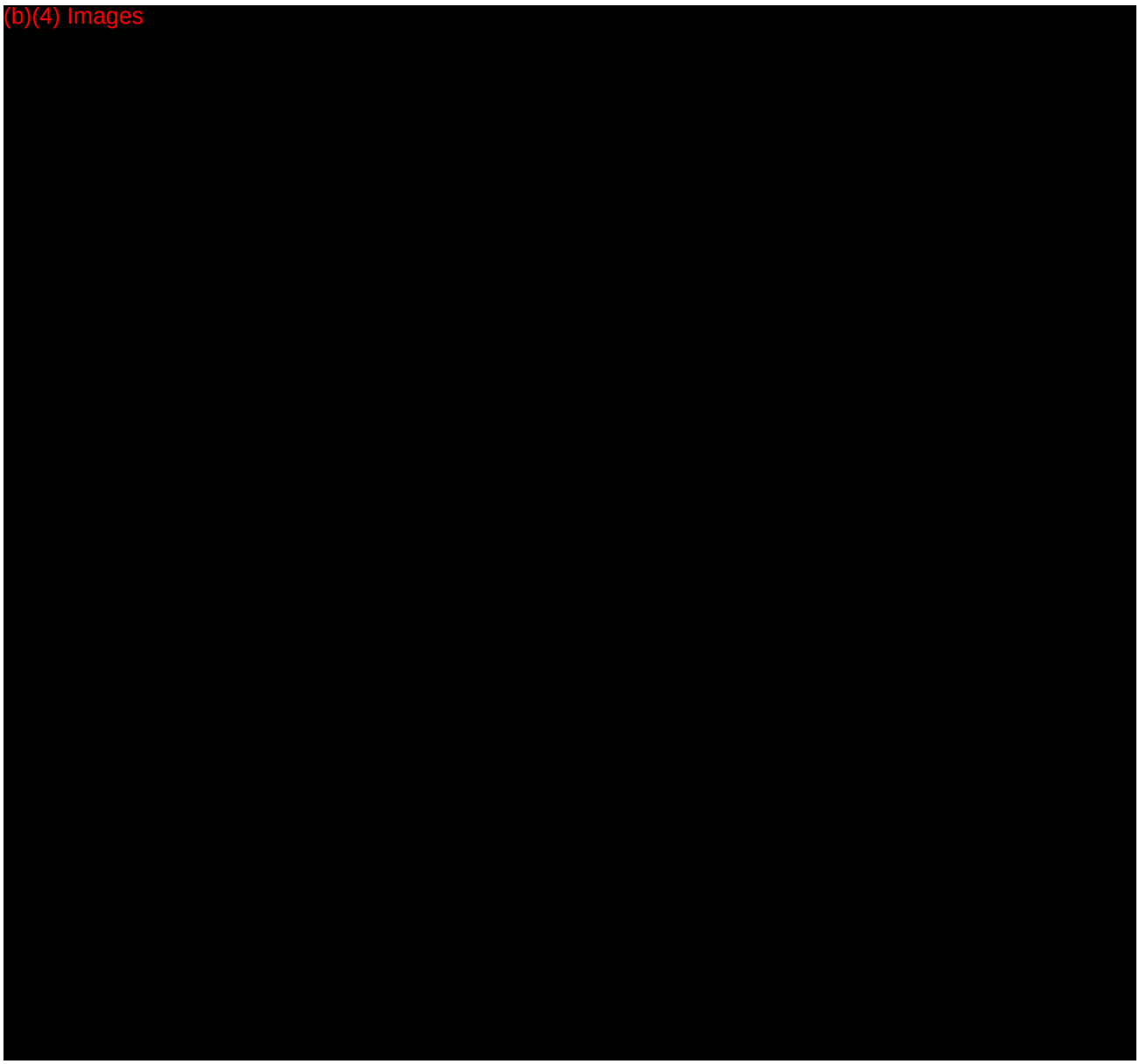
12.1. SIMILARITY WITH PREDICATE DEVICES

The similarities of the proposed ViewFlex Xtra ICE Catheter, the cleared ViewFlex Xtra ICE Catheter (Predicate 1) and the AcuNav Diagnostic Ultrasound Catheter (Predicate 2), are summarized within this section.

12.1.1. INTENDED USE

The currently cleared ViewFlex Xtra ICE Catheter indications for use is being expanded in this 510(k) to include visualizing other devices. The proposed ViewFlex Xtra ICE Catheter and the AcuNav Diagnostic Ultrasound Catheter have similar indications for use. Both of the devices are indicated for visualizing the anatomy and structure of the heart, and other devices within the heart. The proposed ViewFlex Xtra ICE Catheter indications for use is within the scope of the AcuNav Diagnostic Ultrasound Catheter indications for use.

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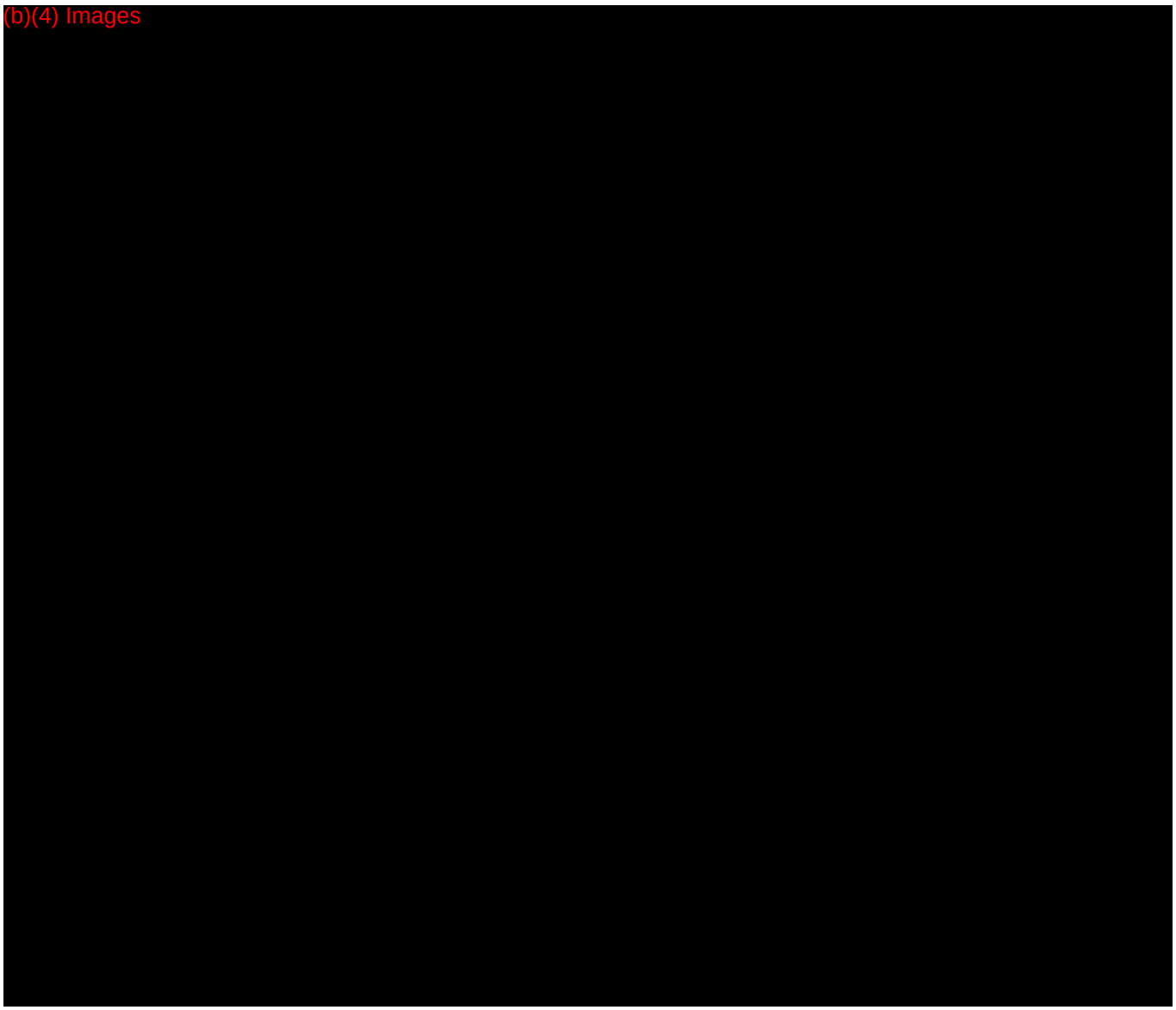
(b)(4) Images



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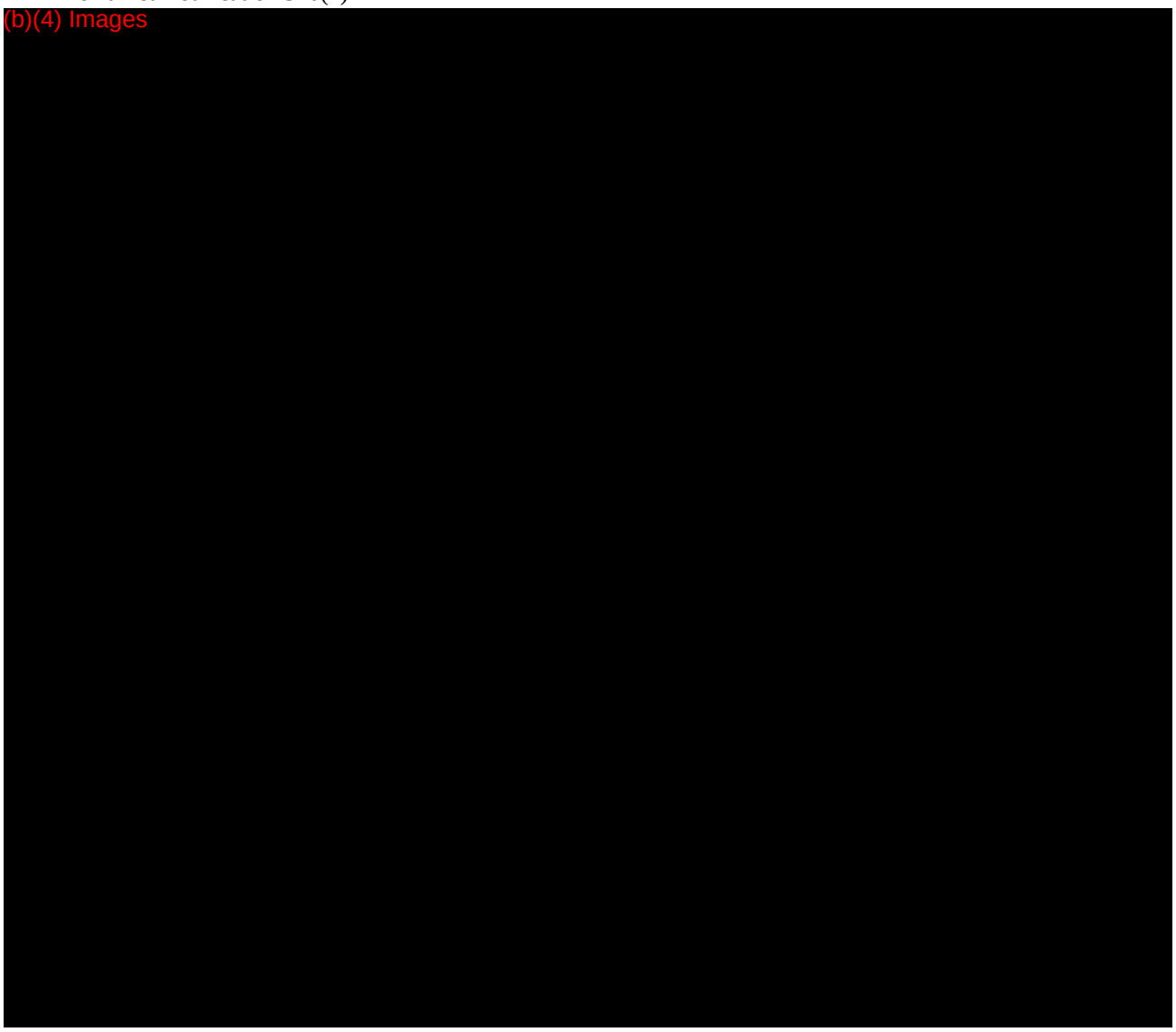

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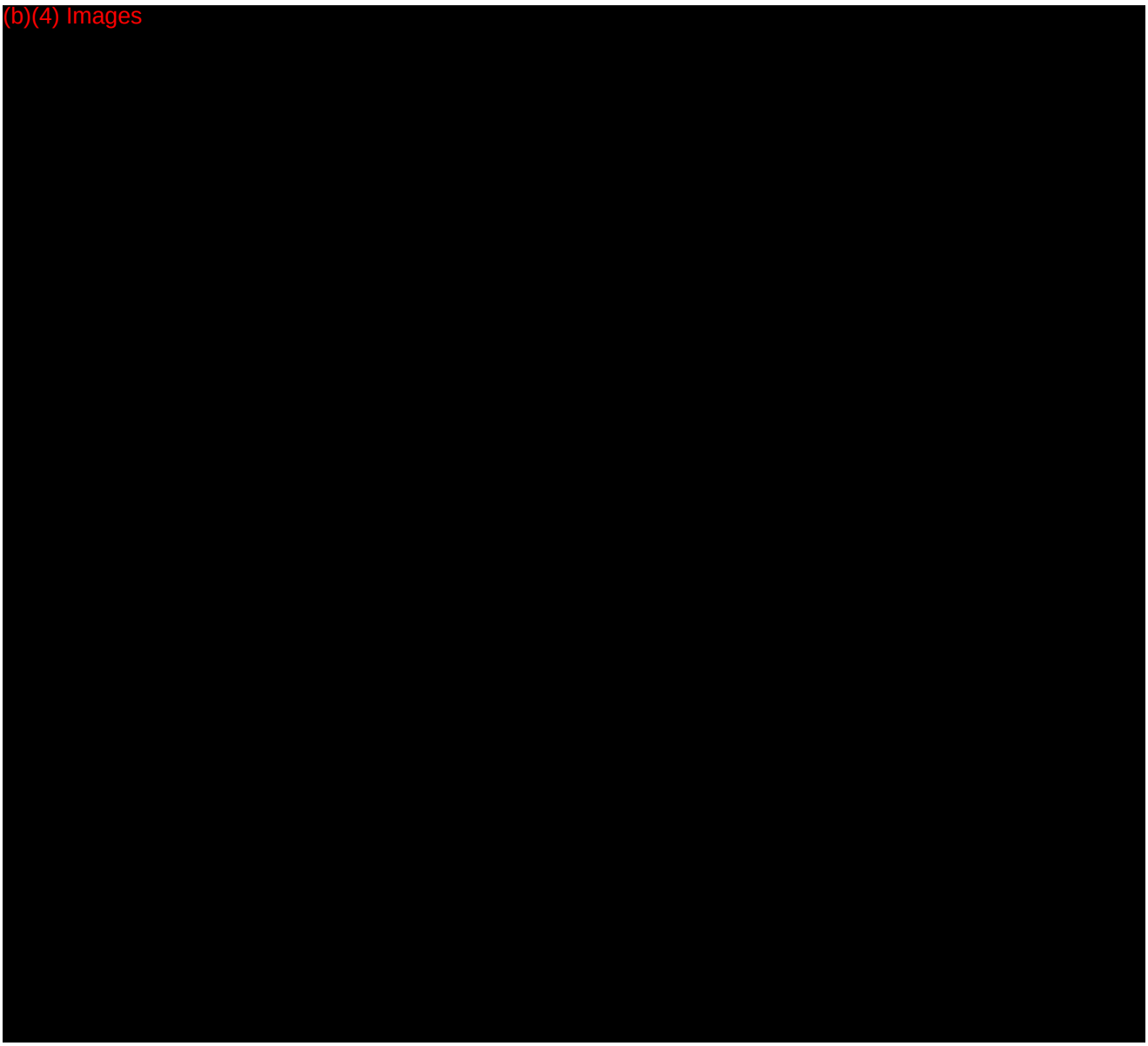

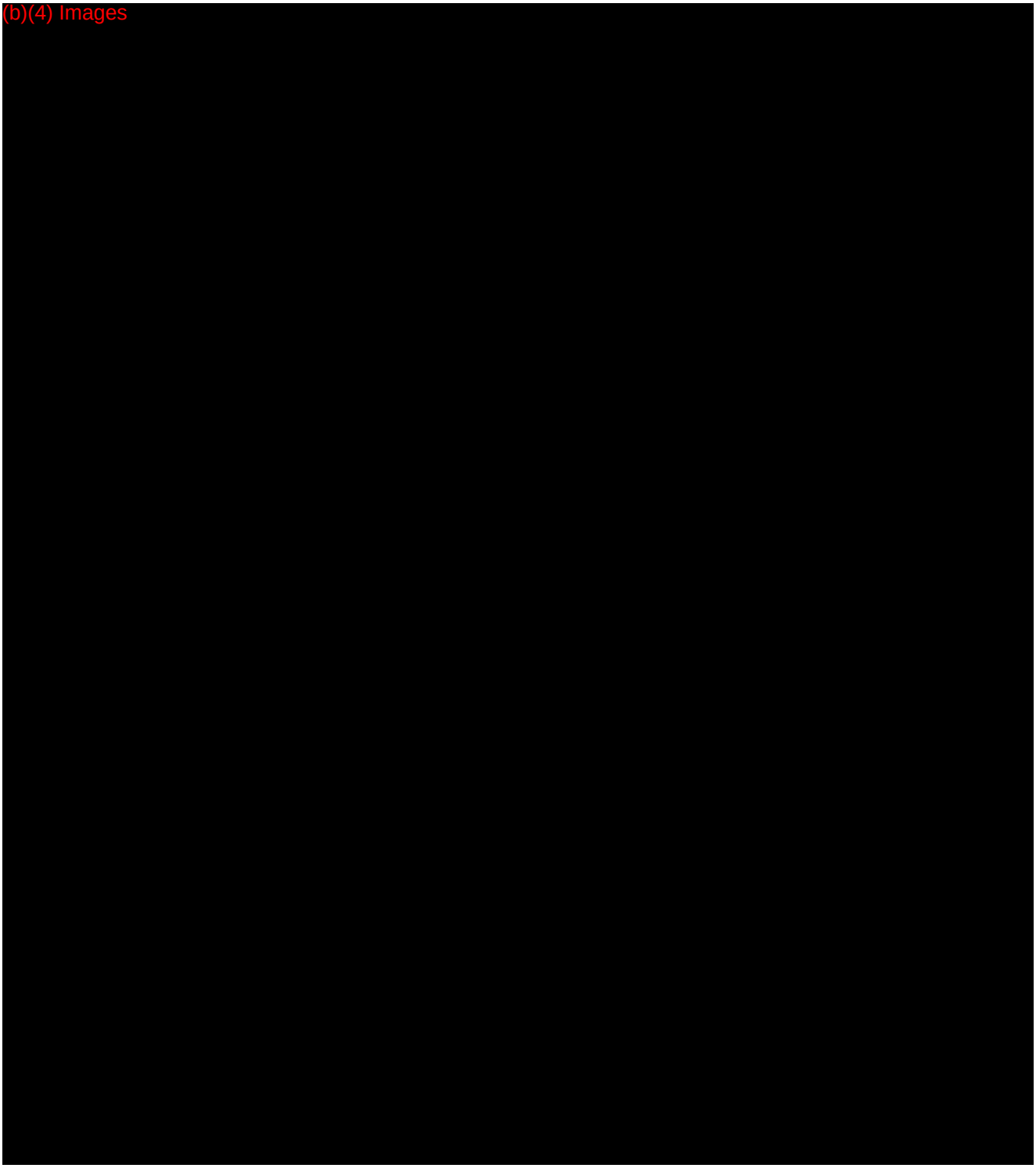
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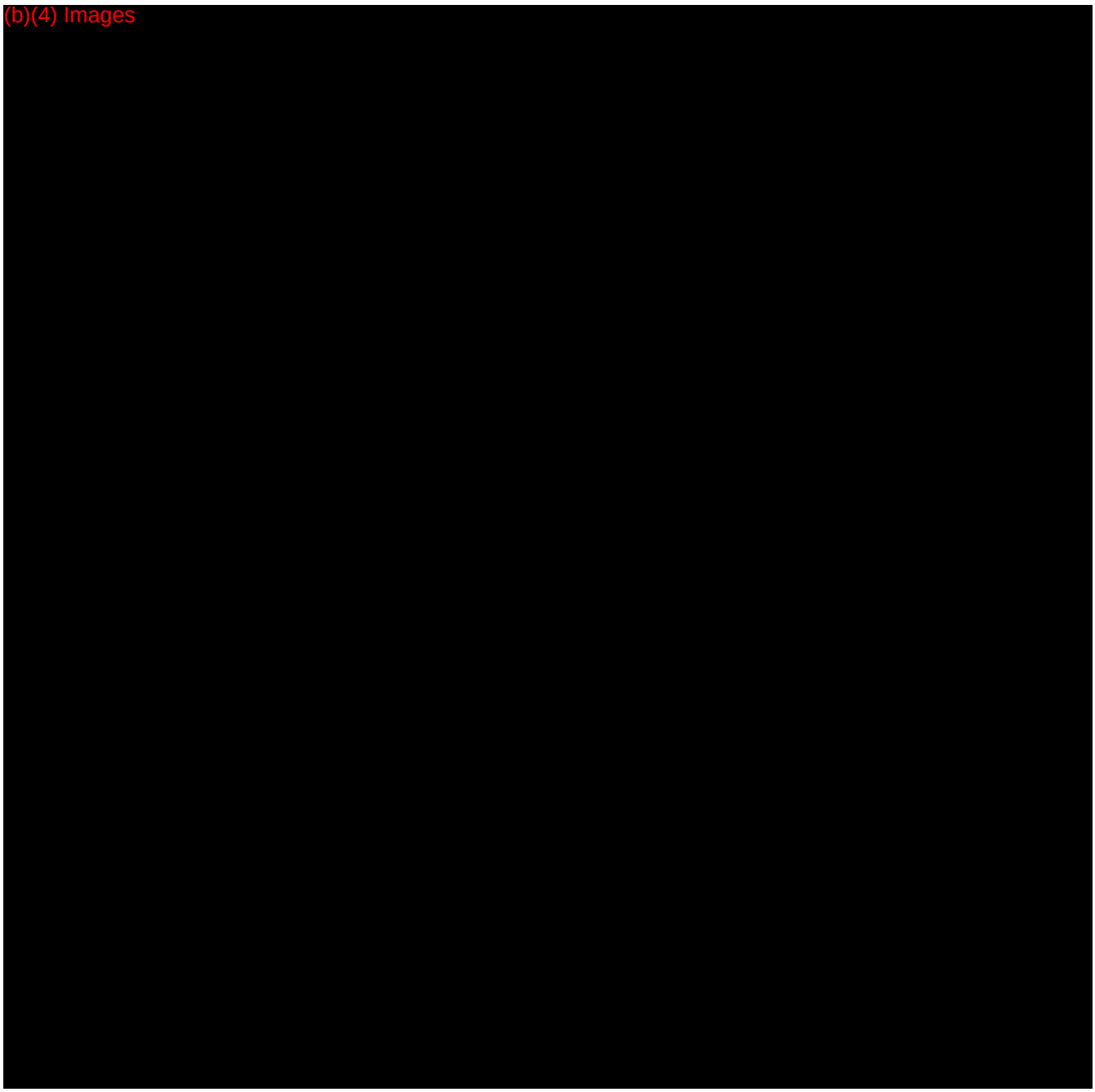

(b)(4) Images


(b)(4) Images

12.1.2. PRODUCT DESIGN

The design and materials of the proposed ViewFlex Xtra ICE Catheter are identical to the cleared ViewFlex Xtra ICE Catheter (Predicate 1). There are no design changes to the device.

12.1.3. STERILITY

The sterility characteristics of the proposed ViewFlex Xtra ICE Catheter are identical to the cleared ViewFlex Xtra ICE Catheter (Predicate 1). There are no changes to the sterility of the device.

12.2. DIFFERENCES WITH THE PREDICATE DEVICES

(b)(4)

12.3. CONCLUSION

(b)(4)

The differences between the proposed ViewFlex Xtra ICE Catheter and its predicate devices do not raise new questions of safety or effectiveness.

13. PROPOSED LABELING

(b)(4)

13.1. EXPANDED INDICATIONS FOR USE

(b)(4)

14. STERILIZATION AND SHELF LIFE

(b)(4)

14.1. METHOD OF STERILIZATION AND STERILIZATION VALIDATION

(b)(4)

14.2. SHELF LIFE AND PACKAGING

(b)(4)

15. BIOCOMPATIBILITY

15.1. BIOCOMPATIBILITY

(b)(4)

16. SOFTWARE

The Software Section of the 510(k) does not apply as the ViewFlex Xtra ICE Catheter does not contain or use any software.

17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

(b)(4)

18. PERFORMANCE TESTING - (b)(4)

(b)(4)

19. PERFORMANCE TESTING – (b)(4)

(b)(4)

20. PERFORMANCE TESTING – (b)(4)

(b)(4)

21. CONCLUSION

(b)(4)

The differences between the proposed device and its predicate devices do not raise new questions of safety or effectiveness. Therefore, the proposed ViewFlex Xtra ICE Catheter is substantially equivalent to the predicate devices.

ATTACHMENT 1: MEDICAL DEVICE USER FEE COVER SHEET

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. 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)

IRVINE BIOMEDICAL INC
2375 MORSE AVE
IRVINE
Orange
CA 92614
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****9722

2. CONTACT NAME
Kellie Stefaniak

2.1 E-MAIL ADDRESS
kstefaniak@sjm.com

2.2 TELEPHONE NUMBER (include Area code)
949-769-5059

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
855-902-0875

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

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)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

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

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

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] 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. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

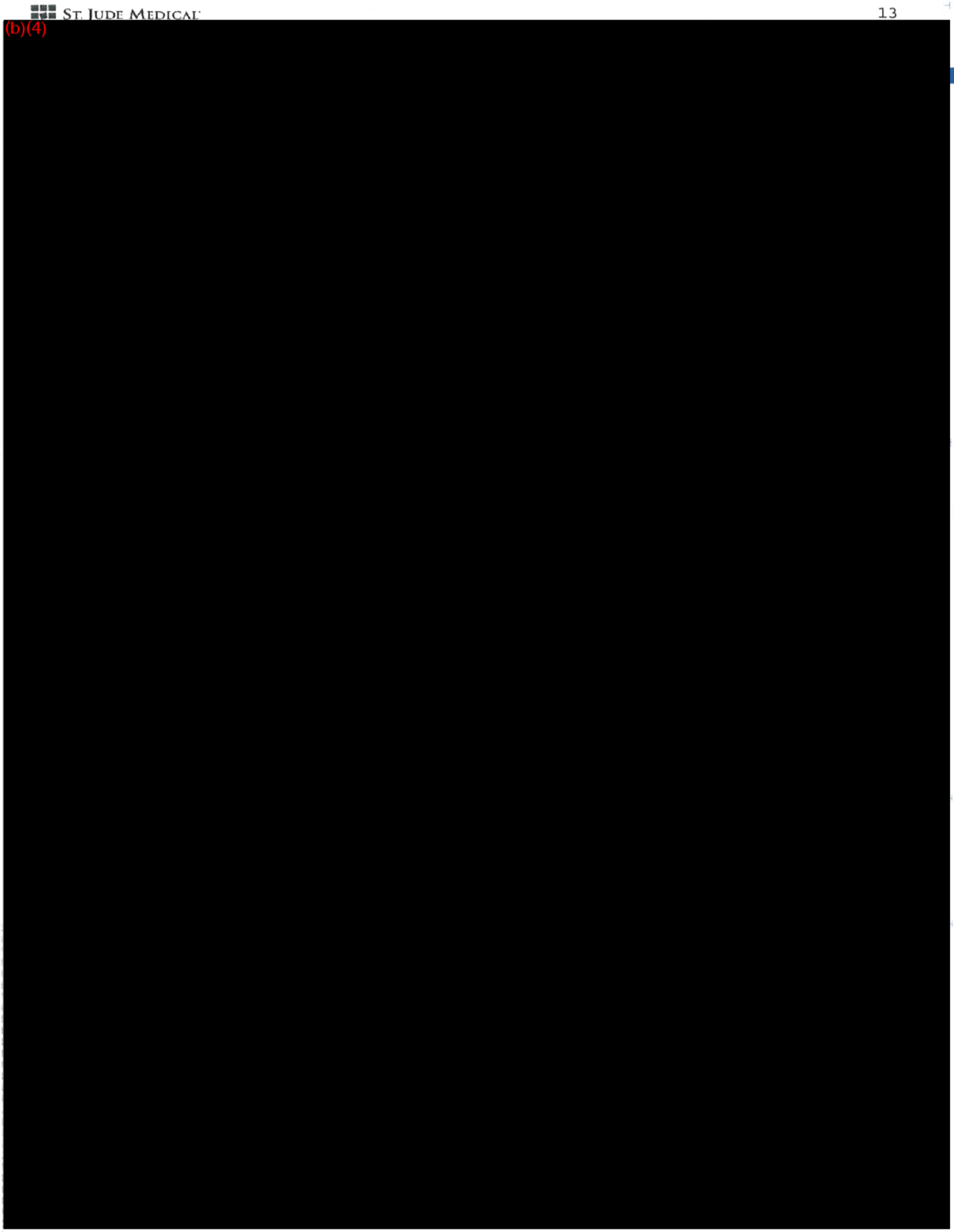
Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 18-Nov-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

(b)(4)



ATTACHMENT 2: CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FDA FORM 3514)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/18/2013	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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)*		
Irvine Biomedical, Inc. a St. Jude Medical Company	2030404		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Cardiovascular and Ablation Technologies Division	949-769-5053		
Street Address	**FAX Number *(including area code)***		
2375 Morse Avenue	877-482-7739		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Irvine	CA	92614	USA
Contact Name			
Jennifer Correa			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Specialist II	jcorrea05@sjm.com		

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

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

PSC Publishing Services (301) 443-6740 EF

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

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

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

- ☐ Response to FDA correspondence:

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

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

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

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

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

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

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OBJ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K121381	1	ViewFlex Xtra ICE Catheter	1	Irvine Biomedical, Inc. a St. Jude Medical Company
2	K071234	2	AcuNav Diagnostic Ultrasound Catheter	2	Siemens Medical Solutions USA, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

ICE Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	ViewFlex Xtra ICE Catheter	1	D087031
2		2	
3		3	
4		4	
5		5	

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

1 K121381	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OBJ	870.1200	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Irvine Biomedical, Inc. a St. Jude Medical Company		Establishment Registration Number: 2030404	
Division Name *(if applicable)*		Phone Number *(including area code)*: 949-769-5000	
Street Address: 2375 Morse Avenue		FAX Number *(including area code)*	
City: Irvine	State / Province: CA	ZIP Code: 92614	Country: USA
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (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 Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (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 Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

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

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

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

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Food and Drug Administration
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1350 Piccard Drive, Room 400
Rockville, MD 20850

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ATTACHMENT 3: VIEWFLEX XTRA ICE CATHETER PROPOSED LABELS

(b)(4)Draft Labels

(b)(4)Draft Labels

ATTACHMENT 4: VIEWFLEX XTRA ICE CATHETER PROPOSED INSTRUCTIONS FOR USE

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

(b)(4)Draft

K133853/S001

ST. JUDE MEDICAL
MORE CONTROL LESS RISK

St. Jude Medical
2375 Morse Ave.
Irvine, CA 92614 USA
Tel 949 769 5000
Fax 949 769 5144

January 24, 2014

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

FDA/CDRH/DCC
JAN 27 2014
RECEIVED

RE: K133853
(b)(4)
ViewFlex Xtra ICE Catheter

To Whom It May Concern:

(b)(4)

34

(b)(4)

[redacted]

Sincerely,

Jennifer Correa
Regulatory Affairs Specialist II
St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

St. Jude Medical
2375 Morse Ave.
Irvine, CA 92614 USA
Tel 949 769 5000
Fax 949 769 5144

January 24, 2014

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

RE: K133853
(b)(4)
ViewFlex Xtra ICE Catheter

To Whom It May Concern:

(b)(4)

(b)(4)

[redacted]

Sincerely,

Jennifer Correa
Regulatory Affairs Specialist II
St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

11. DEVICE DESCRIPTION

11.1. DEVICE CONSTRUCTION & COMPONENTS

The device construction and components of the proposed ViewFlex Xtra ICE Catheter are identical to the cleared ViewFlex Xtra ICE Catheter. The following description provides a summary of the ViewFlex Xtra ICE Catheter device construction and components.

The ViewFlex Xtra ICE Catheter is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. An illustration of the ViewFlex ™ Xtra is provided in Figure 11.1. The catheter is inserted into the heart via intravascular access. The catheter shaft is a 9 French catheter constructed with radiopaque Pebax® tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection with an angle of at least 120 degrees in each direction. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement.

(b)(4)

11.2. DEVICE ACCESSORIES

The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles. The ViewFlex Xtra ICE Catheter is connected to a compatible ultrasound console via the appropriate Catheter Interface Module (CIM). The ViewFlex Xtra ICE Catheter compatible ultrasound consoles and CIMs are described below:

ViewMate II

The ViewMate II console is cleared under K062247as the HD11 Diagnostic Ultrasound System (510(k) submitted by Philips). The ViewMate II and HD11 are identical. St. Jude Medical distributes the device as the ViewMate II with no changes made to the product design, manufacturing or labeling. The compatible ViewFlex CIM (model 100038191) is a Class I device and is 510(k) exempt.

ViewMate Z

The ViewMate Z console is cleared under K101091 as the Z.one Ultra Ultrasound System (510(k) submitted by Zonare Medical Systems Inc.). St. Jude medical distributes the device as the ViewMate Z with no changes made to the product design, manufacturing or labeling. The compatible ViewFlex CIM (model 100043720) is a Class I device and is 510(k) exempt.

Philips CX50

The Philips CX50 console is cleared under K123754 (510(k) submitted by Philips Ultrasound, Inc.). The Philips CX50 clearance included the ViewFlex Xtra ICE Catheter (transducer model listed in the clearance letter). The compatible ViewFlex CIM (model H700296) is a Class I device and is 510(k) exempt.

11.3. PATIENT CONTACT MATERIALS

(b)(4)

16. SOFTWARE

The Software Section of the 510(k) does not apply as the ViewFlex Xtra ICE Catheter does not contain or use any software.

(b)(4)

18. PERFORMANCE TESTING (b)(4)

(b)(4)


(b)(4)

(b)(4)

(b)(4)Design Verification Report

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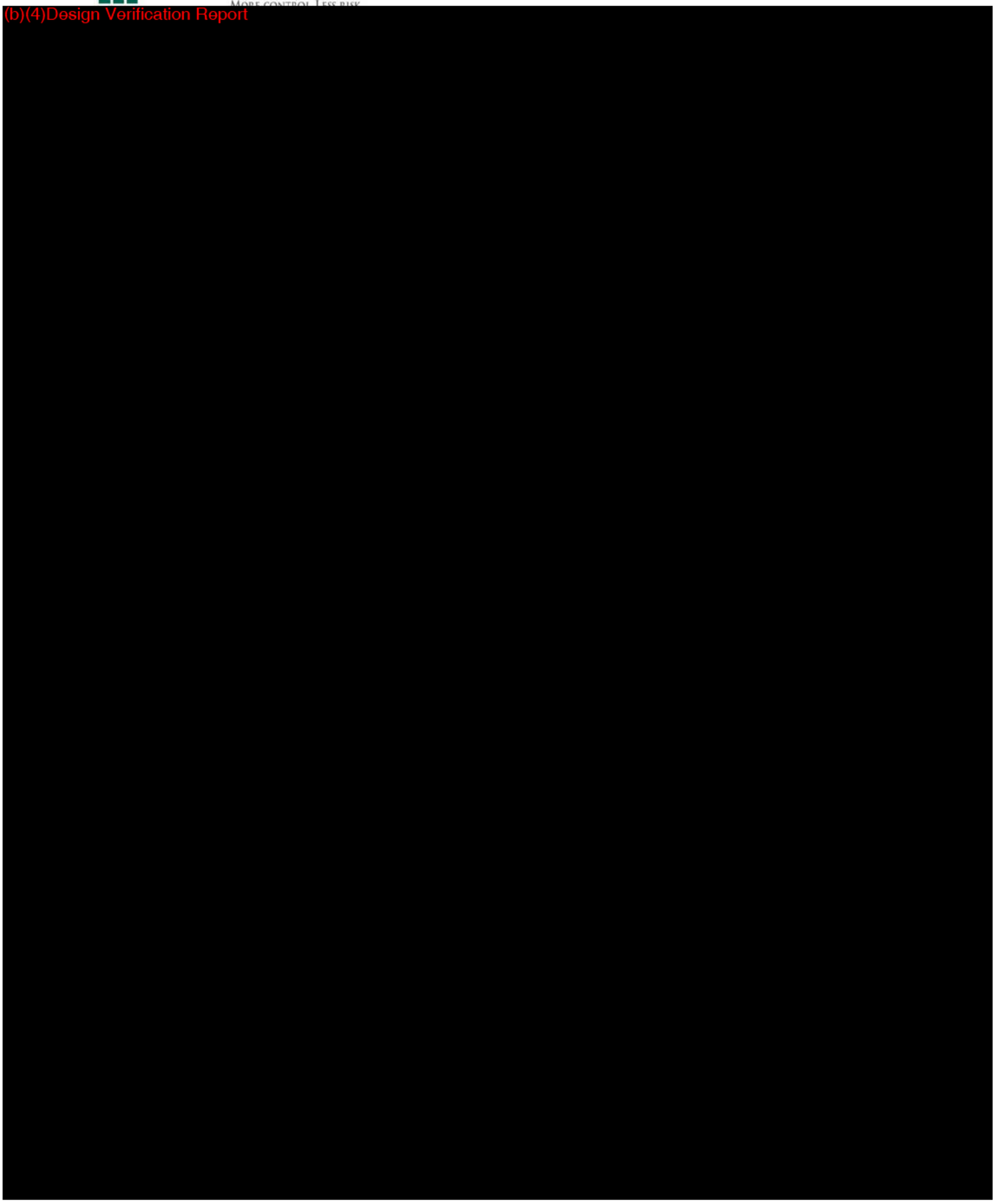

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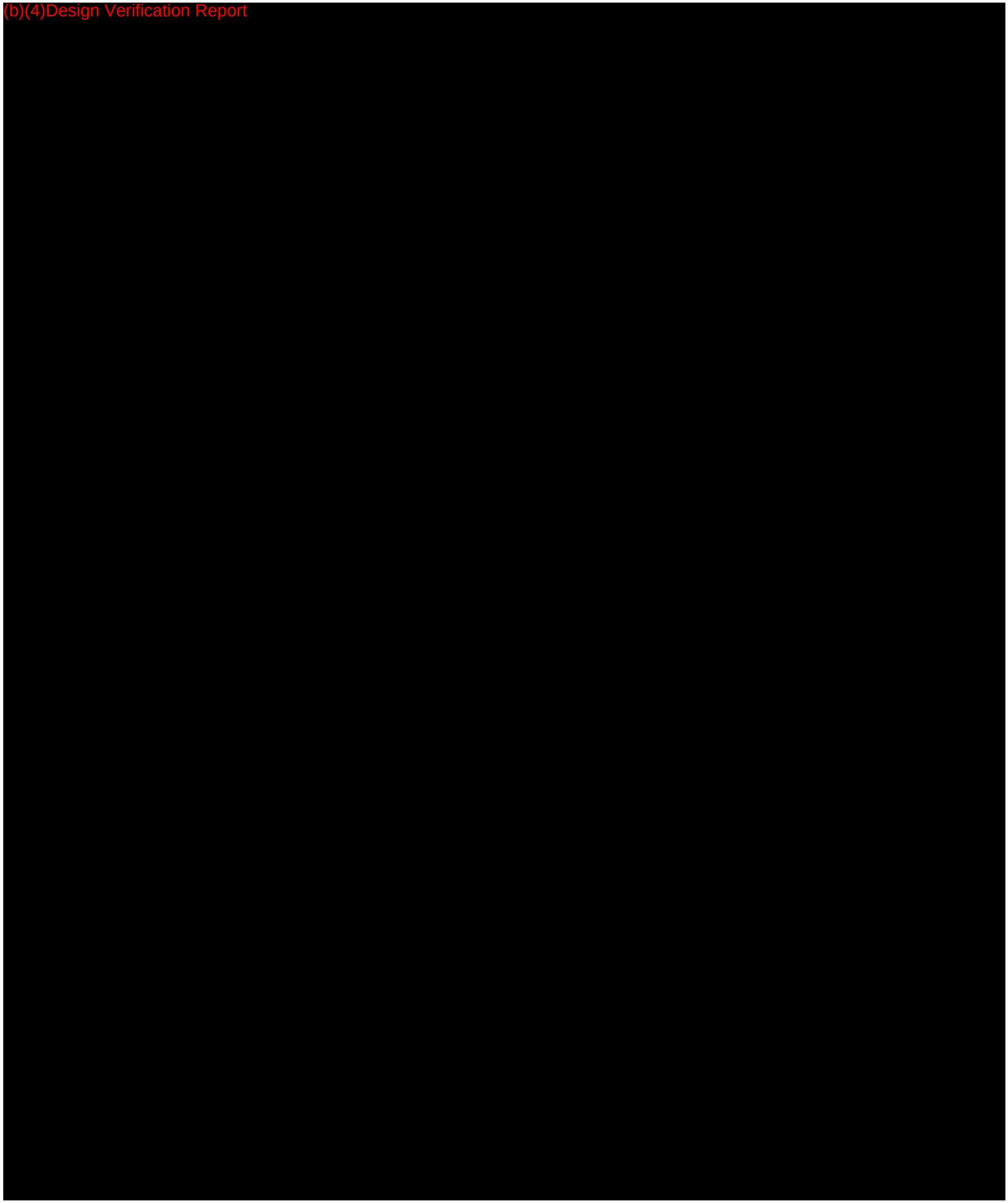

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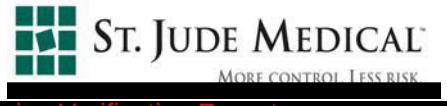

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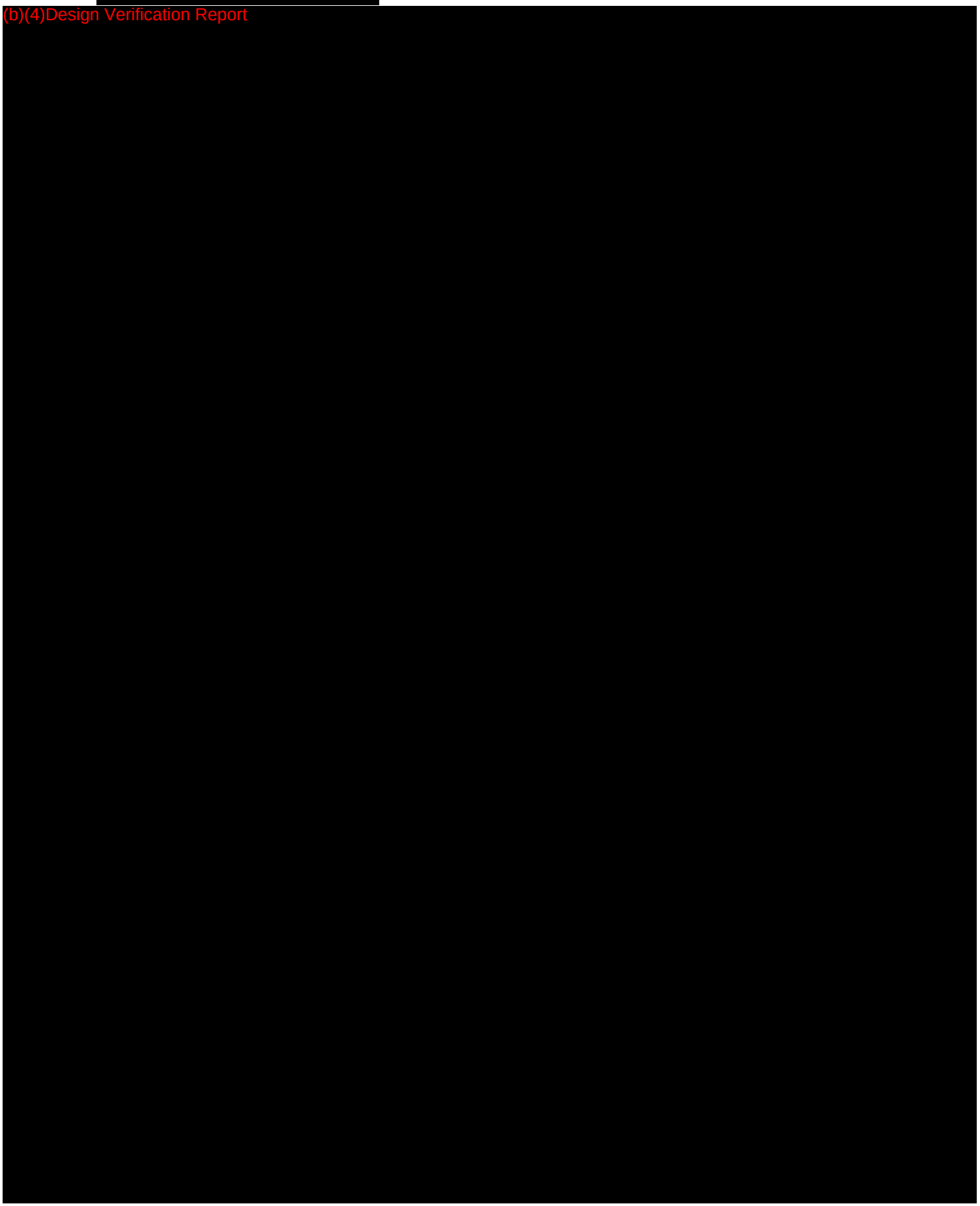

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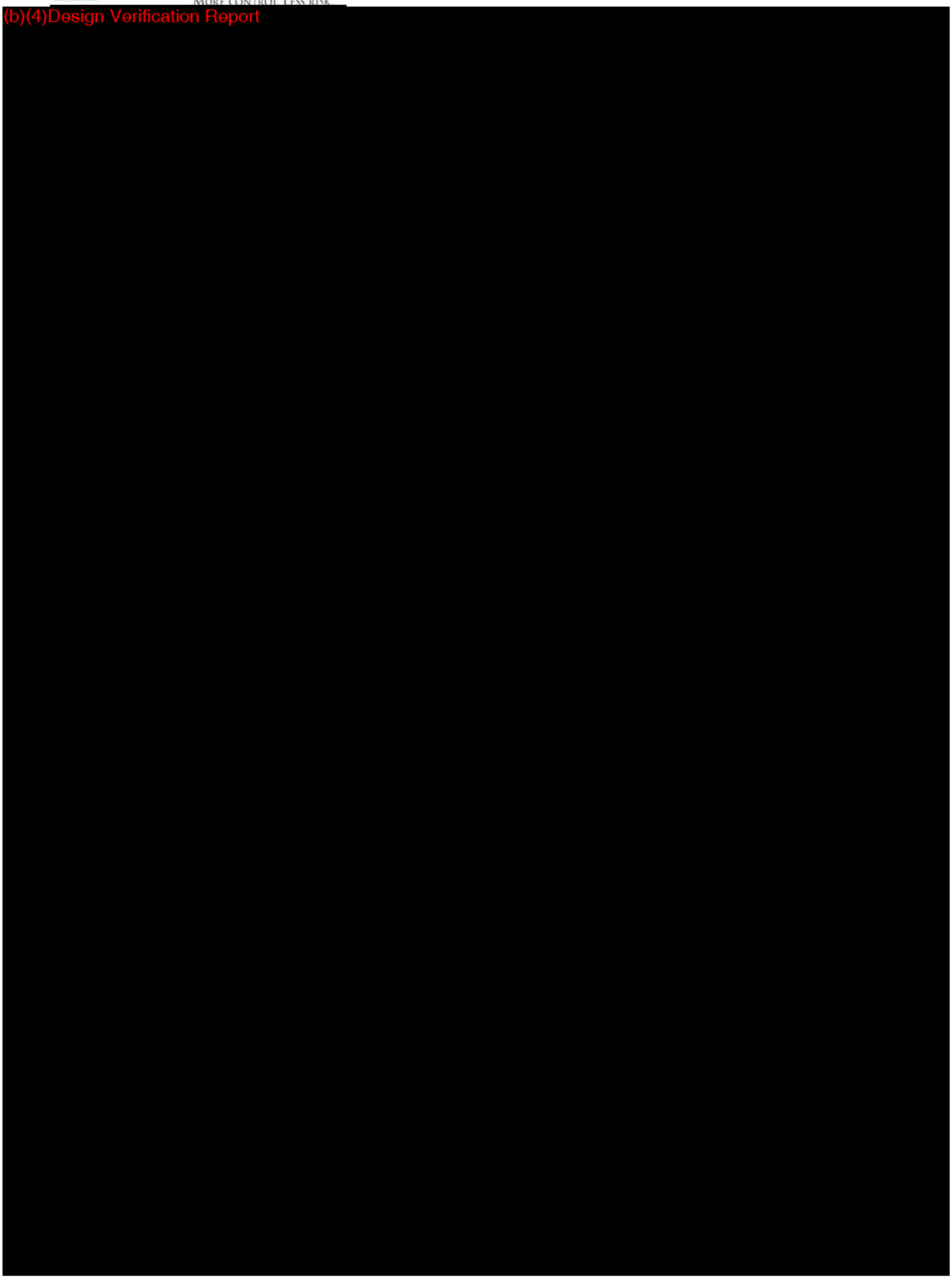

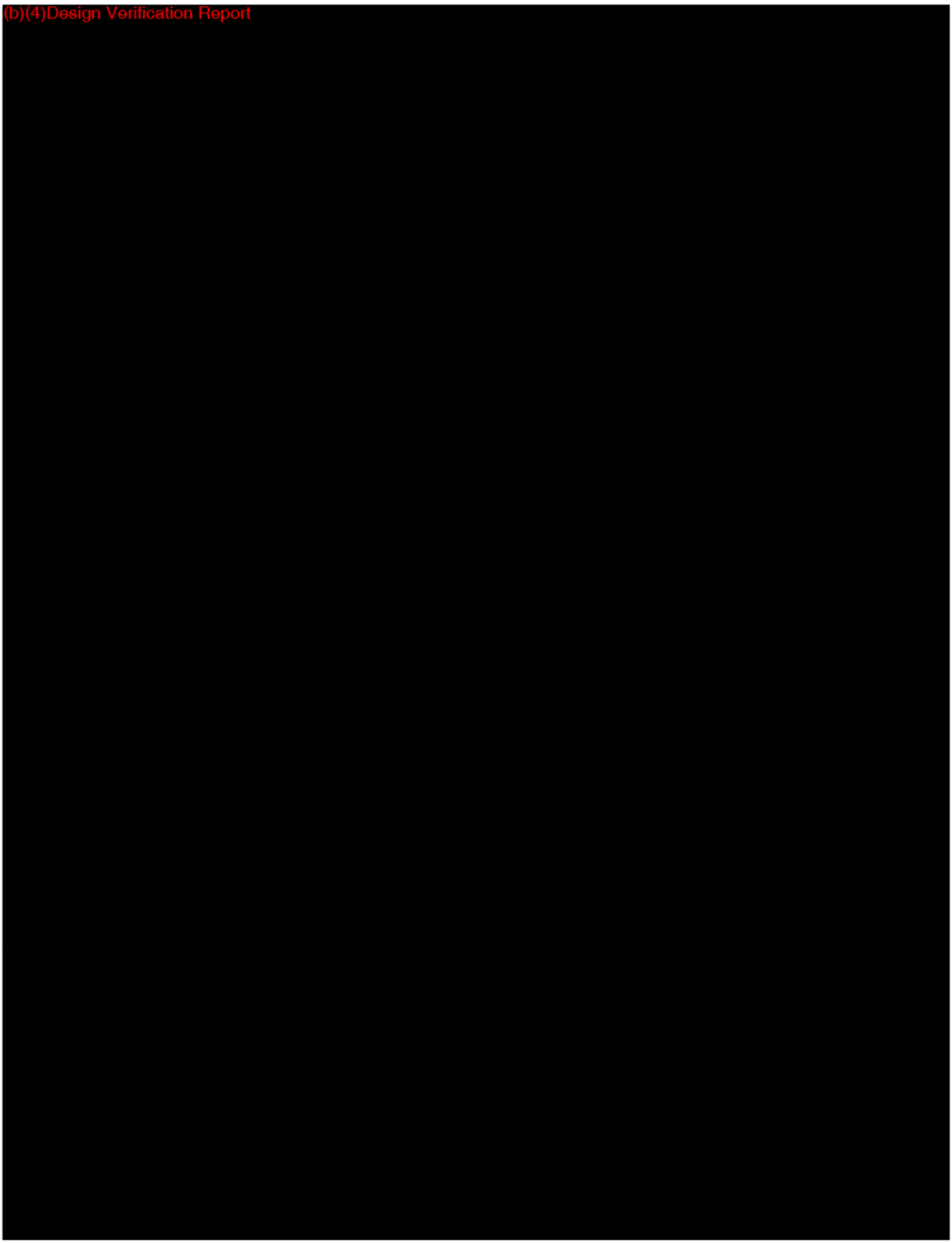

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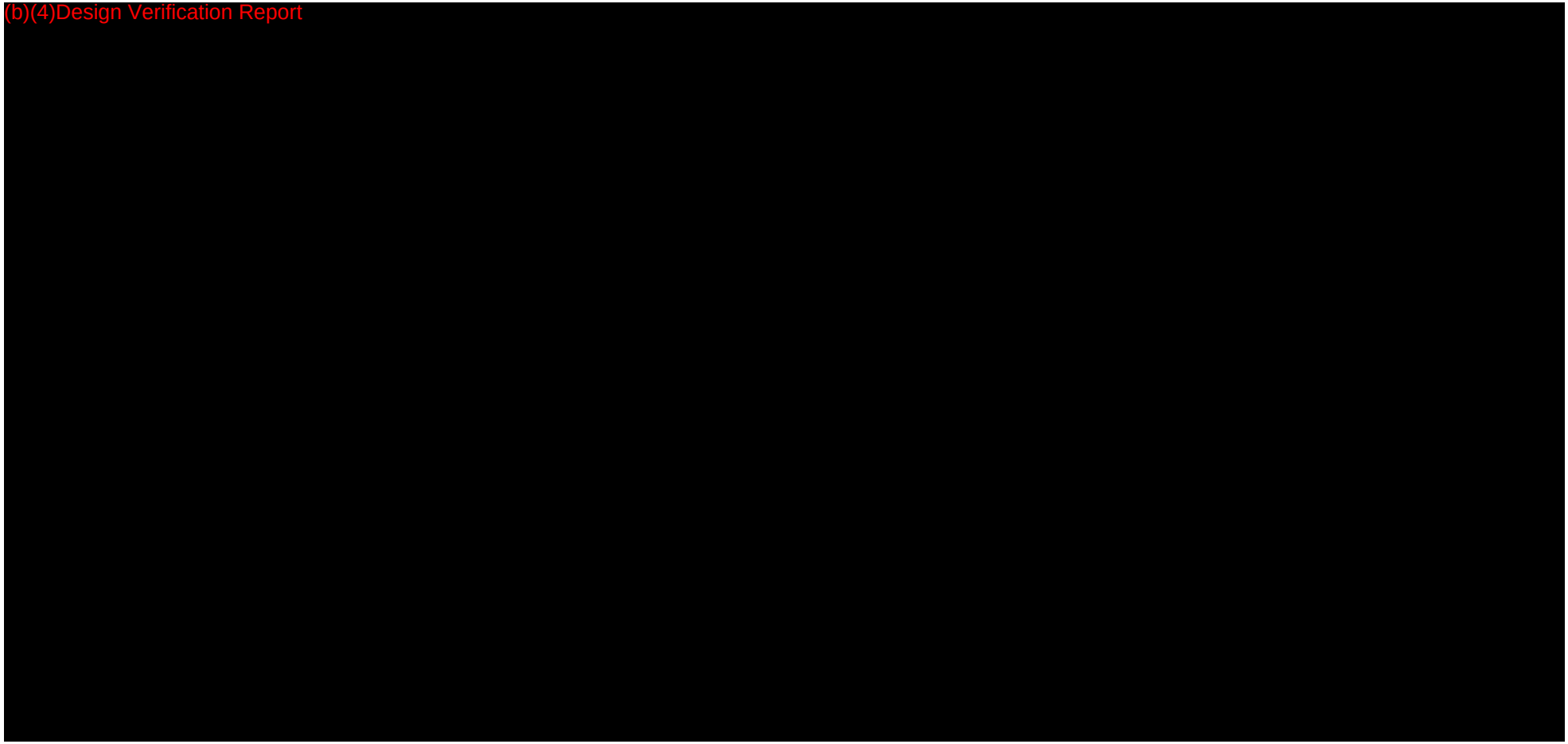

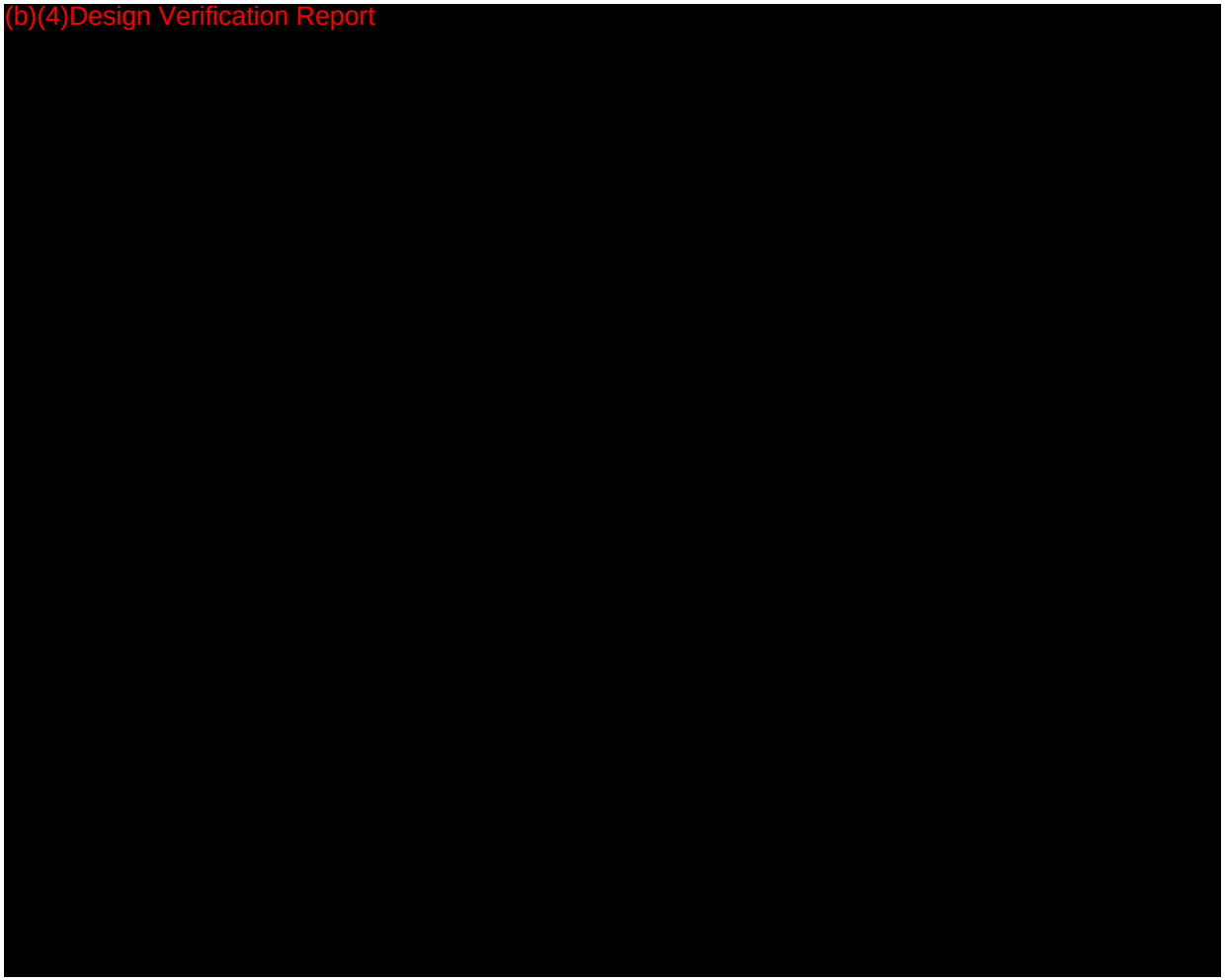
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Production Order Number: 50569800 Material Number: 100046963 Batch Number: 3577202

Operation Number	Operation Description			Production Res Tool		PRT Description		Ref Type	Version Used
0030 Confirmation Required Mile.	CLOSE WORK ORDER / INSPECT			NA		NA		NA	
	Work Ctr/WS	Qty	UoM	Quantity Accept	Quantity Reject	Disp	Date	Performed By	
	IR_ABL	11	EA						

QA CT 01/07/12

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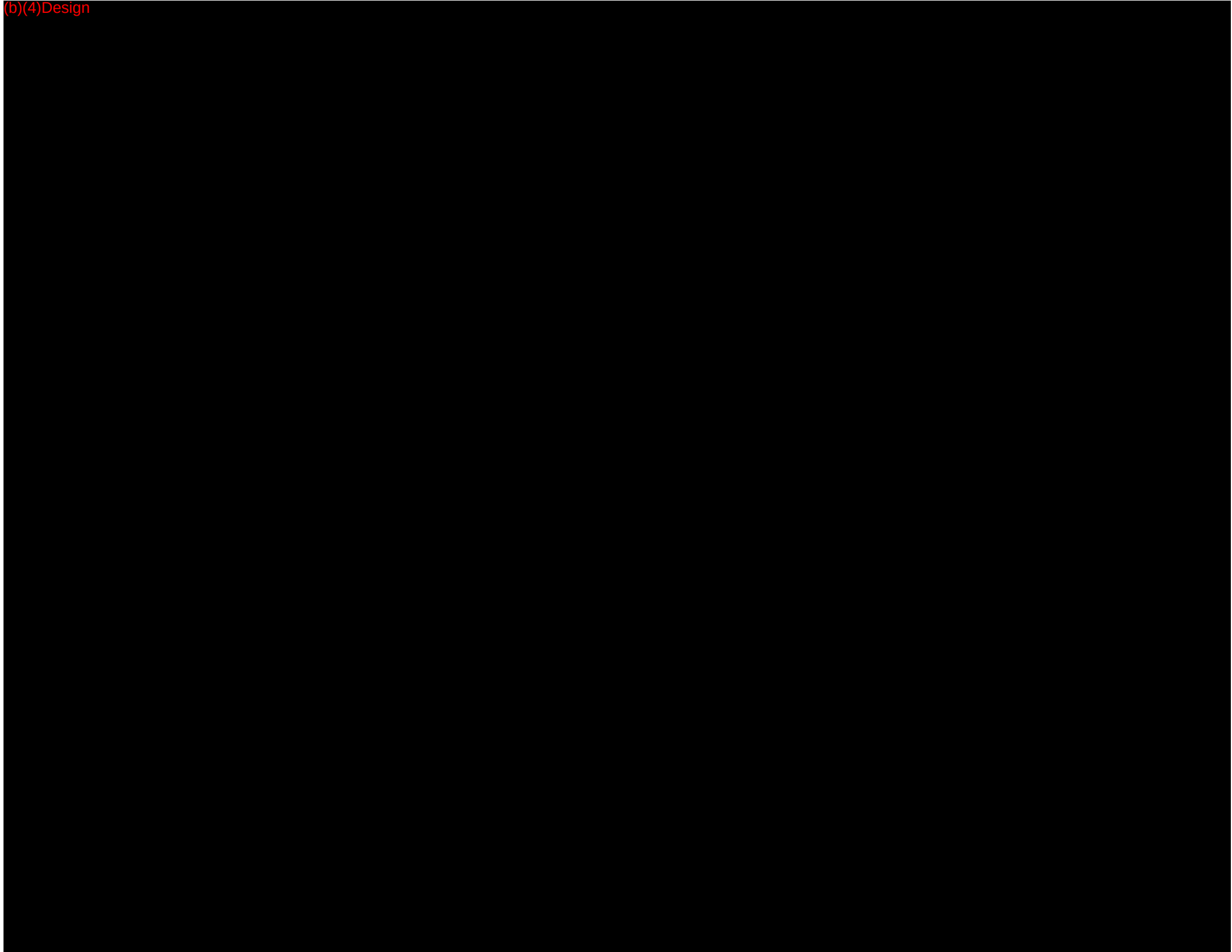
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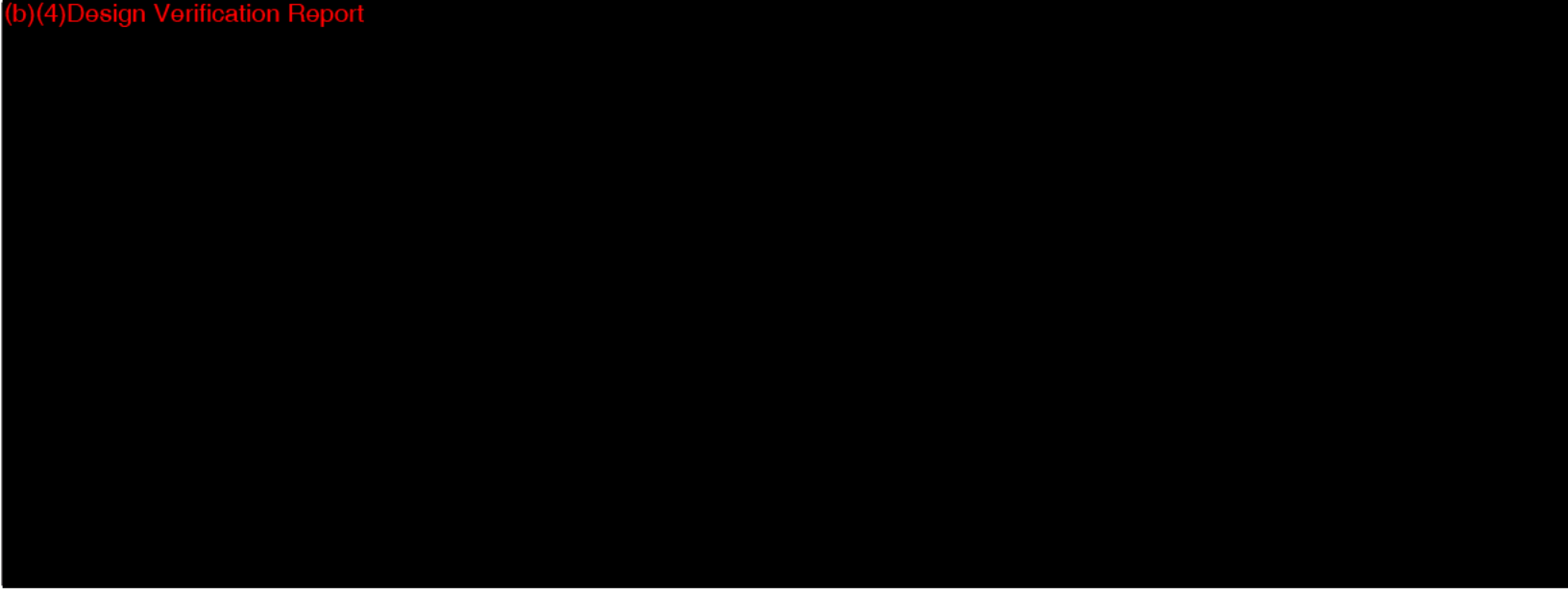

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The QA Cookbook for Ultrasound

Designed and written by GAMMEX RMI with assistance from Paige Medlin and Jean B. Schultz.

Special Thanks to Professor James Zagzebski Ph.D., University of Wisconsin - Madison, Department of Medical Physics for his guidance and expertise.

Printed in the United States of America

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Introduction

The QA Cookbook for Ultrasound is a sonographer's guide to establishing a quality assurance program for gray scale ultrasound scanners. The Cookbook introduces the reader to some of the basic concepts of Quality and then applies these concepts to the problem of maintaining image quality. In this way, you can see *why* each QA step is taken as well as *how* it is performed.

The primary goal of the QA Cookbook is to help you achieve consistent image quality in a department's ultrasound studies. In addition, we hope that you will find opportunities to use these valuable ideas for improving the quality of other parts of your medical practice.

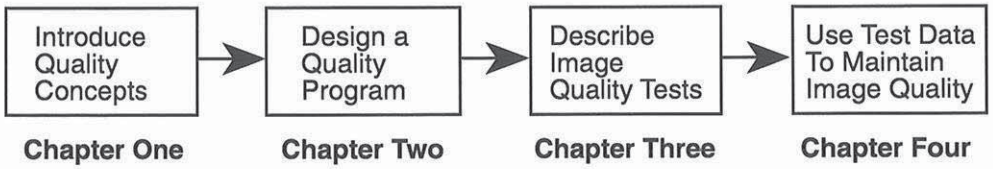
What You Should Know

The Cookbook assumes you have no previous knowledge of quality concepts or image quality measurement tests. You should be familiar with basic ultrasound physics and understand how to operate the ultrasound equipment to be tested.

Overview of the QA Cookbook

Chapter One provides a brief introduction to some of the basic concepts used in all quality programs. To help solidify your understanding of QA, examples and exercises illustrating important ideas and their application are included.

- Read Chapter One if you have no previous knowledge of quality concepts or need a quick review.



The Cookbook's process for developing a quality assurance program.

Chapter Two identifies the image quality indicators and presents a system of procedures and documents to evaluate and document image quality in ultrasound.

Chapter Three describes how to perform the image quality tests. Worksheets for recording and analyzing the measurement data are included in the Appendix and may be used as "masters" for copying.

Chapter Four explains how to use the quality test data to achieve consistent image quality. Suggestions for customizing the QA program to fit your particular applications are included.

The Appendix contains information on how to select a phantom, a bibliography of books on quality, and the Data and Graph Sheets for documenting and analyzing the image quality test data.

Chapter One
Basic Quality Concepts

What Is Quality?

Quality means different things to different people. People usually think of quality in subjective terms such as "feels better" or "lasts longer." A famous oil painting and a German engineered automobile both have an aura of quality. In the case of the painting, the quality is the result of the work being done in a way that isn't always measurably superior, but simply looks better to the eye. On the other hand, the quality of the automobile is the result of painstaking design and manufacturing effort intended to produce measurable superiority: safer, faster and more reliable.

Modern quality "gurus" have developed tools and ideas that can be used in any situation to produce better, more consistent quality. The new approach is that quality *can* be measured and that attempts to improve quality should be based on data rather than on hunches.

Quality is still defined in many ways. Some common definitions are

- Conforming to requirements
- Maximizing satisfaction while minimizing dissatisfaction
- Meeting expectations
- Delivering what was promised

In the following sections, we'll use "meeting expectations" as our working definition of quality.

Exercise: Quality in the Real World

Make a list of products or services that impress you with their quality. Beside each item describe what characteristic provides that sense of quality and determine if that characteristic is objective or subjective.

Product	**Characteristic**
German engineered automobile	safe
Swiss watch	reliable
Blue jeans	comfortable
Menu-driven computer	easy to use

Customers, Products and Suppliers

Quality is an issue whenever somebody receives something from someone else. It helps to think in terms of a customer receiving a product from a supplier. (Although these terms sound insensitive in a healthcare setting, they help to emphasize the roles and dependencies in the relationship.) The amount of satisfaction a customer receives from the product is a reflection of how well their expectations are met. Therefore the supplier's first task is to identify and meet the customer's expectations.

For instance, the sonographer is a customer and a supplier. As a customer, the sonographer uses the products of the imaging system and the hospital support staff. As a supplier, the sonographer provides images and measurements to the customers, the patient and physician.

Organizations often think in terms of internal and external suppliers and customers. Internal suppliers and customers are members of the organization who exchange products within the organization. The external customer receives the final product of the entire organization's efforts. In the example above, the physician is an internal customer of the sonographer while the patient is the hospital's external customer.

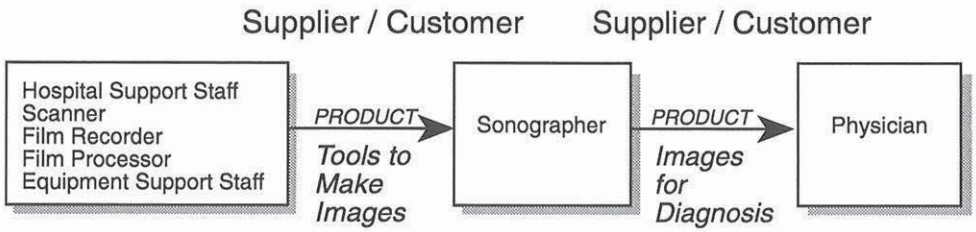


Fig. 1.1 A sonographer's customer and supplier relationships.

Exercise: Quality in the Real World

Make a list of five things that contribute to producing a good ultrasound image.

Contributor	Expectation
1. Patient	On time for appointment
2. System	Accurate distance measurements
3.	
4.	
5.	

Quality Indicators

"I can't define it, but I know it when I see it."

To stay in business, suppliers must satisfy their customer's expectations. For an automobile manufacturer, this might translate into building a car that doesn't need too much maintenance. The problem is that "too much maintenance" is subjective. Exactly how much is too much? If, for example, potential customers tell the manufacturer that a tune-up every 24,000 miles is acceptable, then a subjective *expectation* has been converted into an objective *requirement.* In developing a product to meet this requirement, the manufacturer can now use tests to measure how well it satisfies the customer's expectations.

A *quality indicator* is a measurable product characteristic that corresponds to a customer expectation. Using the example of a car, quality indicators can be used at many different levels within a product. In addition to measuring the quality of the car in terms of its maintenance requirements, quality indicators could also be used to monitor manufacturing quality (e.g., flaws in body panels) or design quality (e.g., time needed to stop from 60 mph).

Although quality indicators are straightforward in theory, a customer's expectations often extend beyond their stated requirements. Unspoken expectations exist for every product and are often the ultimate source of dissatisfaction. Therefore, the first step in improving quality is to define it.

Exercise: Quality in the Real World

For each of the contributors and expectations in the previous exercise, choose a quality indicator that would allow you to measure its performance with respect to your expectations. Which of these indicators do you think are regularly measured? Which ones should be measured?

Contributor	Expectation	Quality Indicator
1. Patient	Cooperative	Minutes late for appointment
2. System	Accurate Distance	Measurement Error
3.		
4.		
5.		

Processes, Variations and Defects

The supplier is a collection of people, machines and supplies performing tasks to create a product. The manner in which these tasks are done is the *process*. A process can be well thought out or it can just happen. The comment "that's how we've always done it" is usually a good indication that the process in question "just happened."

The quality of each unit of product created by the process should be consistently high enough to satisfy the customer's expectations. Unfortunately, everyone and everything in the process changes over time: the quality of the supplies vary, the people get tired and the machines go out of adjustment. These changes can cause the physical characteristics of the product to vary from the customer's desired values. This variation is said to be the enemy of quality.

The *tolerance* is the amount of variation the customer can tolerate in the product. Product specifications normally include a desired or specified value "S," plus or minus a tolerance value "T" and are written in the form S±T.

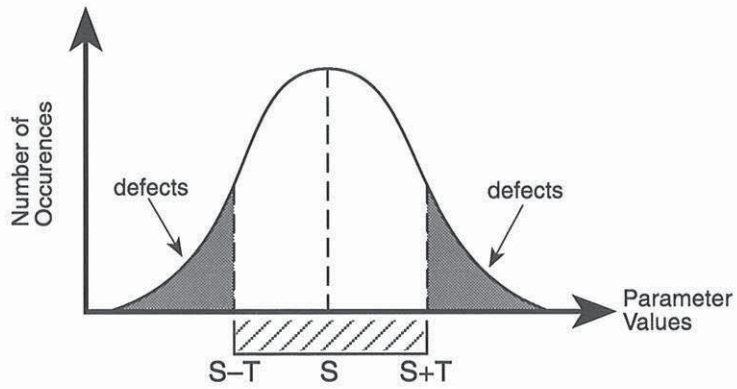


Fig. 1.2 The process capability describes the process' ability to produce product within the specified values of S–T and S+T (striped box). Product that falls outside of the specifications is defective (shaded areas).

Variations greater than the customer's tolerances are *defects*. In many cases defects are caused not by the people working in the process, but by the process in which the people work. Every process will have a characteristic range of variations in its output. The ability of the process to produce product within the customer's tolerances is called the *process capability*. To minimize the number of defects, the supplier strives to make the variations in the process as narrow as possible while making the tolerance in each product specification as wide as possible.

A common situation is that a process will consistently produce too many units that fall outside of the customer's tolerances (defects). When a process is incapable of producing the desired results, better results are not achieved by forcing the people and machines to work harder. The process itself is defective and must be improved to reduce the number of defects.

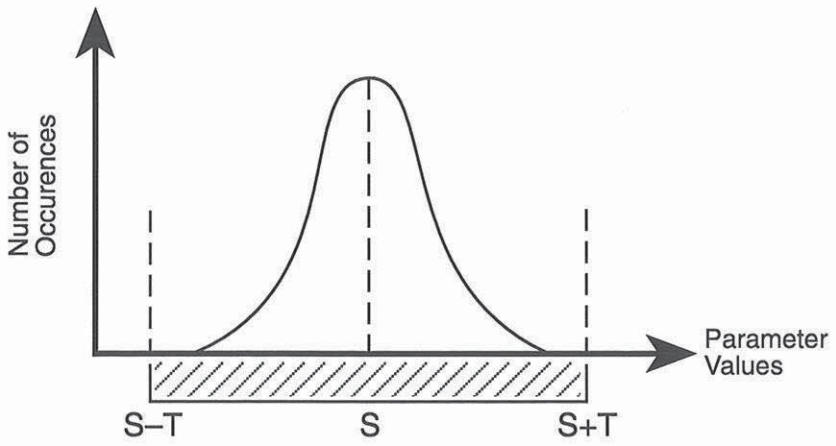


Fig. 1.3 Ideally the range of process variations are narrower than the customer's specifications. When this happens no defects are produced.

Exercise: Quality in the Real World

Use a flow chart to describe the process of producing an ultrasound image. Where in the process would each of your previous expectations be important?

For each of the quality indicators listed in the previous exercise, choose a tolerance indicating the amount of variation acceptable to you or your customers.

Contributor	Expectation	Quality Indicator	Tolerance
1. Patient	On time	Minutes late	5 min
2. System	Accurate Distance	Measurement Error	±3 mm
3.			
4.			
5.			

Quality Control

"What can be measured can be controlled."

Once the process is running, the supplier must ensure that defective product is not delivered to the customer. The most basic approach is *quality control*, which inspects product and removes the defective ones. Quality control or 'QC' is sometimes referred to as "inspecting the quality in" because the inspection process, rather than the production process, is responsible for achieving a consistent quality level in the delivered product.

Although quality control keeps defective product away from the customer, it is expensive because the defective units cost as much to produce as the acceptable ones. In addition, they must be either thrown away or repaired at additional expense. The extra resources spent on correcting defects are known as the "hidden factory". Organizations can easily spend 20-30% of their operating budgets on the hidden factory.

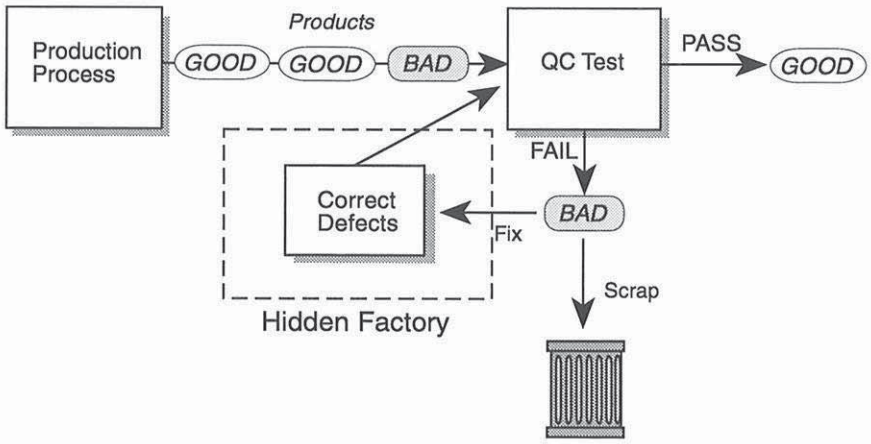


Fig. 1.4 Quality control is a process of measuring quality indicators and filtering out defects. The hidden factory used to correct defects can absorb a large portion of an organization's budget.

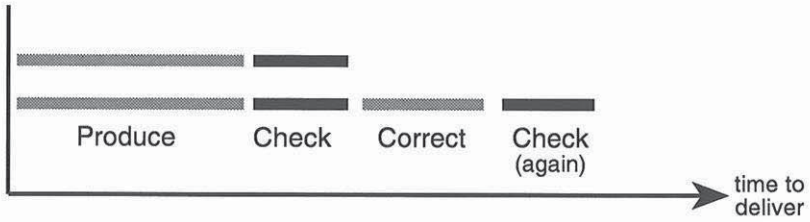


Fig. 1.5 Correcting defects adds time and cost to the process. Organizations that fail to include these hidden costs in their budgets may run out of time and money before the job is done.

Exercise: Quality in the Real World

For the quality indicators from the previous exercise, determine where in the process you could locate and correct defects. How much extra time and effort does it cost to correct a defect?

Contributor	Quality Indicator	QC Check
1. Patient	Minutes late	Time
2. System	Distance Error	Compare with known distance
3.		
4.		
5.		

Quality Assurance
"Making Things Go Right"

Unlike Quality Control, which reacts to defects after they occur, Quality Assurance or 'QA' attempts to prevent defects from happening in the first place. A QA program spans the supplier's entire process and attempts to keep it running at peak performance as often as possible. Quality assurance programs frequently contain the following activities:

- Periodic quality indicator measurements
- Corrective actions triggered by action levels
- Preventive maintenance
- Operator training
- Incoming QC of supplies
- Outgoing QC of product

Defects are often caused by process variations that slowly grow until tolerances are exceeded and defects are produced. By detecting subtle changes in the process, the QA program can often identify and correct a source of potential

defects before quality drops to unacceptable levels. The mechanism for triggering corrective action is the *action level.* The action level is a predefined value that indicates when a variation is approaching defective levels. By automatically correcting sources of variation before a defective level is reached, defects are more effectively prevented.

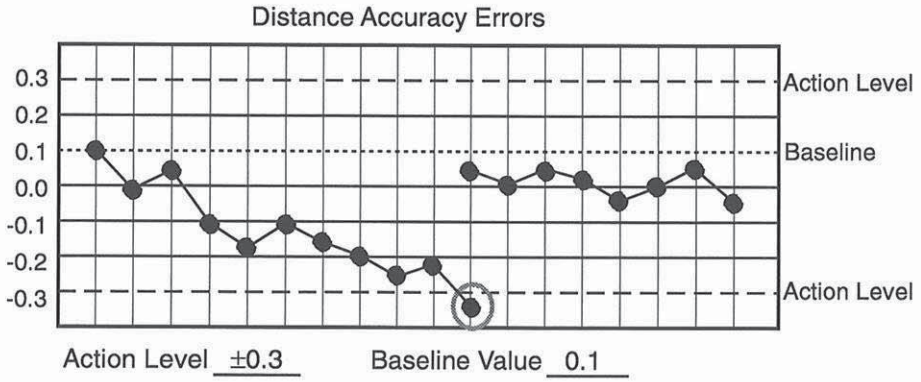


Fig. 1.6 A run chart showing a distance measurement error increasing over time. The action levels indicate the value at which corrective action is triggered. The circled data point indicates that the action level has been exceeded.

In addition to preventive maintenance, QA programs may also monitor the inputs and outputs of the process. To guard against defects in the raw materials, an "incoming QC system" would be established to monitor the quality of the process's inputs. This may be as simple as checking the expiration date on a film pack or as comprehensive as requiring an elaborate inspection process.

A QA program would also be concerned with developing and maintaining the skills of the workers at all stages of the process (another important process input). An "outgoing QC system" is also needed to filter out the defects that are still produced. The number of defects reaching the final QC stage is a good indicator of the effectiveness of the overall QA program.

Exercise: Quality in the Real World

For the quality indicators and defects you selected in the previous exercise, think of a way to eliminate or minimize the source of the defect.

Contributor	Quality Indicator	Preventive Action
1. Patient	Minutes late	Schedule appointments 10 minutes early to account for patient prep and time differences.
2. System	Distance Error	Monitor system accuracy periodically and request service when error reaches action level.
3.		
4.		
5.		

Quality Improvement

Successful quality assurance programs can maintain consistent quality levels, but every process has a limit to the quality level that can be achieved. Quality improvement or 'QI' is the practice of increasing the potential quality level of a process.

The Joint Commission for Accrediting Hospital Organizations (JCAHO) states that "a hospital's principal goal should be to help everyone improve the process in which he/she is involved." Quality improvement is a people-oriented approach based on the ideas that defective processes produce defective products and the best people to improve a defective process are the ones working in it.

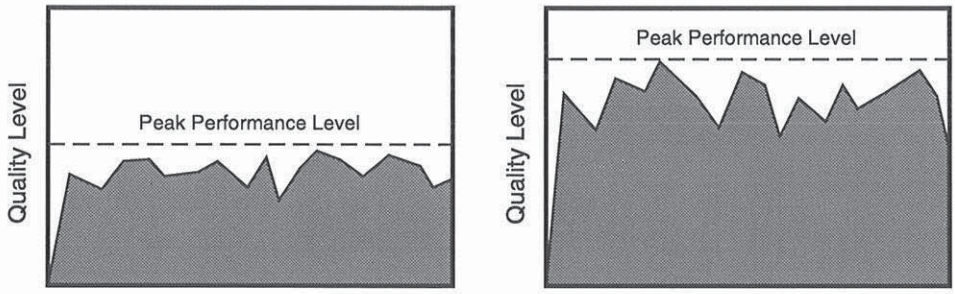


Fig. 1.7 Quality assurance activities attempt to keep a process operating as close to its peak performance as possible. Quality improvement seeks to raise the process' peak performance level.

The basic quality improvement approach can be described as follows:

- Identify a problem or situation in need of improvement
- Determine the possible root causes of the problem
- Develop potential solutions
- Implement the solutions as a controlled experiment
- Evaluate the results of the experiment
- If the results of the experiment are desirable, incorporate the changes into the process and maintain (QA work)
- Repeat for the next problem*

* Quality gurus like to say that there are no problems, only opportunities.

Although tremendous quality breakthroughs are exciting to think about, quality improvement efforts are most effective when approached as a continuous stream of incremental improvements. Effective quality improvement requires time, teamwork and a long-term commitment from top management to change the way things are done. Quality expert Philip Crosby likes to say that "quality is free, but it's not a gift".

Exercise: Quality in the Real World

For the quality indicators and defects you selected in the previous exercise, think of a way to eliminate or minimize the source of the defect.

Contributor	Problem	Root Cause/Process Improvement
1. Patient	Late for appointment	Patients have trouble finding parking spaces. Improvement: Reserve parking spaces for scheduled patients.
2. System	Distance Error	Excess heat causes electronics to drift. Improvement: Clean air filters to improve air flow and cooling.
3.		
4.		
5.		

Chapter Two
Establishing a Quality Assurance Program

Introduction

Quality was defined in Chapter One as 'meeting the customer's expectations'. The remaining chapters address how to meet the image quality expectations of the sonographer's customers. The working definition of the customer's expectation will simply be that "the ultrasound images consistently and accurately represent the patient's anatomy."

Establishing the QA Program: *Who, What, When and How?*

The quality assurance program seeks to establish a process that 1) maintains image quality levels within acceptable limits and 2) documents the image quality. To prevent defective images, the QA program combines periodic preventive activities with image quality testing. The QA program consists of these major components:

- A definition of customer expectations and associated quality indicators and action levels
- A system to measure and record the image quality indicators
- A system to identify potential quality problems and "trigger" corrective action
- Additional preventive maintenance measures to maintain the performance of equipment and operators

Maintaining consistent image quality is difficult because the accuracy of a clinical ultrasound image is difficult to assess. There is no "reference patient" for day-to-day comparison. This problem is solved by using a tissue mimicking phantom with known target geometries and characteristics to measure the image quality indicators (see "Choosing A Tissue Mimicking Phantom" in the Appendix).

Sonographers sometimes argue that testing is unnecessary because they can detect image quality defects during normal scanning. While it is true that a clinical evaluation approach can detect image defects, it's probable that a number of images contained the defect before it was detected. Gradual degradation makes it even more difficult to detect obvious defects. Quality assurance measures and corrects image quality defects at levels normally undetectable to the sonographer's unaided eye, so blatant defects are seldom encountered during patient scanning.

Image Quality Indicators

Image quality indicators have been developed to measure the characteristics of system performance that affect the diagnostic value of the ultrasound image. The image quality indicators used in this QA program are:

- Depth of Penetration
- Image Uniformity
- Lateral Resolution
- Cyst Imaging
- Distance Accuracy
- Axial Resolution
- Dead Zone
- Image Recorder Quality

The cause and effect of each image quality indicator and a procedure for measuring the indicator is discussed in Chapter Three.

Implementing the QA Program

The process for setting up the QA program is described in the flow chart and sections that follow.

Who's Responsible?

Although the department chairman is ultimately responsible for quality, the department's quality assurance program is normally maintained by the sonographer(s) who routinely use the equipment. Quality programs are most effective when their plans and results are periodically reviewed by a committee representing all functions within the department.

Consistency makes or breaks a quality assurance program, so the people running the program should be carefully selected. Individuals should be detail-oriented, adequate time and resources must be allotted to perform the tests and the QA activities should be made part of the job description.

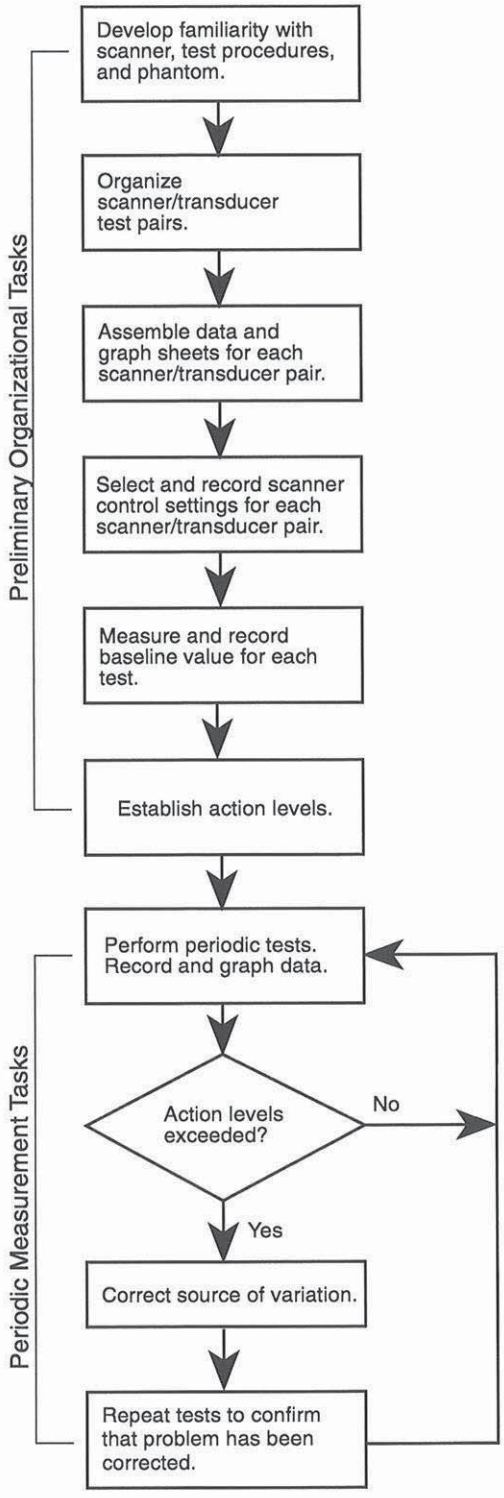


Fig. 2.1 The process of establishing and maintaining the scanner QA program.

What To Do?

The QA activities consist of two parts: the preliminary organizational tasks and the periodic measurement, documentation and maintenance tasks.

Preliminary Tasks:

- Organizing the worksheets for recording and plotting measurement data and defining the test schedule.
- Establishing baseline values for image quality to detect degradation in future measurements.
- Defining action levels for each quality indicator.

Periodic Tasks:

- Measuring the image quality indicators as indicated by the test schedule.
- Recording the measurements on the Data Sheet and plotting the indicator values on the respective Graph Sheets.
- Identifying situations (as indicated by the action levels) that require corrective action.
- Repeating measurements to verify the effectiveness of the corrective actions.
- Scheduling preventive maintenance visits.
- Holding operator training sessions.

Instructions for the organizational tasks are provided later in this chapter. The image quality test procedures are described in Chapter Three and the handling of the test data is described in Chapter Four. A guide to choosing a tissue mimicking phantom is provided in the Appendix.

Preventive Maintenance

The need for preventive maintenance applies to humans and machines. Preventive maintenance programs for ultrasound systems are offered by manufacturers and independent service contractors and are one of the best investments for consistent and predictable performance and operating cost. The date, work performed and the engineer's comments should all be recorded and stored with the image quality test data.

Operator error is a common cause of image quality problems. This, combined with the increasing complexity of systems, makes formal training and periodic

refresher courses a useful addition to the quality assurance program. The manufacturer's applications specialists are usually happy to provide hands-on demonstrations of the features and proper operation of their systems. New users should be given a thorough introduction to the system and everyone should be "trained" whenever a significant upgrade in hardware or software occurs.

When To Do It?

There are two schools of thought on the frequency of image quality tests. The first approach recommends measuring image quality at fixed time intervals (for example, the first Wednesday of each month). Although reproducible, this method doesn't consider varying workloads or environmental factors like overheating which may stress a heavily used system. The second approach measures image quality after a pre-determined number of procedures or operating hours have elapsed. This ensures that testing reflects the actual use of the system.

Where the instrument is used is another important factor to consider. An instrument exposed to high temperatures or used in a mobile unit will likely require more frequent checkups than one in a normal clinical setting. As there are no specific regulations for the frequency of image quality tests, each lab must select a schedule based on their particular systems and operating environment. Service and clinical engineers can provide valuable advice on appropriate test intervals.

Other Reasons to Test Image Quality

In addition to the regularly scheduled tests, image quality should be measured immediately after any event that could affect the system. This includes service calls (to ensure that repairs were successful), system upgrades or modifications (to detect new system "bugs") and any incident that could damage the system (for example, a dropped transducer, a power surge, or impact to the system).

Quick Scans

A daily "quick scan" of the phantom is a useful habit for mobile or heavily used machines. Performed before the first patient is scanned, a quick scan might check distance accuracy, penetration and overall image uniformity to assure the sonographer that the system is performing acceptably.

Procedures:

Organizing the Documentation

The image quality test data must be properly recorded and organized to be useful. This requires:

- ❑ Three ring binder,
- ❑ Dividers for the binder
- ❑ Plastic sleeves for the hard copy images
- ❑ A set of the Data and Graph Sheets (masters for copying provided in the Appendix) for each transducer to be tested.

The Data Sheet identifies the scanner/transducer pair tested and contains the scanner control setup information and the measurements from each test. Each image quality test uses a separate Graph Sheet to graphically represent the data and record important events such as equipment failures and repairs. The graphical representation of your data will help you identify the subtle degradation processes quality assurance seeks to correct.

Labs with multiple systems and transducers should match each transducer with a particular scanner. Testing the same scanner/transducer pairs improves the consistency and reliability of the program. Because equipment often moves from room-to-room, it's usually best to identify the devices by their serial numbers.

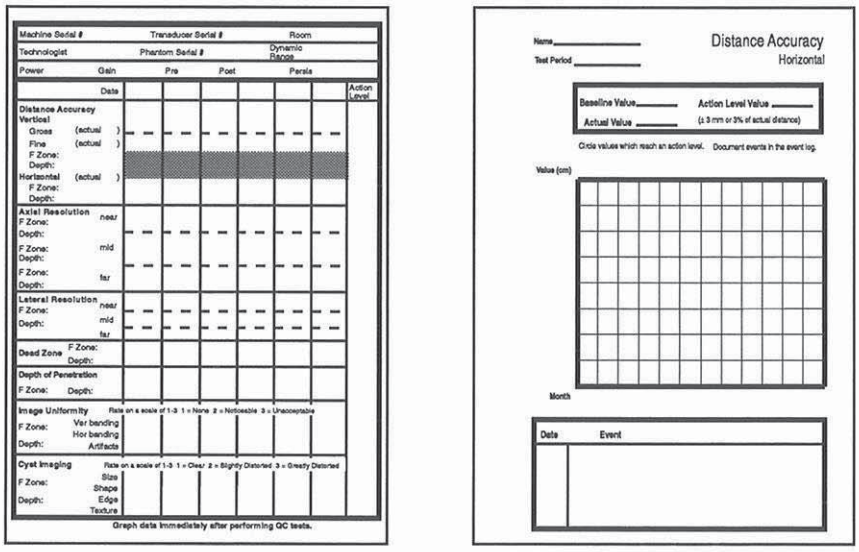


Figure 2.2 The Data Sheet and Graph Sheets are used to record and analyze test data for each transducer. Full page copies are located in the Appendix.

Scheduling the Tests

The table below offers a good starting point for a test schedule. Notice that instruments used in mobile applications should be examined more frequently. Transducers used less often can be tested on a rotating basis so that every session examines roughly the same number of probes. Your service engineer can assist you in determining testing frequencies.

The Data Sheet provided in the Appendix is configured for a monthly test interval. Some boxes are shaded to indicate that a particular test does not require testing in that session. Axial resolution, for example, only requires a semi-annual check.

Scanner Test Schedule	
Stationary Units	**Frequency**
Scanner:	Monthly
Transducers:	
- daily use	Monthly
- occasional use	2-3 months
Mobile Units	**Frequency**
Scanner:	Weekly
Transducers:	
- daily use	Weekly
- occasional use	Monthly

Fig. 2.3 Suggested frequency of testing for scanners and transducers.

To organize a test schedule,

1) **Compile a list of the scanner/transducer pairs to be tested.**
2) **For each pair determine and record the appropriate test frequency. Note the highest frequency i.e. weekly or monthly.**
3) **Using a copy of the scheduling sheet (provided in the Appendix), list the test dates and each of the scanner/ transducer pairs to be tested.**
4) **For each scanner/transducer pair, write a single 'slash' in each box corresponding with the scheduled test date for the pair.**
5) **When the scheduled test for the pair has been completed, make an "X" in the date box to indicate that it is done (see example below).**

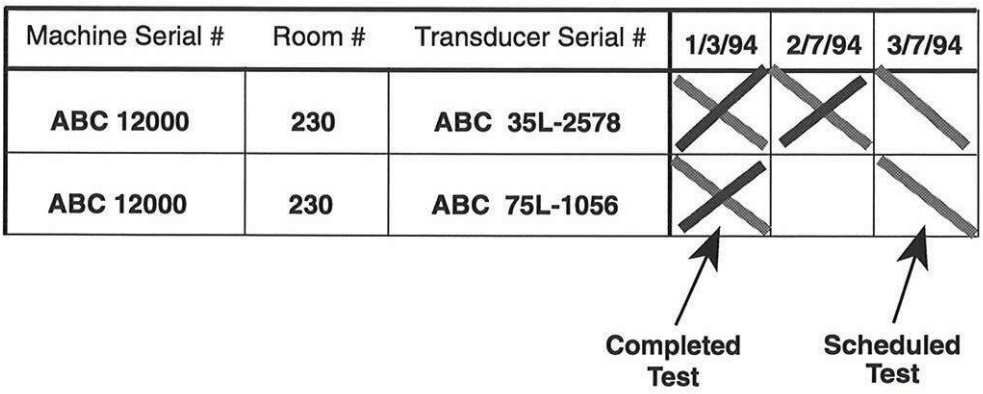


Fig. 2.4 Boxes coresponding to the scheduled test dates for each scanner/ transducer pair are filled with a single 'slash' mark. An 'X' is formed in the box when the test has been completed.

Performing the Baseline Tests

The baseline represents the instrument's peak performance for a particular image quality indicator. Subtle changes in image quality can be detected by comparing the current value with the baseline value. The baseline tests establish the instrument control settings to be used for the periodic image quality tests and determine the baseline values for each image quality indicator. For the best representation of an instrument's peak performance, the baseline tests should be performed immediately after the instrument has been installed and accepted. To ensure that existing systems are operating up to specification, it is best to perform the baseline tests immediately after a service or preventive maintenance visit by a qualified engineer. If the system is between service calls, perform the baseline tests as described on the following page. Immediately after the next service call, measure each image quality indicator and adjust the original baseline values if the measurements improve (if the indicator values degrade, call the service engineer). Remember, the baseline values are your landmarks for detecting changes in image quality.

Selecting Instrument Control Settings

A good tissue mimicking phantom allows the use of normal control settings. on the scanner To select the control settings for the image quality tests, scan the phantom as you would a patient and adjust the controls to produce the best possible clinical image, taking care not to emphasize or exaggerate a particular image attribute. Be sure that the video monitor's brightness and contrast controls

are in their "standard" settings. When you have arrived at an acceptable set-up, record each of the control settings on the Data Sheet for the scanner/transducer pair in use. Some of the image quality tests will require different settings for image and focal zone depth; be sure to record these settings on the Data Sheet and use them every time the tests are performed.

Determining Baseline Values

To determine the baseline value for each image quality indicator (i.e. Depth of Penetration, Distance Accuracy, Lateral Resolution, etc.),

1) **Scan the phantom using the control settings listed on the Data Sheet. Adjust the depth and focal zone settings as needed and record these settings on the Data Sheet for future tests.**
2) **Perform the test exactly as described in the test procedure and immediately record the measurement values on the Data Sheet. Save all hard copy images and label them as Baseline Images. Clearly write the identification number and measurement data on the back of each image for future reference.**

When you have completed the tests,

1) **Record the baseline value for each quality indicator in the box at the top of the appropriate Graph Sheet (located in the Appendix).**
2) **Plot the baseline value on the centerline of the graph and label the vertical and horizontal axes of the graph as shown below. Do not fill in the action levels.**

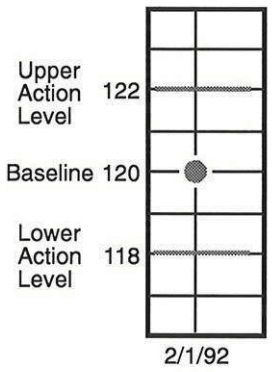


Figure 2.5 Graph box showing recommended format for baseline and action levels.

Selecting the Action Levels

The action level indicates the image quality indicator value at which corrective action should be taken. Action levels are located well within the instrument's specified tolerances to ensure that image quality never actually reaches defective levels. A value somewhere between one half and three quarters of the tolerance works well for most action levels. For example, if the maximum acceptable distance measurement error should not exceed 2%, an action level of 0.75 of the maximum acceptable error would be appropriate. If the distance tested is 120 mm, the acceptable error is 120 x 0.02 = 2.4 mm and the action level range would be 2.4 x .75 = 1.8 mm. The upper and lower action levels would be the expected distance of 120 mm plus or minus the action level range (120+1.8 = 121.8 mm and 120–1.8 = 118.2). In some cases thebaseline value may not equal the expected value. When this occurs the action levels will not be evenly distributed around the baseline.

A space for the desired action level is provided on each Graph Sheet. Because each system will have different performance levels, you may wish to review these values with your service engineer or physicist and modify them as needed. Once the QA program has been established, all that remains is to perform the quality tests and preventive maintenance tasks as scheduled and correct the symptoms of potential quality problems when identified by the tests. This process is shown in the flow chart in Figure 2.1 of this chapter.

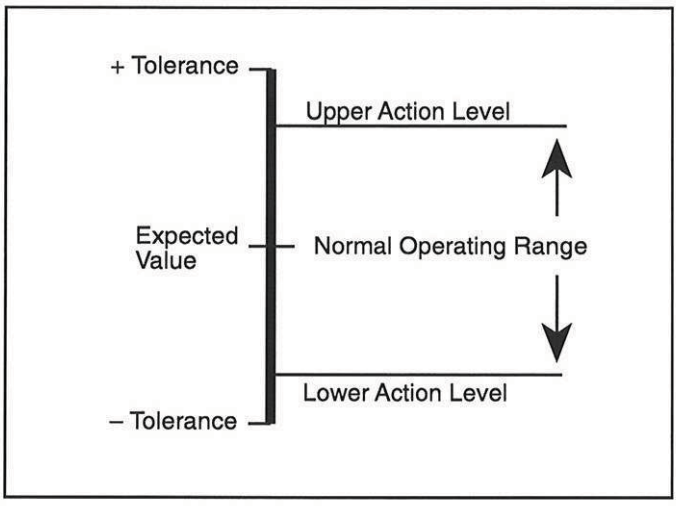


Fig. 2.6 Action levels are placed inside of the tolerance limits to ensure that corrective action occurs before defective quality levels are reached.

Suggested Action Levels for Image Quality Indicators

The table below provides suggested defect and action levels for the eight image quality indicators used in the program. Please note that these are not inflexible standards but instead guidelines to help you establish levels appropriate for your particular applications.

Image Quality Indicator	Suggested Defect Level	Suggested Action Level
Depth of Penetration	Change ≥1 cm from baseline	Change ≥0.6 cm from baseline
Vertical Distance Accuracy	Error ≥1.5%	Error ≥1.0%
Horizontal Distance Accuracy	Error ≥3% or 3 mm, whichever is greater.	Error ≥2% or 2 mm, whichever is greater.
Image Uniformity	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Axial Resolution	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Lateral Resolution	Change >1.5 mm from baseline value	Change >1 mm from baseline value
Cyst Imaging	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Dead Zone	Any consistent measurable change from baseline	Any consistent measurable change from baseline

Chapter Three
Image Quality Measurement Procedures

Introduction

This chapter describes how to perform the image quality tests recommended in Chapter Two. Each section contains a brief discussion of the particular image quality indicator, the method for measuring it, a step-by-step procedure for performing the measurement and guidelines for acting on the results.

To Ensure An Effective QA Program:

- Adjust all scanner controls (including the monitor) to the exact values recorded on the Data Sheet.
- Record the test data immediately on the Data Sheet.
- Label all hard copy with the date and scanner/transducer identification information.
- Record all incidents, repairs or discoveries on the event logs.

Mechanical Inspection

The physical condition of the scanner's mechanical components should be evaluated before the image quality tests are performed. Some of the basic items are described below; your system's user manuals and service engineer should provide a full set of items to periodically check and maintain the equipment.

Transducers

Check cables, housings and transmitting surfaces for cracks, separations and discolorations.

Power Cord

Check for cracks, discoloration and damage to cable and plug.

Controls

Check for dirty or broken switches and knobs, burnt out lights. Note any controls that are functioning intermittently.

Video Monitor

The monitor should be clean and free of scratches. Controls should function smoothly.

Dust Filters

Filters should be clean and relatively free of lint and clumps of dirt. Dirty filters cause overheating which shortens the life of electronic components.

Scanner Housing

Dents or other 'cosmetic' damage to the scanner indicate events that could cause damage to the internal electronics.

Action:

Remove damaged systems or components from clinical service and repair before using on patients.

Depth of Penetration

The sensitivity of an ultrasound instrument determines the weakest echo signal level that can be detected and clearly displayed. In practical terms this translates into how far one can "see" into the patient, i.e. the depth of penetration. The maximum depth of penetration is limited by the frequency of the transducer and the output power and electrical noise of the system electronics.

The maximum depth of penetration should remain constant over time; variations indicate performance degradation. Changes in the depth of penetration are caused by damage to the transducer or cable or malfunctions in the system's transmit and receive circuits.

Method

The maximum sensitivity or depth of penetration is determined by measuring the depth in a tissue mimicking phantom at which usable echo information disappears.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet.**
2. **Scan the phantom, positioning the phantom's vertical pin targets in the center of the image.**
3. **Freeze the image and make a hard copy of it.**
   • If you're using a video printer, compare the hard copy with the monitor image to verify their similarity.
4. **Compare the on-screen image with the hard copy of the original baseline image. Determine the depth at which the normal tissue speckle pattern of the phantom fades into black or noise.**
   • Comparing the on-screen and baseline images helps to make this subjective test more reproducible.
5. **Record the depth of penetration on the Data and Graph Sheets.**

Action

Contact your service engineer if the depth of penetration changes by more than 0.6 cm.

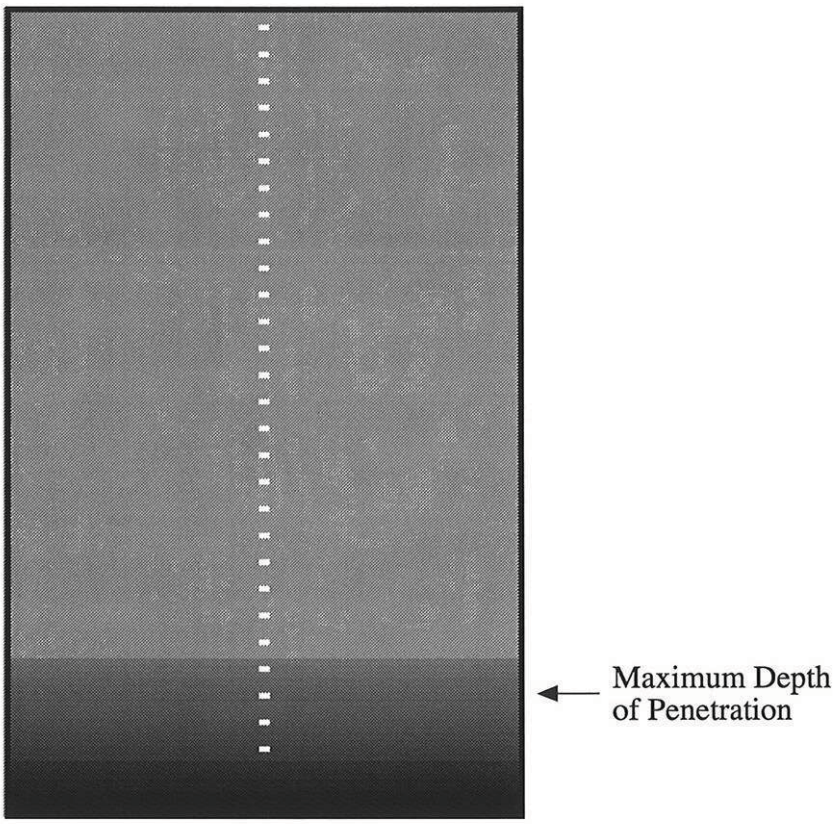


Fig. 3.1 The maximum depth of penetration is the point at which usable tissue echoes disappear from the image.

Distance Accuracy

Vertical and horizontal distance measurement errors are not always obvious and can easily go unnoticed. The vertical distance test determines the accuracy of distances measured along the beam axis. Vertical distance errors can be caused by drift or failure in the system's internal timing circuits. The horizontal distance test assesses the accuracy of distances measured perpendicular to the beam axis. Horizontal distance errors can be the result of flaws in the transducer geometry, either in its design or through damage.

Method

Distance accuracy is assessed by comparing the measured distance between selected pin targets in the phantom with the known distance. The test distance used should correspond with the distances normally measured in your studies.

Procedure: Distance Accuracy, Vertical Test

1. **Scan the vertical column of pin targets.**
2. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the vertical distance measurement.**
3. **Freeze the image and measure the distance between the selected pins.**
   • Be careful to measure the distance displayed and not the distance expected!
4. **Record the measured distance on the Data Sheet.**
5. **Graph the measurements on the vertical distance accuracy Graph Sheet.**

Procedure: Distance Accuracy, Horizontal Test

1. **Scan the horizontal row of pins nearest the transducer.**
2. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the horizontal distance measurement.**
3. **Freeze the image and measure the distance between the selected pins.**
   • Be careful to measure the distance displayed and not the distance expected!

4. **Record the measured distance on the Data Sheet.**
5. **Repeat for the horizontal row of pins farthest from the transducer.**
6. **Graph the measurements on the horizontal distance accuracy Graph Sheet.**

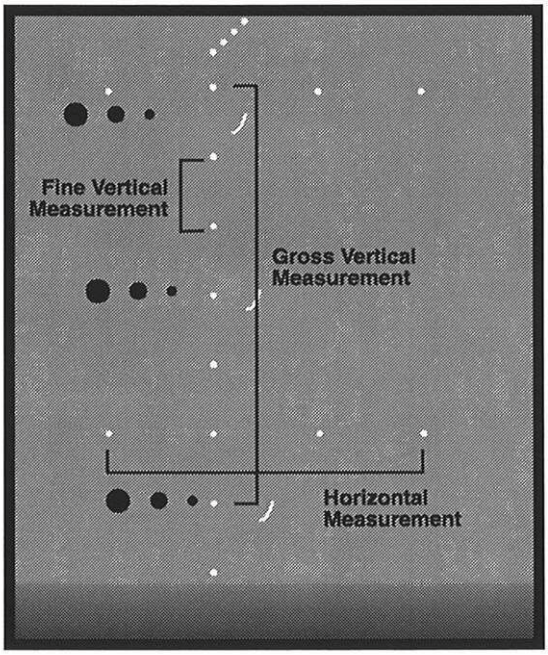


Fig. 3.2 Pin target patterns in the RMI 403 phantom used for the distance accuracy tests.

Action

Contact your service engineer if

- **Vertical measurement error exceeds the action level of 1.0% of the actual distance.**
- **Horizontal measurement error exceeds the action level of 2 mm or 2% of the actual distance, whichever is greater.**

Lateral Resolution

Lateral resolution describes the instrument's ability to distinguish small, adjacent structures perpendicular to the beam's major axis. Lateral resolution is approximately equal to beam width and varies with depth, the transducer focusing characteristics, and the system's gain and sensitivity settings. Objects smaller than the ultrasound beam are displayed with a width equal to the width of the ultrasound beam at that depth. The lateral resolution of transducers with a fixed focus will vary noticeably with depth. Systems with multiple focal zones or "dynamic focus" may produce more uniform lateral resolution over a wider range of depths. Lateral resolution is typically affected by the loss of transducer elements or by problems in the system's beam-forming circuits.

Method

Lateral resolution is measured indirectly by measuring the width of pin targets at depths corresponding to the transducer's near, mid, and far field zones.

Procedure

1. **Adjust the control settings to the values on the Data Sheet.**
2. **Obtain a clear image that shows as many of the vertical pin targets as possible.**
3. **Freeze the image.**
   • For baseline tests, select three pins at depths representing the near, mid, and far field zones of the transducer. Record these depths on the Data Sheet.
4. **Measure the width of the three pin images with the calipers and record on the data sheet.**
   • Always measure the pin width from edge-to-edge as shown in Figure 3.3.
5. **Graph the measurements on the lateral resolution Graph Sheet.**

Action

Although minor variations are normal, the pin width should remain relatively constant (within 1 mm) over time.

• Call your service engineer if the beam width changes by more than 1 mm for 2 successive test periods.

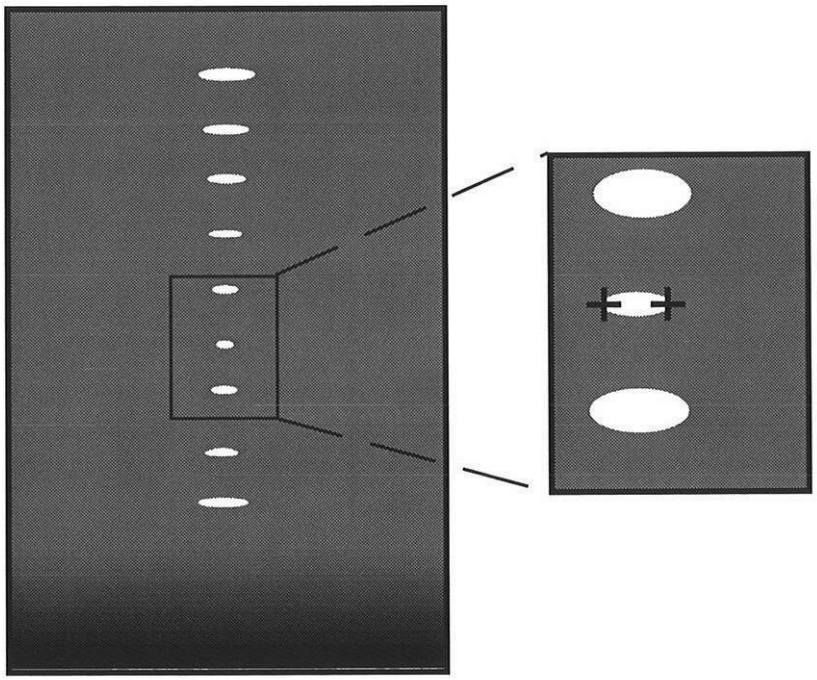


Fig. 3.3 The lateral resolution at a particular depth is determined by measuring the width of the pin target at that depth.

Axial Resolution

Axial resolution describes the scanner's ability to detect and clearly display closely spaced objects that lie on the beam's axis. Axial resolution depends on the transducer's spatial pulse length or pulse duration, which depend on the center frequency and damping factor.

Method

The phantom's axial resolution targets contain pin targets with decreasing vertical spacing. Each pin target is offset horizontally by a small distance to avoid shadowing. The system's axial resolution is determined by locating the two pin targets with the smallest vertical separation.

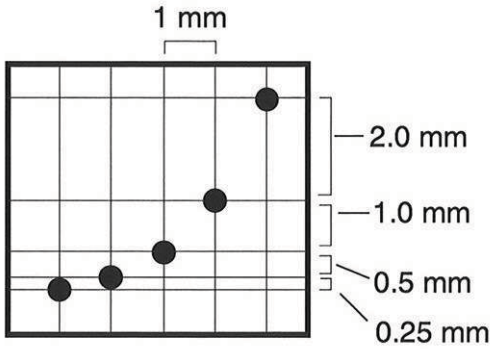


Fig. 3.4 Dimensions and locations of the pin targets in the RMI 403 axial resolution target groups.

Be careful with targets whose images overlap vertically. The targets are resolved only if a horizontal line can be drawn between the targets as shown below.

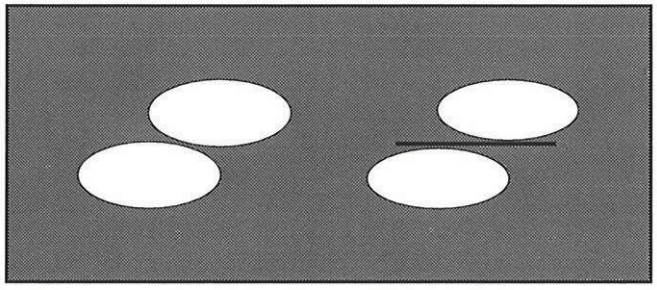


Fig. 3.5 Pin targets are resolved axially if an imaginary horizontal line can be drawn between the targets without touching either target. The targets on the left are not resolved. The targets on the right are resolved

Procedure

For each axial resolution target group (near, mid and far depths):

1. **Adjust the focal zone and depth controls to the value listed on the Data Sheet.**
2. **Scan the target group.**
3. **Freeze the image and make a hard copy.**
4. **Determine the axial resolution by finding the two pin targets with the smallest vertical spacing that are visible as distinct objects and have no vertical overlap. Record the resolution on the Data Sheet.**
5. **Repeat for the other target groups.**
6. **Graph the measurements on the axial resolution Graph Sheet.**

Note: Pin targets larger than 0.15 mm in diameter may produce a doubling artifact for transducer frequencies ≥ 5 MHz.

Action

Axial resolution should remain stable over time:

- **Contact your service engineer if you observe any changes.**

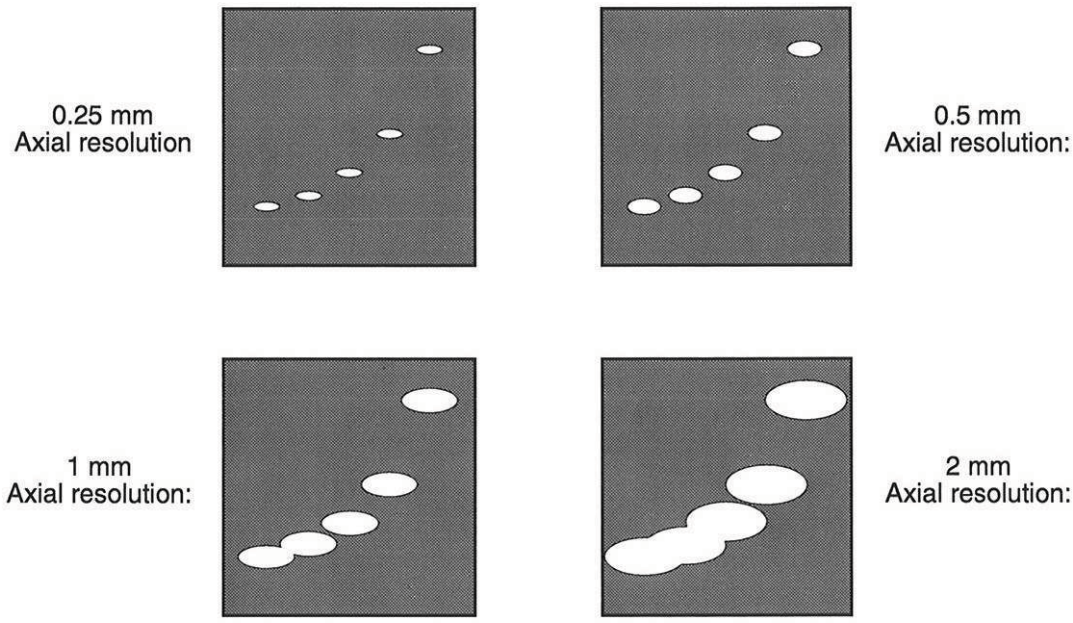


Fig. 3.6 Examples of the appearance of the pin targets at different degrees of axial resolution. Notice the minor vertical overlap of the targets in the 0.5, 1.0 and 2.0 mm examples.

Image Uniformity

Ultrasound systems can experience various image artifacts and nonuniformities. Image nonuniformities are a serious problem because they can mask subtle variations in tissue texture and increase the risk of false negatives. Major non-uniformities should be corrected immediately. Even though one can often "work around" minor non-uniformities, these defects should be seen as a potentially large problem and should also be corrected if consistently present.

Nonuniformities may be caused by hardware malfunctions such as bad transducer elements or poor electrical contacts in cables or circuit boards. Failures in the image processing circuitry and/or software bugs can also introduce nonuniformities. Poor acoustic coupling between the patient and transducer may also introduce reverberations and other artifacts.

Method

Image uniformity is assessed by scanning a uniform region of the tissue mimicking phantom that is relatively free of targets and identifying any deviations from the expected smooth tissue texture.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet.**
2. **Scan the region of the phantom with the fewest targets. For most RMI phantoms, this is the area opposite the cysts.**
3. **Freeze the image and make a hard copy.**
4. **On a scale from 1 to 3, grade the image for each of the categories on the Data Sheet. Refer to baseline hard copy image for reference.**

   1 = none
   2 = noticeable nonuniformities
   3 = serious nonuniformities
5. **Record the scores and graph the ratings on the image uniformity Graph Sheet.**

Action

Contact your service engineer if

- **any serious non-uniformities (rating of 3) are scored.**
- **any noticeable non-uniformities (rating of 2) are scored for two consecutive test periods.**

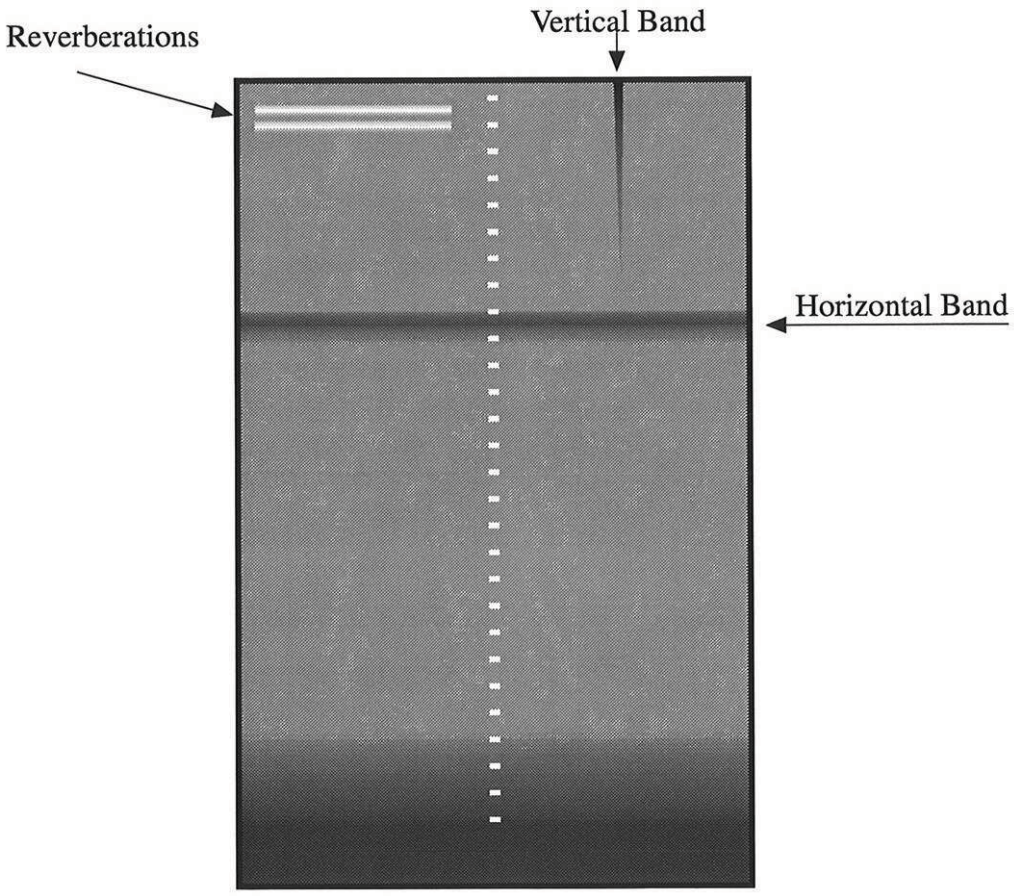


Fig. 3.7 Examples of common nonuniformities. Horizontal bands are often caused by circuitry problems while vertical bands indicate a damaged transducer element.

Dead Zone

The dead or "ring down" zone is the portion of the image directly under the transducer where image detail is missing or distorted. The dead zone is the result of reverberations in the transducer and adjacent tissue and the scanner's attempts to compensate for these problems. Although many of today's instruments are normally free from noticeable dead zones, damage to the transducer or poor acoustic coupling may produce this defect.

Method

The dead zone is measured by identifying the depth of the pin target nearest the transducer.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the dead zone measurement.**
2. **Scan the dead zone target group.**
3. **Freeze the image and determine the closest pin which can be imaged and record its depth on the Data Sheet.**
4. **Graph the measurements on the dead zone Graph Sheet.**

Action

Contact your service engineer if

- **the dead zone depth increases from the baseline value.**

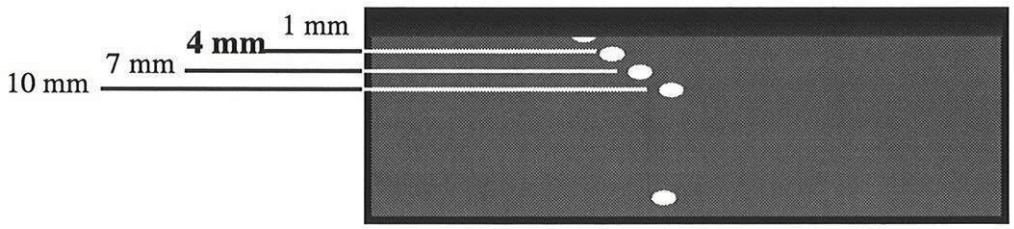


Fig. 3.8 The depth of an instrument's dead zone is determined by identifying the shallowest pin target that can be clearly visualized. In this example the dead zone is 4 mm deep.

Cyst Imaging

The cyst imaging test looks at the system's ability to accurately display a round, negative contrast object. This test combines aspects of contrast resolution and image uniformity into a single test. Cyst image quality can be affected by electrical noise, side lobes in the transducer beam and problems in the image processing hardware.

Method

Evaluate the smallest cyst in each cyst group that can be easily seen in the image and grade the image with the following criteria. Because this test is subjective, images from previous tests should be used for comparison.

Cyst Image Characteristics

Shape: Measure the height and width. The two measurements should be equal.

Edge: The edge of the cyst should be sharply defined.

Texture: The cyst interior should be echo free.

NOTE: Bright spots at the top and bottom of the cysts are specular reflections and are normal for some systems.

Procedure

For each cyst group:

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet. Obtain a clear image of the group.**
2. **Freeze the image and make a hard copy.**
3. **For the largest cyst target, rate the three image characteristics on a scale from 1-3. Use the baseline image as a reference for grading.**

   1 = No Distortion
   2 = Minor Distortion
   3 = Major Distortion

4. **If your phantom has cysts of different sizes, determine the smallest visible cyst at near, mid and far depths. Keep the final image stored on the monitor for the next test.**
   - For baseline tests, record the minimum visible diameter on the Data Sheet.
   - For standard tests, compare the current minimum with the baseline minimum. Note changes in event log.
5. **Record and graph the scores on the cyst imaging Data and Graph Sheet.**

Action

Contact your service engineer if

- **any major distortions (rating of 3) are detected.**
- **minor distortions (rating of 2) are observed for two consecutive tests.**

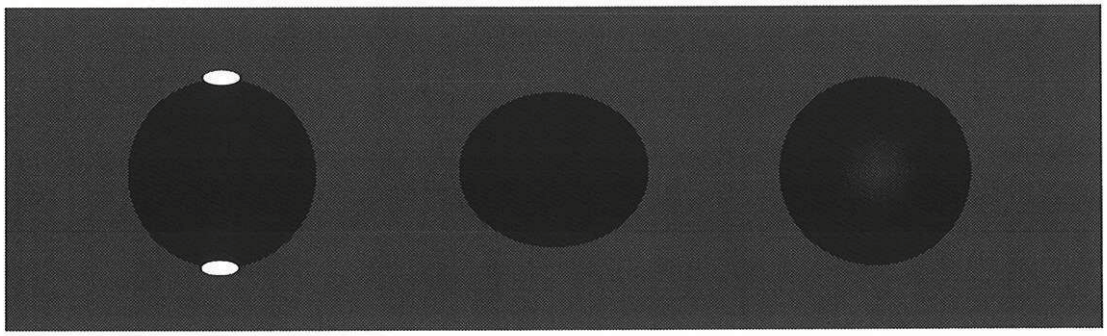


Fig. 3.9 (Left) The normal appearance of a low scatter "cyst" target. Notice the sharp edges, clear black appearance and round shape. Bright artifacts at the top and bottom are normal specular reflections. (Center) Flattened cyst indicates geometric distortion. (Right) Echoes inside the cyst may be the result of system noise or side lobe contamination.

Image Recorder Tests

Drift in the alignment and gray values can cause distortions in the hard copy images. These problems may be the result of failures in either the ultrasound system or the image recorder. Film processors can also introduce distortions and should also be closely monitored with a separate QA program.

Method

Hard copy images of the phantom are generated and checked for their similarity to the video monitor image. Geometric distortion is detected by physically measuring and comparing the displayed distances on the monitor screen with the hard copy images.

Procedure

1. **Inspect the hard copy images of the cyst imaging and depth of penetration tests.**
2. **Compare the hard copy image from the cyst imaging test to the monitor image. Check that the brightest and darkest image features are similar on the hard copy image and monitor. Record the result on the Data Sheet.**
3. **Repeat the depth of penetration test on the phantom and freeze the image. Check that the depth at which echo data disappears on the hard copy is the same as on the monitor. Record the result on the Data Sheet.**
4. **Check that the number of gray bars on the hard copy image and the video monitor are equal. Indicate the number of gray bars on the Data Sheet.**

Action

Contact your service engineer if

- **any artifacts are observed.**
- **the difference between the measured depth of penetration on the video monitor and hard copy images exceeds 3 mm.**
- **the number of gray bars on the monitor image and hard copy are not equal.**

Chapter Four
Using the Image Quality Test Data

Graphing the Test Data

Plot the image quality data on the Graph Sheets as soon as the tests have been completed. Graphical representations of the data are more useful than columns of numbers for identifying changes and trends in the image quality indicators.

Good notation and a little color can improve the legibility of your graphs. For example,

- The upper and lower action levels can be identified by coloring those lines with a yellow highlighting marker.
- The data point corresponding to a significant event can be identified by a box or circle.
- Data points that reach or exceed an action level are circled. When the cause of the defect has been corrected, the indicator is remeasured and a box is drawn around the new data point to indicate that it is a corrected value. Connecting the points with a line can also help to visually associate them.

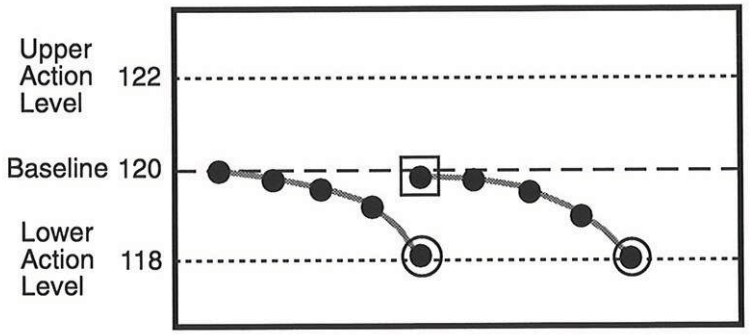


Fig. 4.1 Identifying significant data points makes it easier to assess overall system performance.

Using the Event Logs

The event logs help improve your perception of the significance of events that may contribute to image quality changes in the future. In many cases a minor event will mark the beginning of an unrecognized trend. For example, the failure of an air conditioner in a lab might not cause an immediate system failure, but the higher room temperature combined with other factors might cause electronic components to fail at a later date. "Useful parameters for assessing potential damage are shown below.

Image Quality Indicator	What To Look For:
Dead Zone	Increased dead zone depth or reverberation artifacts
Horizontal Distance	Increased measurement errors
Axial Resolution	Resolution loss
Lateral Resolution	Resolution loss
Depth of Penetration	Reduced depth of penetration
Image Uniformity	Erroneous echoes

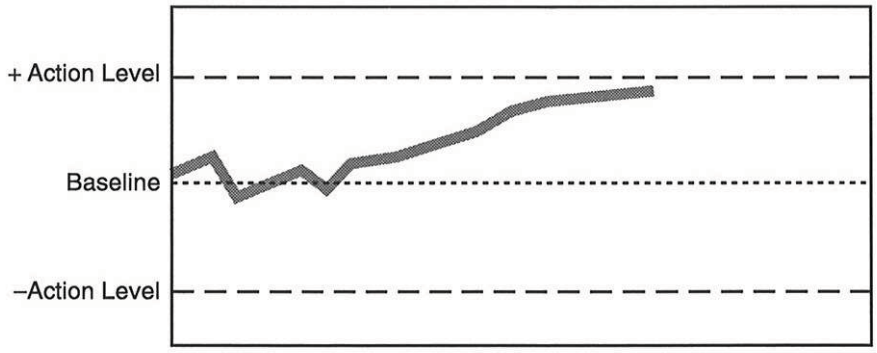
Fig. 4.2 An instrument can be evaluated for damage by measuring the following image quality indicators.

Evaluating the Service Program

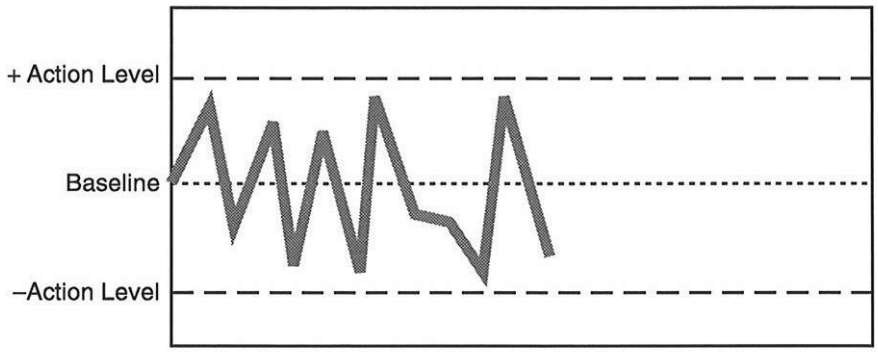
Recording the dates of service visits on the event log gives you the ability to compare the effect on image quality for each visit. This information can illustrate the effectiveness of the preventive maintenance/repair program and help you identify ways to improve it.

Looking At the Data

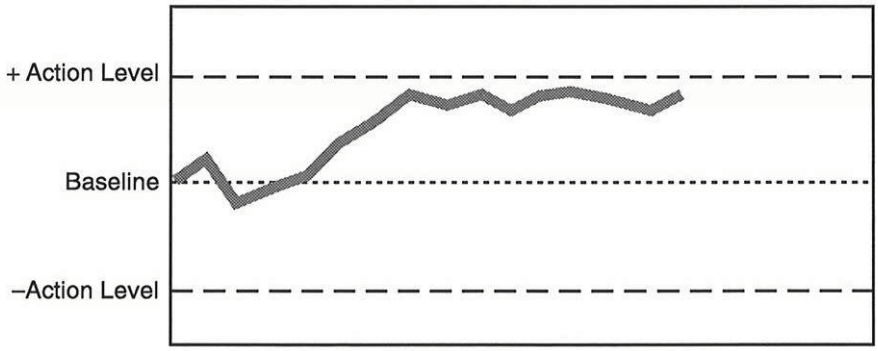
In addition to taking corrective action whenever an action level is exceeded, you should also watch for other signs of potential problems. For example, data will normally have a certain amount of random movement around the baseline value. You should consult your service engineer if the image quality test data demonstrates any of the trends shown on the next page.



- **A consistent movement in one direction towards an action level.**



- **Wide, regular oscillation from one side of the baseline to the other, frequently approaching the action levels.**



- **Flat spots in the data curve that come close to the action level.**

Adjusting Tolerances and Action Levels

You may wish to adjust the tolerance and action levels for a particular image quality indicator to reflect the demands of your applications. For example, the recommended error limit for horizontal distance measurements is 3 mm or 3%. If your lab is documenting changes in tumor size following radiation or chemo-therapy, you might decrease the limit to 2 mm or 2% with a corresponding decrease in the action levels.

You may also need to increase the values of the action levels to accommodate the variations in the test data caused by experimental error. If the image quality levels are relatively stable over five to ten test periods and the occaisional "spike" has no apparent correlation with events (from the event logs) or a particular operator, then increase the action level to let the spike pass. In cases like this, experience with the performance of your instruments, good test data and the advice of a trusted physicist and service engineer are your best guides.

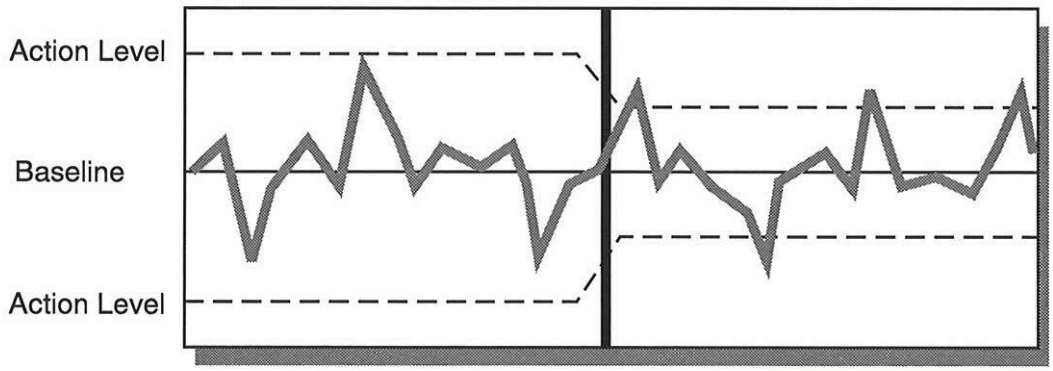


Fig. 4.3 Normal fluctuations in data that are acceptable for the action levels on the left will trigger corrective actions for the action levels on the right.

Archiving the Data

It's a good idea to retain the Data Sheets for the life of the instrument. If the instrument is sold or performance questions arise, the Data Sheets are valuable evidence that the machine was carefully maintained. Documentation can also support your claims if you feel that the system is a "lemon". The Graph Sheets are especially valuable for the long term because they provide a quick visual summary

of the instrument's performance over time. To save storage space, old Graph and Data Sheets can be reduced to half or quarter size with a photocopier.

If your department or facility has a quality committee, a periodic summary of the quality activities performed in the ultrasound lab should be added to the official 'minutes' of the committee meetings.

Where To Go For Help

Many health care organizations now have a quality manager or quality assurance committee than can provide valuable ideas and support in the development of your quality assurance program. Many radiology/oncology departments have a physicist on staff or employed as a consultant. You may want to seek the advice of this individual regarding the implementation and interpretation of your quality tests.

Operator error is a frequent cause of poor image quality. Take advantage of the expertise of the manufacturer's applications specialists in producing high quality clinical images. Getting the service engineer involved in your quality program will provide you with useful experience and advice in interpreting your results. In addition, your experience can provide valuable feedback to help the manufacturer improve the reliabilty and performance of their products.

A wide variety of written material is available on general and specific quality issues. The Appendix provides a short list of recommended resources. Remember, simply being aware of image quality will have a positive effect on the quality of medicine.

Appendix

- Selecting a Phantom
- Suggested Readings
- Data & Graph Sheets

Selecting A Tissue Mimicking Phantom

A tissue mimicking phantom is a required tool for every ultrasound QA program. Image quality tests must be performed with the ultrasound beam operating in an environment that is acoustically similar to the patient's body. Because the acoustic characteristics of the phantom will affect the accuracy of your tests, it is important to choose your phantom wisely.

Phantom Selection Checklist

The following features are important in a tissue mimicking phantom.

- ❑ Speed of sound: 1540±10 m/s at 22 °C with a temperature dependence of less than 2 m/s/°C.

- ❑ Attenuation coefficient 0.5 or 0.7 dB/cm/MHz for typical operating frequencies and be approximately proportional to frequency.
  Note: Specifications should state the frequency at which the attenuation was measured.

- ❑ Vertical Column of pin targets with spacing of 2 cm or less.

- ❑ Horizontal Row of pin targets with spacing of 3 cm or less.
  Several rows at various depths are useful for assessing geometric accuracy.

- ❑ Axial Resolution pattern with minimum spacing of 0.5 mm or less.
  Note: Many users prefer multiple resolution target groups.

- ❑ Diagonal "dead zone" or "ring down" pin target group with a minimum spacing of 3 mm.
  Note: Although the dead zone is less of an issue on newer systems, the dead zone targets are useful for very near field lateral resolution tests.

- ❑ Low scatter cylinder, diameter of 4 to 6 mm.
  Groups of cylinders with diameters from 1 to 6 mm are useful.
  Groups at several depths can show the effect of depth on performance.

A Discussion of Phantom Characteristics

Speed of Sound

To calculate distances, ultrasound scanners normally assume an average speed of sound in the patient of 1540 m/s. To properly measure distance accuracy, the material in the phantom must provide the same speed of sound. The recommended speed of sound for phantoms is 1540±10 m/s at 22°C.

The correct speed of sound is essential for accurate focusing of the ultrasound beam, particularly for phased array transducers. An incorrect speed of sound may cause the ultrasound beam to focus at the wrong point in space and may produce misleading lateral resolution measurements.

Phantoms with incorrect speed of sound values attempt to compensate by adjusting the spacing of targets to fool the scanner. Although this may yield correct distance measurements, it fails to address the beam focus phenomenon and can produce unreliable results.

Attenuation

Sound waves are attenuated as they pass through tissue. The attenuation coefficient describes the amount of signal loss per unit distance of tissue traveled. Attenuation coefficients are commonly expressed in decibels per centimeter (dB/cm). Attenuation in tissue is approximately proportional to frequency. In practice, this means that a 4 MHz ultrasound beam will experience roughly four times the decibel signal loss of a 1 MHz beam for the same tissue path.

Because the beams generated by "broad band" and "multi-frequency" transducers contain a wider range of component frequencies, accurate measurements of penetration and axial resolution require that all frequencies (not just the center frequency) be properly attenuated. For example, excessive high frequency attenuation will result in reduced depth of penetration for high frequency probes and degraded axial resolution.

Echogenicity and Speckle Texture

The phantom should be scanned with the same power and gain settings normally used on patients. For this reason, the tissue mimicking material in the phantom should have an echogenicity or 'brightness' that is similar to commonly scanned soft tissue such as liver parenchyma. To highlight image artifacts and

nonuniformities, the tissue mimicking material should produce a smooth, even speckle texture throughout the phantom .

Phantom Components

Tissue Mimicking Materials

The heart of the phantom is the tissue mimicking material. Tissue mimicking materials based on water, foam, oil, hydrogels, and rubber-like materials have been developed and described in the literature. To date, only graphite/hydrogel-based materials have achieved the acoustic characteristics and repeatability necessary for reliable performance testing.

Phantom Targets

A phantom for standard ultrasound image quality tests requires certain target types and configurations. Although large numbers of targets are impressive the experienced users tend to prefer phantoms with fewer targets to increase the area of unobstructed phantom material for depth of penetration and image uniformity tests.

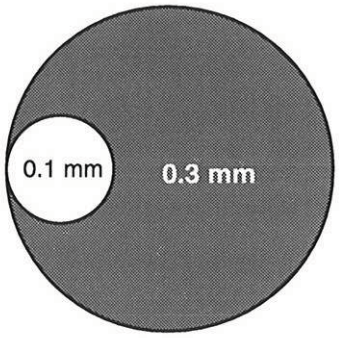
Contrast Cylinders

Cylinders of hypoechoic or 'low scatter' material are useful for observing geometric distortion and nonuniformities in a more complex shape. To ensure good propagation of the ultrasound pulse, the cylinder should have the same speed of sound characteristics as the surrounding tissue mimicking material. Because the target mimicks a fluid-filled cyst, a low attenuation coefficient (~0.05 dB/cm-MHz) is common.

A single cylinder with a diameter of 4-6 mm is enough to get the job done. Many users prefer several sets of cylinders with a range of diameters and depths to look at the effect of target depth on image quality. Target diameters between 1 and 6 mm are most useful. Target depths corresponding to near, mid and far-field depths (3, 8, 14 cm) are popular because they minimize the beam interference caused by numerous targets.

Pin Targets

Pin targets are small diameter rods that function as point reflectors. Although steel has been used in the past, nylon is the most popular target material. Pin targets are arranged in rows and columns for distance accuracy tests and in various patterns for axial and lateral resolution tests. For systems with transducers operating below 5 MHz, a pin diameter of 0.3 mm is acceptable. However, the 0.3 mm pins may experience reverberations at frequencies above 5 MHz, making a 0.1 mm pin diameter more appropriate for high performance systems.



The smaller cross section of the 0.1 mm diameter pin target eliminates the doubling artifacts commonly experienced by higher frequency transducers with 0.3 mm diameter pin targets.

Scanning Surfaces

Phantoms are currently available in both single and multiple scanning surface designs. Experienced users tend to choose single scanning surfaces design for convenience and durability. Single surface phantoms allow the user to scan all of the targets from one position, thereby reducing the amount of gel and cleanup required. In addition, single scanning surface phantoms have less surface area and will last longer. Additional viewing angles of the targets can be achieved by scanning through the walls of the phantom.

Suggested Readings

Quality Assurance in Ultrasound

- AIUM Standard Methods for Measuring Performance of Pulse Echo Ultrasound Equipment. American Institute of Ultrasound in Medicine, 1990.
- Instrument Quality Assurance (Chapter 6), James Zagzebski, Textbook of Diagnostic Ultrasonography, edited S. Hagen Ansert, C.V. Mosby, St. Louis, 1989.
- Understanding Ultrasound Physics, Sidney Edelman.
- Physics in Medical Ultrasound, Report 47, The Institute of Physical Sciences in Medicine, 1986.
- Essential Physics of Medical Imaging, Stewart C. Bushong, William and Wilkins, Baltimore, 1993.

Quality in Healthcare

- JCAHO Accreditation Manual for Hospitals
- Curing Health Care: New Strategies for Quality Improvement, Donald Berwick, M.D., Jossey Bass Publishers, 1990

General Quality

- Juran's Quality Control Handbook - Fourth Edition, J.M. Juran, Editor, McGraw Hill, 1988
- Quality is Free, Philip Crosby, Mentor, 1980
- The Memory Jogger, Goal/QPC, Muethen MA, 1988
- Juran on Leadership for Quality, Joseph M. Juran, The Free Press, 1989
- Out of the Crisis, W. Edwards Deming

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The QA Cookbook for Ultrasound

Designed and written by GAMMEX RMI with assistance from Paige Medlin and Jean B. Schultz.

Special Thanks to Professor James Zagzebski Ph.D., University of Wisconsin - Madison, Department of Medical Physics for his guidance and expertise.

Printed in the United States of America

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Introduction

The QA Cookbook for Ultrasound is a sonographer's guide to establishing a quality assurance program for gray scale ultrasound scanners. The Cookbook introduces the reader to some of the basic concepts of Quality and then applies these concepts to the problem of maintaining image quality. In this way, you can see *why* each QA step is taken as well as *how* it is performed.

The primary goal of the QA Cookbook is to help you achieve consistent image quality in a department's ultrasound studies. In addition, we hope that you will find opportunities to use these valuable ideas for improving the quality of other parts of your medical practice.

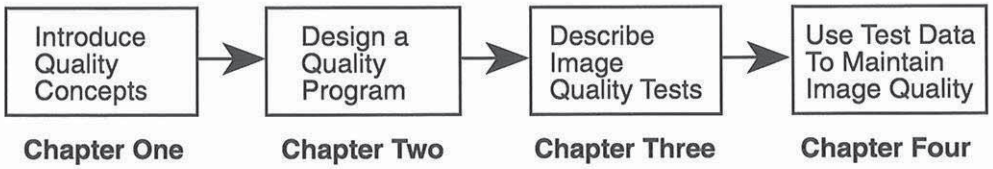
What You Should Know

The Cookbook assumes you have no previous knowledge of quality concepts or image quality measurement tests. You should be familiar with basic ultrasound physics and understand how to operate the ultrasound equipment to be tested.

Overview of the QA Cookbook

Chapter One provides a brief introduction to some of the basic concepts used in all quality programs. To help solidify your understanding of QA, examples and exercises illustrating important ideas and their application are included.

- Read Chapter One if you have no previous knowledge of quality concepts or need a quick review.



The Cookbook's process for developing a quality assurance program.

Chapter Two identifies the image quality indicators and presents a system of procedures and documents to evaluate and document image quality in ultrasound.

Chapter Three describes how to perform the image quality tests. Worksheets for recording and analyzing the measurement data are included in the Appendix and may be used as "masters" for copying.

Chapter Four explains how to use the quality test data to achieve consistent image quality. Suggestions for customizing the QA program to fit your particular applications are included.

The Appendix contains information on how to select a phantom, a bibliography of books on quality, and the Data and Graph Sheets for documenting and analyzing the image quality test data.

Chapter One
Basic Quality Concepts

What Is Quality?

Quality means different things to different people. People usually think of quality in subjective terms such as "feels better" or "lasts longer." A famous oil painting and a German engineered automobile both have an aura of quality. In the case of the painting, the quality is the result of the work being done in a way that isn't always measurably superior, but simply looks better to the eye. On the other hand, the quality of the automobile is the result of painstaking design and manufacturing effort intended to produce measurable superiority: safer, faster and more reliable.

Modern quality "gurus" have developed tools and ideas that can be used in any situation to produce better, more consistent quality. The new approach is that quality *can* be measured and that attempts to improve quality should be based on data rather than on hunches.

Quality is still defined in many ways. Some common definitions are

- Conforming to requirements
- Maximizing satisfaction while minimizing dissatisfaction
- Meeting expectations
- Delivering what was promised

In the following sections, we'll use "meeting expectations" as our working definition of quality.

Exercise: Quality in the Real World

Make a list of products or services that impress you with their quality. Beside each item describe what characteristic provides that sense of quality and determine if that characteristic is objective or subjective.

Product	**Characteristic**
German engineered automobile	safe
Swiss watch	reliable
Blue jeans	comfortable
Menu-driven computer	easy to use

Customers, Products and Suppliers

Quality is an issue whenever somebody receives something from someone else. It helps to think in terms of a customer receiving a product from a supplier. (Although these terms sound insensitive in a healthcare setting, they help to emphasize the roles and dependencies in the relationship.) The amount of satisfaction a customer receives from the product is a reflection of how well their expectations are met. Therefore the supplier's first task is to identify and meet the customer's expectations.

For instance, the sonographer is a customer and a supplier. As a customer, the sonographer uses the products of the imaging system and the hospital support staff. As a supplier, the sonographer provides images and measurements to the customers, the patient and physician.

Organizations often think in terms of internal and external suppliers and customers. Internal suppliers and customers are members of the organization who exchange products within the organization. The external customer receives the final product of the entire organization's efforts. In the example above, the physician is an internal customer of the sonographer while the patient is the hospital's external customer.

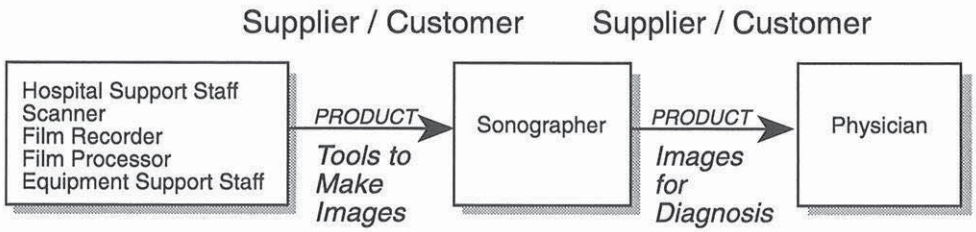


Fig. 1.1 A sonographer's customer and supplier relationships.

Exercise: Quality in the Real World

Make a list of five things that contribute to producing a good ultrasound image.

Contributor	Expectation
1. Patient	On time for appointment
2. System	Accurate distance measurements
3.	
4.	
5.	

Quality Indicators

"I can't define it, but I know it when I see it."

To stay in business, suppliers must satisfy their customer's expectations. For an automobile manufacturer, this might translate into building a car that doesn't need too much maintenance. The problem is that "too much maintenance" is subjective. Exactly how much is too much? If, for example, potential customers tell the manufacturer that a tune-up every 24,000 miles is acceptable, then a subjective *expectation* has been converted into an objective *requirement.* In developing a product to meet this requirement, the manufacturer can now use tests to measure how well it satisfies the customer's expectations.

A *quality indicator* is a measurable product characteristic that corresponds to a customer expectation. Using the example of a car, quality indicators can be used at many different levels within a product. In addition to measuring the quality of the car in terms of its maintenance requirements, quality indicators could also be used to monitor manufacturing quality (e.g., flaws in body panels) or design quality (e.g., time needed to stop from 60 mph).

Although quality indicators are straightforward in theory, a customer's expectations often extend beyond their stated requirements. Unspoken expectations exist for every product and are often the ultimate source of dissatisfaction. Therefore, the first step in improving quality is to define it.

Exercise: Quality in the Real World

For each of the contributors and expectations in the previous exercise, choose a quality indicator that would allow you to measure its performance with respect to your expectations. Which of these indicators do you think are regularly measured? Which ones should be measured?

Contributor	Expectation	Quality Indicator
1. Patient	Cooperative	Minutes late for appointment
2. System	Accurate Distance	Measurement Error
3.		
4.		
5.		

Processes, Variations and Defects

The supplier is a collection of people, machines and supplies performing tasks to create a product. The manner in which these tasks are done is the *process*. A process can be well thought out or it can just happen. The comment "that's how we've always done it" is usually a good indication that the process in question "just happened."

The quality of each unit of product created by the process should be consistently high enough to satisfy the customer's expectations. Unfortunately, everyone and everything in the process changes over time: the quality of the supplies vary, the people get tired and the machines go out of adjustment. These changes can cause the physical characteristics of the product to vary from the customer's desired values. This variation is said to be the enemy of quality.

The *tolerance* is the amount of variation the customer can tolerate in the product. Product specifications normally include a desired or specified value "S," plus or minus a tolerance value "T" and are written in the form S±T.

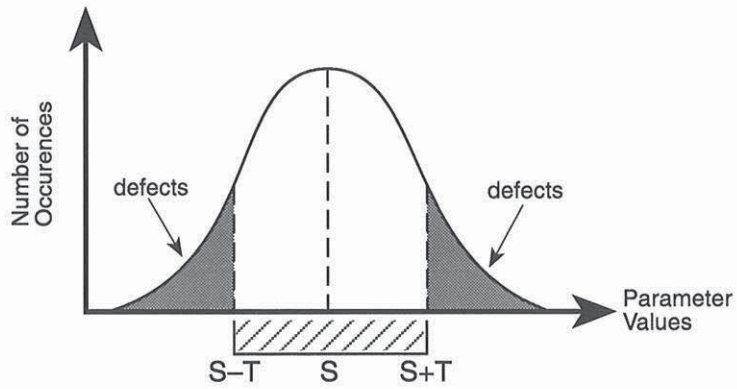


Fig. 1.2 The process capability describes the process' ability to produce product within the specified values of S–T and S+T (striped box). Product that falls outside of the specifications is defective (shaded areas).

Variations greater than the customer's tolerances are *defects*. In many cases defects are caused not by the people working in the process, but by the process in which the people work. Every process will have a characteristic range of variations in its output. The ability of the process to produce product within the customer's tolerances is called the *process capability*. To minimize the number of defects, the supplier strives to make the variations in the process as narrow as possible while making the tolerance in each product specification as wide as possible.

A common situation is that a process will consistently produce too many units that fall outside of the customer's tolerances (defects). When a process is incapable of producing the desired results, better results are not achieved by forcing the people and machines to work harder. The process itself is defective and must be improved to reduce the number of defects.

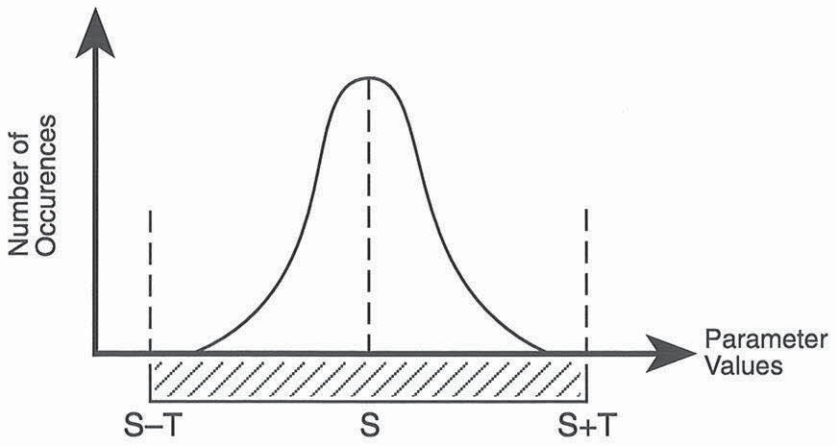


Fig. 1.3 Ideally the range of process variations are narrower than the customer's specifications. When this happens no defects are produced.

Exercise: Quality in the Real World

Use a flow chart to describe the process of producing an ultrasound image. Where in the process would each of your previous expectations be important?

For each of the quality indicators listed in the previous exercise, choose a tolerance indicating the amount of variation acceptable to you or your customers.

Contributor	Expectation	Quality Indicator	Tolerance
1. Patient	On time	Minutes late	5 min
2. System	Accurate Distance	Measurement Error	±3 mm
3.			
4.			
5.			

Quality Control

"What can be measured can be controlled."

Once the process is running, the supplier must ensure that defective product is not delivered to the customer. The most basic approach is *quality control*, which inspects product and removes the defective ones. Quality control or 'QC' is sometimes referred to as "inspecting the quality in" because the inspection process, rather than the production process, is responsible for achieving a consistent quality level in the delivered product.

Although quality control keeps defective product away from the customer, it is expensive because the defective units cost as much to produce as the acceptable ones. In addition, they must be either thrown away or repaired at additional expense. The extra resources spent on correcting defects are known as the "hidden factory". Organizations can easily spend 20-30% of their operating budgets on the hidden factory.

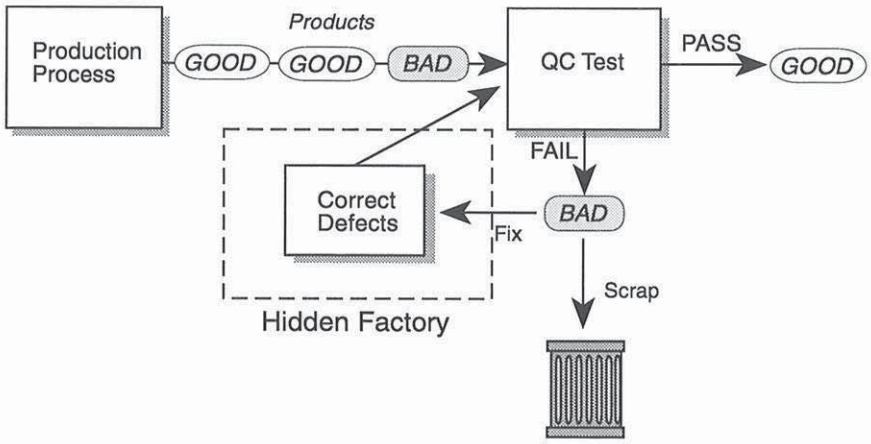


Fig. 1.4 Quality control is a process of measuring quality indicators and filtering out defects. The hidden factory used to correct defects can absorb a large portion of an organization's budget.

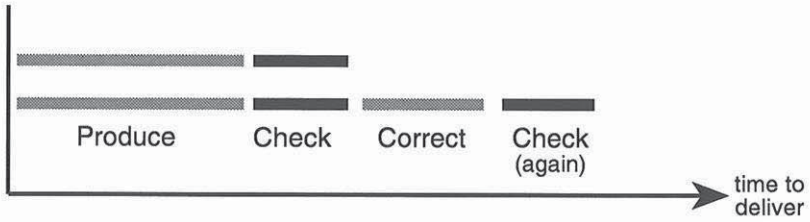


Fig. 1.5 Correcting defects adds time and cost to the process. Organizations that fail to include these hidden costs in their budgets may run out of time and money before the job is done.

Exercise: Quality in the Real World

For the quality indicators from the previous exercise, determine where in the process you could locate and correct defects. How much extra time and effort does it cost to correct a defect?

Contributor	Quality Indicator	QC Check
1. Patient	Minutes late	Time
2. System	Distance Error	Compare with known distance
3.		
4.		
5.		

Quality Assurance
"Making Things Go Right"

Unlike Quality Control, which reacts to defects after they occur, Quality Assurance or 'QA' attempts to prevent defects from happening in the first place. A QA program spans the supplier's entire process and attempts to keep it running at peak performance as often as possible. Quality assurance programs frequently contain the following activities:

- Periodic quality indicator measurements
- Corrective actions triggered by action levels
- Preventive maintenance
- Operator training
- Incoming QC of supplies
- Outgoing QC of product

Defects are often caused by process variations that slowly grow until tolerances are exceeded and defects are produced. By detecting subtle changes in the process, the QA program can often identify and correct a source of potential

defects before quality drops to unacceptable levels. The mechanism for triggering corrective action is the *action level.* The action level is a predefined value that indicates when a variation is approaching defective levels. By automatically correcting sources of variation before a defective level is reached, defects are more effectively prevented.

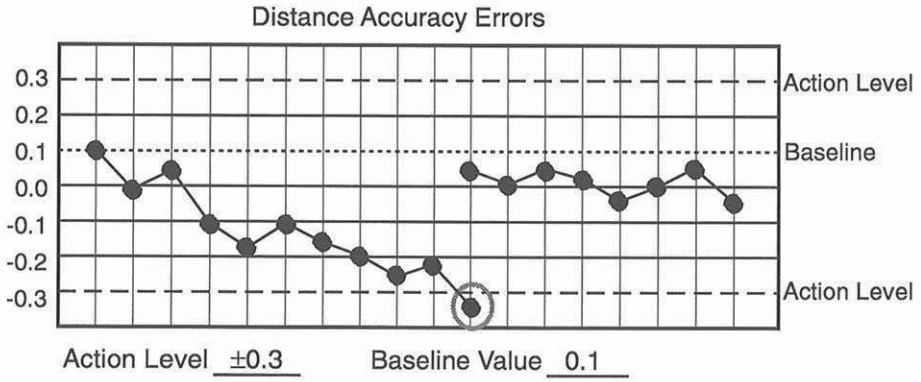


Fig. 1.6 A run chart showing a distance measurement error increasing over time. The action levels indicate the value at which corrective action is triggered. The circled data point indicates that the action level has been exceeded.

In addition to preventive maintenance, QA programs may also monitor the inputs and outputs of the process. To guard against defects in the raw materials, an "incoming QC system" would be established to monitor the quality of the process's inputs. This may be as simple as checking the expiration date on a film pack or as comprehensive as requiring an elaborate inspection process.

A QA program would also be concerned with developing and maintaining the skills of the workers at all stages of the process (another important process input). An "outgoing QC system" is also needed to filter out the defects that are still produced. The number of defects reaching the final QC stage is a good indicator of the effectiveness of the overall QA program.

Exercise: Quality in the Real World

For the quality indicators and defects you selected in the previous exercise, think of a way to eliminate or minimize the source of the defect.

Contributor	Quality Indicator	Preventive Action
1. Patient	Minutes late	Schedule appointments 10 minutes early to account for patient prep and time differences.
2. System	Distance Error	Monitor system accuracy periodically and request service when error reaches action level.
3.		
4.		
5.		

Quality Improvement

Successful quality assurance programs can maintain consistent quality levels, but every process has a limit to the quality level that can be achieved. Quality improvement or 'QI' is the practice of increasing the potential quality level of a process.

The Joint Commission for Accrediting Hospital Organizations (JCAHO) states that "a hospital's principal goal should be to help everyone improve the process in which he/she is involved." Quality improvement is a people-oriented approach based on the ideas that defective processes produce defective products and the best people to improve a defective process are the ones working in it.

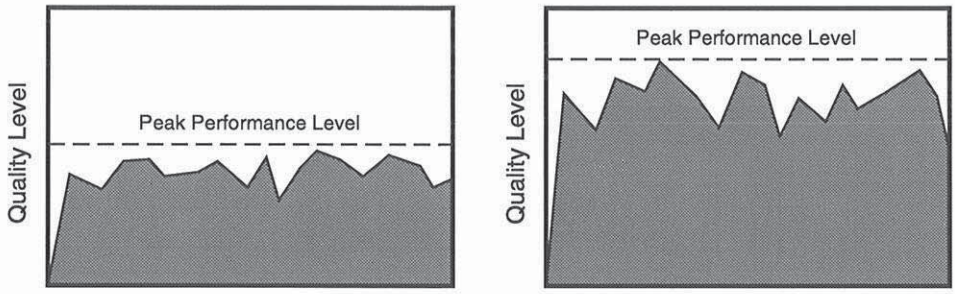


Fig. 1.7 Quality assurance activities attempt to keep a process operating as close to its peak performance as possible. Quality improvement seeks to raise the process' peak performance level.

The basic quality improvement approach can be described as follows:

- Identify a problem or situation in need of improvement
- Determine the possible root causes of the problem
- Develop potential solutions
- Implement the solutions as a controlled experiment
- Evaluate the results of the experiment
- If the results of the experiment are desirable, incorporate the changes into the process and maintain (QA work)
- Repeat for the next problem*

* Quality gurus like to say that there are no problems, only opportunities.

Although tremendous quality breakthroughs are exciting to think about, quality improvement efforts are most effective when approached as a continuous stream of incremental improvements. Effective quality improvement requires time, teamwork and a long-term commitment from top management to change the way things are done. Quality expert Philip Crosby likes to say that "quality is free, but it's not a gift".

Exercise: Quality in the Real World

For the quality indicators and defects you selected in the previous exercise, think of a way to eliminate or minimize the source of the defect.

Contributor	Problem	Root Cause/Process Improvement
1. Patient	Late for appointment	Patients have trouble finding parking spaces. Improvement: Reserve parking spaces for scheduled patients.
2. System	Distance Error	Excess heat causes electronics to drift. Improvement: Clean air filters to improve air flow and cooling.
3.		
4.		
5.		

Chapter Two
Establishing a Quality Assurance Program

Introduction

Quality was defined in Chapter One as 'meeting the customer's expectations'. The remaining chapters address how to meet the image quality expectations of the sonographer's customers. The working definition of the customer's expectation will simply be that "the ultrasound images consistently and accurately represent the patient's anatomy."

Establishing the QA Program: *Who, What, When and How?*

The quality assurance program seeks to establish a process that 1) maintains image quality levels within acceptable limits and 2) documents the image quality. To prevent defective images, the QA program combines periodic preventive activities with image quality testing. The QA program consists of these major components:

- A definition of customer expectations and associated quality indicators and action levels
- A system to measure and record the image quality indicators
- A system to identify potential quality problems and "trigger" corrective action
- Additional preventive maintenance measures to maintain the performance of equipment and operators

Maintaining consistent image quality is difficult because the accuracy of a clinical ultrasound image is difficult to assess. There is no "reference patient" for day-to-day comparison. This problem is solved by using a tissue mimicking phantom with known target geometries and characteristics to measure the image quality indicators (see "Choosing A Tissue Mimicking Phantom" in the Appendix).

Sonographers sometimes argue that testing is unnecessary because they can detect image quality defects during normal scanning. While it is true that a clinical evaluation approach can detect image defects, it's probable that a number of images contained the defect before it was detected. Gradual degradation makes it even more difficult to detect obvious defects. Quality assurance measures and corrects image quality defects at levels normally undetectable to the sonographer's unaided eye, so blatant defects are seldom encountered during patient scanning.

Image Quality Indicators

Image quality indicators have been developed to measure the characteristics of system performance that affect the diagnostic value of the ultrasound image. The image quality indicators used in this QA program are:

- Depth of Penetration
- Image Uniformity
- Lateral Resolution
- Cyst Imaging
- Distance Accuracy
- Axial Resolution
- Dead Zone
- Image Recorder Quality

The cause and effect of each image quality indicator and a procedure for measuring the indicator is discussed in Chapter Three.

Implementing the QA Program

The process for setting up the QA program is described in the flow chart and sections that follow.

Who's Responsible?

Although the department chairman is ultimately responsible for quality, the department's quality assurance program is normally maintained by the sonographer(s) who routinely use the equipment. Quality programs are most effective when their plans and results are periodically reviewed by a committee representing all functions within the department.

Consistency makes or breaks a quality assurance program, so the people running the program should be carefully selected. Individuals should be detail-oriented, adequate time and resources must be allotted to perform the tests and the QA activities should be made part of the job description.

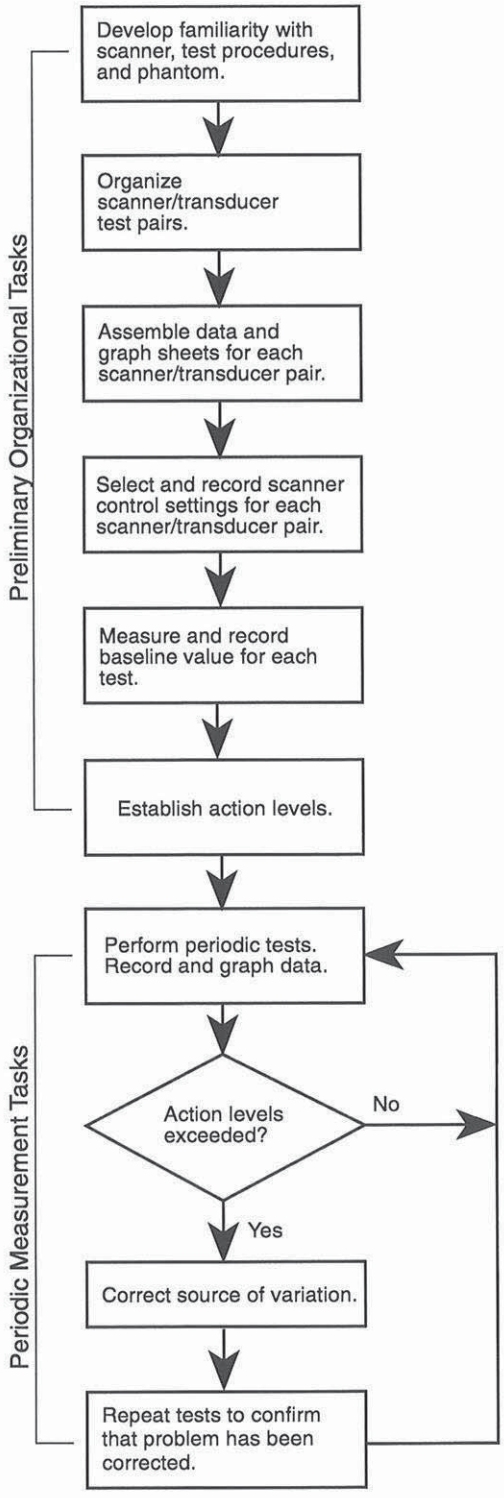


Fig. 2.1 The process of establishing and maintaining the scanner QA program.

What To Do?

The QA activities consist of two parts: the preliminary organizational tasks and the periodic measurement, documentation and maintenance tasks.

Preliminary Tasks:

- Organizing the worksheets for recording and plotting measurement data and defining the test schedule.
- Establishing baseline values for image quality to detect degradation in future measurements.
- Defining action levels for each quality indicator.

Periodic Tasks:

- Measuring the image quality indicators as indicated by the test schedule.
- Recording the measurements on the Data Sheet and plotting the indicator values on the respective Graph Sheets.
- Identifying situations (as indicated by the action levels) that require corrective action.
- Repeating measurements to verify the effectiveness of the corrective actions.
- Scheduling preventive maintenance visits.
- Holding operator training sessions.

Instructions for the organizational tasks are provided later in this chapter. The image quality test procedures are described in Chapter Three and the handling of the test data is described in Chapter Four. A guide to choosing a tissue mimicking phantom is provided in the Appendix.

Preventive Maintenance

The need for preventive maintenance applies to humans and machines. Preventive maintenance programs for ultrasound systems are offered by manufacturers and independent service contractors and are one of the best investments for consistent and predictable performance and operating cost. The date, work performed and the engineer's comments should all be recorded and stored with the image quality test data.

Operator error is a common cause of image quality problems. This, combined with the increasing complexity of systems, makes formal training and periodic

refresher courses a useful addition to the quality assurance program. The manufacturer's applications specialists are usually happy to provide hands-on demonstrations of the features and proper operation of their systems. New users should be given a thorough introduction to the system and everyone should be "trained" whenever a significant upgrade in hardware or software occurs.

When To Do It?

There are two schools of thought on the frequency of image quality tests. The first approach recommends measuring image quality at fixed time intervals (for example, the first Wednesday of each month). Although reproducible, this method doesn't consider varying workloads or environmental factors like overheating which may stress a heavily used system. The second approach measures image quality after a pre-determined number of procedures or operating hours have elapsed. This ensures that testing reflects the actual use of the system.

Where the instrument is used is another important factor to consider. An instrument exposed to high temperatures or used in a mobile unit will likely require more frequent checkups than one in a normal clinical setting. As there are no specific regulations for the frequency of image quality tests, each lab must select a schedule based on their particular systems and operating environment. Service and clinical engineers can provide valuable advice on appropriate test intervals.

Other Reasons to Test Image Quality

In addition to the regularly scheduled tests, image quality should be measured immediately after any event that could affect the system. This includes service calls (to ensure that repairs were successful), system upgrades or modifications (to detect new system "bugs") and any incident that could damage the system (for example, a dropped transducer, a power surge, or impact to the system).

Quick Scans

A daily "quick scan" of the phantom is a useful habit for mobile or heavily used machines. Performed before the first patient is scanned, a quick scan might check distance accuracy, penetration and overall image uniformity to assure the sonographer that the system is performing acceptably.

Procedures:

Organizing the Documentation

The image quality test data must be properly recorded and organized to be useful. This requires:

- ❑ Three ring binder,
- ❑ Dividers for the binder
- ❑ Plastic sleeves for the hard copy images
- ❑ A set of the Data and Graph Sheets (masters for copying provided in the Appendix) for each transducer to be tested.

The Data Sheet identifies the scanner/transducer pair tested and contains the scanner control setup information and the measurements from each test. Each image quality test uses a separate Graph Sheet to graphically represent the data and record important events such as equipment failures and repairs. The graphical representation of your data will help you identify the subtle degradation processes quality assurance seeks to correct.

Labs with multiple systems and transducers should match each transducer with a particular scanner. Testing the same scanner/transducer pairs improves the consistency and reliability of the program. Because equipment often moves from room-to-room, it's usually best to identify the devices by their serial numbers.

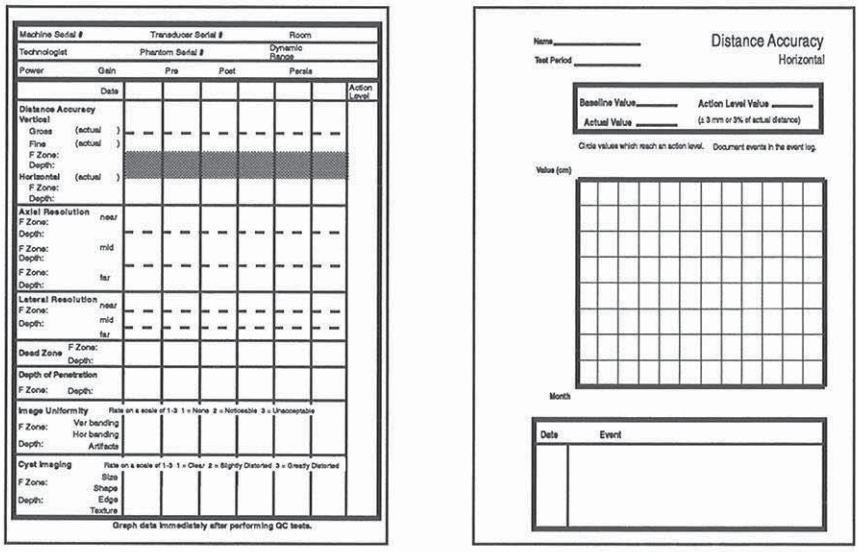


Figure 2.2 The Data Sheet and Graph Sheets are used to record and analyze test data for each transducer. Full page copies are located in the Appendix.

Scheduling the Tests

The table below offers a good starting point for a test schedule. Notice that instruments used in mobile applications should be examined more frequently. Transducers used less often can be tested on a rotating basis so that every session examines roughly the same number of probes. Your service engineer can assist you in determining testing frequencies.

The Data Sheet provided in the Appendix is configured for a monthly test interval. Some boxes are shaded to indicate that a particular test does not require testing in that session. Axial resolution, for example, only requires a semi-annual check.

Scanner Test Schedule	
Stationary Units	**Frequency**
Scanner:	Monthly
Transducers:	
- daily use	Monthly
- occasional use	2-3 months
Mobile Units	**Frequency**
Scanner:	Weekly
Transducers:	
- daily use	Weekly
- occasional use	Monthly

Fig. 2.3 Suggested frequency of testing for scanners and transducers.

To organize a test schedule,

1) **Compile a list of the scanner/transducer pairs to be tested.**
2) **For each pair determine and record the appropriate test frequency. Note the highest frequency i.e. weekly or monthly.**
3) **Using a copy of the scheduling sheet (provided in the Appendix), list the test dates and each of the scanner/ transducer pairs to be tested.**
4) **For each scanner/transducer pair, write a single 'slash' in each box corresponding with the scheduled test date for the pair.**
5) **When the scheduled test for the pair has been completed, make an "X" in the date box to indicate that it is done (see example below).**

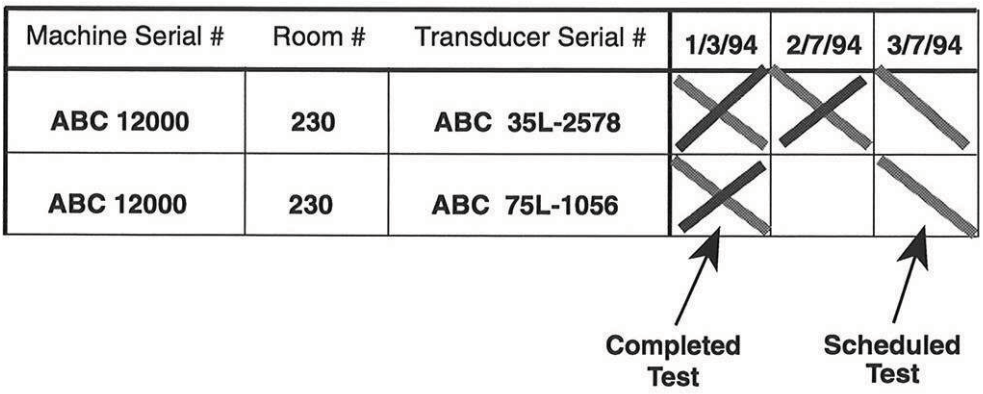


Fig. 2.4 Boxes coresponding to the scheduled test dates for each scanner/ transducer pair are filled with a single 'slash' mark. An 'X' is formed in the box when the test has been completed.

Performing the Baseline Tests

The baseline represents the instrument's peak performance for a particular image quality indicator. Subtle changes in image quality can be detected by comparing the current value with the baseline value. The baseline tests establish the instrument control settings to be used for the periodic image quality tests and determine the baseline values for each image quality indicator. For the best representation of an instrument's peak performance, the baseline tests should be performed immediately after the instrument has been installed and accepted. To ensure that existing systems are operating up to specification, it is best to perform the baseline tests immediately after a service or preventive maintenance visit by a qualified engineer. If the system is between service calls, perform the baseline tests as described on the following page. Immediately after the next service call, measure each image quality indicator and adjust the original baseline values if the measurements improve (if the indicator values degrade, call the service engineer). Remember, the baseline values are your landmarks for detecting changes in image quality.

Selecting Instrument Control Settings

A good tissue mimicking phantom allows the use of normal control settings. on the scanner To select the control settings for the image quality tests, scan the phantom as you would a patient and adjust the controls to produce the best possible clinical image, taking care not to emphasize or exaggerate a particular image attribute. Be sure that the video monitor's brightness and contrast controls

are in their "standard" settings. When you have arrived at an acceptable set-up, record each of the control settings on the Data Sheet for the scanner/transducer pair in use. Some of the image quality tests will require different settings for image and focal zone depth; be sure to record these settings on the Data Sheet and use them every time the tests are performed.

Determining Baseline Values

To determine the baseline value for each image quality indicator (i.e. Depth of Penetration, Distance Accuracy, Lateral Resolution, etc.),

1) **Scan the phantom using the control settings listed on the Data Sheet. Adjust the depth and focal zone settings as needed and record these settings on the Data Sheet for future tests.**
2) **Perform the test exactly as described in the test procedure and immediately record the measurement values on the Data Sheet. Save all hard copy images and label them as Baseline Images. Clearly write the identification number and measurement data on the back of each image for future reference.**

When you have completed the tests,

1) **Record the baseline value for each quality indicator in the box at the top of the appropriate Graph Sheet (located in the Appendix).**
2) **Plot the baseline value on the centerline of the graph and label the vertical and horizontal axes of the graph as shown below. Do not fill in the action levels.**

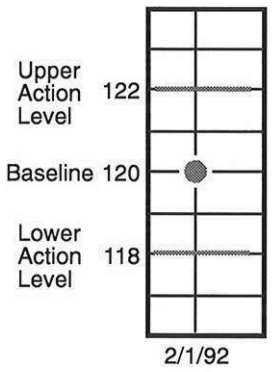


Figure 2.5 Graph box showing recommended format for baseline and action levels.

Selecting the Action Levels

The action level indicates the image quality indicator value at which corrective action should be taken. Action levels are located well within the instrument's specified tolerances to ensure that image quality never actually reaches defective levels. A value somewhere between one half and three quarters of the tolerance works well for most action levels. For example, if the maximum acceptable distance measurement error should not exceed 2%, an action level of 0.75 of the maximum acceptable error would be appropriate. If the distance tested is 120 mm, the acceptable error is 120 x 0.02 = 2.4 mm and the action level range would be 2.4 x .75 = 1.8 mm. The upper and lower action levels would be the expected distance of 120 mm plus or minus the action level range (120+1.8 = 121.8 mm and 120–1.8 = 118.2). In some cases thebaseline value may not equal the expected value. When this occurs the action levels will not be evenly distributed around the baseline.

A space for the desired action level is provided on each Graph Sheet. Because each system will have different performance levels, you may wish to review these values with your service engineer or physicist and modify them as needed. Once the QA program has been established, all that remains is to perform the quality tests and preventive maintenance tasks as scheduled and correct the symptoms of potential quality problems when identified by the tests. This process is shown in the flow chart in Figure 2.1 of this chapter.

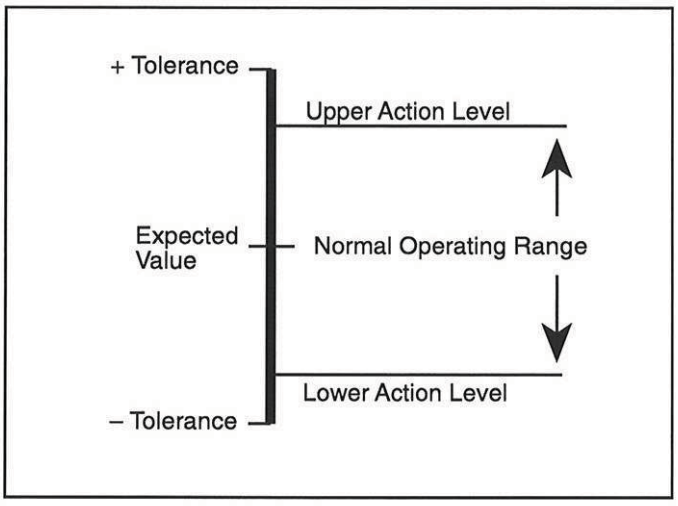


Fig. 2.6 Action levels are placed inside of the tolerance limits to ensure that corrective action occurs before defective quality levels are reached.

Suggested Action Levels for Image Quality Indicators

The table below provides suggested defect and action levels for the eight image quality indicators used in the program. Please note that these are not inflexible standards but instead guidelines to help you establish levels appropriate for your particular applications.

Image Quality Indicator	Suggested Defect Level	Suggested Action Level
Depth of Penetration	Change ≥1 cm from baseline	Change ≥0.6 cm from baseline
Vertical Distance Accuracy	Error ≥1.5%	Error ≥1.0%
Horizontal Distance Accuracy	Error ≥3% or 3 mm, whichever is greater.	Error ≥2% or 2 mm, whichever is greater.
Image Uniformity	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Axial Resolution	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Lateral Resolution	Change >1.5 mm from baseline value	Change >1 mm from baseline value
Cyst Imaging	Any consistent measurable change from baseline	Any consistent measurable change from baseline
Dead Zone	Any consistent measurable change from baseline	Any consistent measurable change from baseline

Chapter Three
Image Quality Measurement Procedures

Introduction

This chapter describes how to perform the image quality tests recommended in Chapter Two. Each section contains a brief discussion of the particular image quality indicator, the method for measuring it, a step-by-step procedure for performing the measurement and guidelines for acting on the results.

To Ensure An Effective QA Program:

- Adjust all scanner controls (including the monitor) to the exact values recorded on the Data Sheet.
- Record the test data immediately on the Data Sheet.
- Label all hard copy with the date and scanner/transducer identification information.
- Record all incidents, repairs or discoveries on the event logs.

Mechanical Inspection

The physical condition of the scanner's mechanical components should be evaluated before the image quality tests are performed. Some of the basic items are described below; your system's user manuals and service engineer should provide a full set of items to periodically check and maintain the equipment.

Transducers

Check cables, housings and transmitting surfaces for cracks, separations and discolorations.

Power Cord

Check for cracks, discoloration and damage to cable and plug.

Controls

Check for dirty or broken switches and knobs, burnt out lights. Note any controls that are functioning intermittently.

Video Monitor

The monitor should be clean and free of scratches. Controls should function smoothly.

Dust Filters

Filters should be clean and relatively free of lint and clumps of dirt. Dirty filters cause overheating which shortens the life of electronic components.

Scanner Housing

Dents or other 'cosmetic' damage to the scanner indicate events that could cause damage to the internal electronics.

Action:

Remove damaged systems or components from clinical service and repair before using on patients.

Depth of Penetration

The sensitivity of an ultrasound instrument determines the weakest echo signal level that can be detected and clearly displayed. In practical terms this translates into how far one can "see" into the patient, i.e. the depth of penetration. The maximum depth of penetration is limited by the frequency of the transducer and the output power and electrical noise of the system electronics.

The maximum depth of penetration should remain constant over time; variations indicate performance degradation. Changes in the depth of penetration are caused by damage to the transducer or cable or malfunctions in the system's transmit and receive circuits.

Method

The maximum sensitivity or depth of penetration is determined by measuring the depth in a tissue mimicking phantom at which usable echo information disappears.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet.**
2. **Scan the phantom, positioning the phantom's vertical pin targets in the center of the image.**
3. **Freeze the image and make a hard copy of it.**
   • If you're using a video printer, compare the hard copy with the monitor image to verify their similarity.
4. **Compare the on-screen image with the hard copy of the original baseline image. Determine the depth at which the normal tissue speckle pattern of the phantom fades into black or noise.**
   • Comparing the on-screen and baseline images helps to make this subjective test more reproducible.
5. **Record the depth of penetration on the Data and Graph Sheets.**

Action

Contact your service engineer if the depth of penetration changes by more than 0.6 cm.

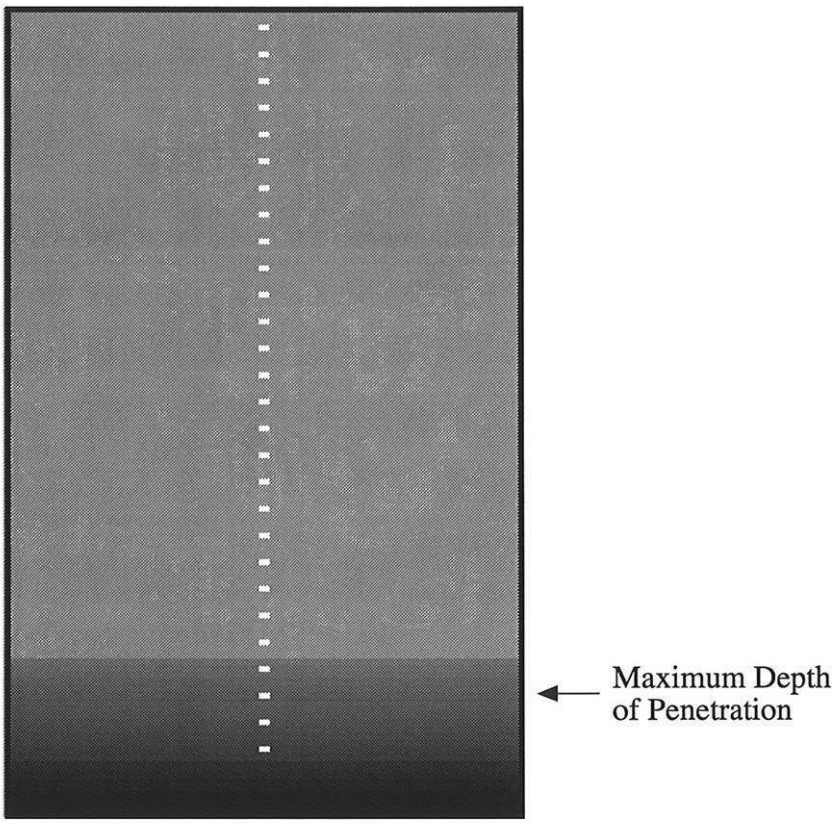


Fig. 3.1 The maximum depth of penetration is the point at which usable tissue echoes disappear from the image.

Distance Accuracy

Vertical and horizontal distance measurement errors are not always obvious and can easily go unnoticed. The vertical distance test determines the accuracy of distances measured along the beam axis. Vertical distance errors can be caused by drift or failure in the system's internal timing circuits. The horizontal distance test assesses the accuracy of distances measured perpendicular to the beam axis. Horizontal distance errors can be the result of flaws in the transducer geometry, either in its design or through damage.

Method

Distance accuracy is assessed by comparing the measured distance between selected pin targets in the phantom with the known distance. The test distance used should correspond with the distances normally measured in your studies.

Procedure: Distance Accuracy, Vertical Test

1. **Scan the vertical column of pin targets.**
2. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the vertical distance measurement.**
3. **Freeze the image and measure the distance between the selected pins.**
   • Be careful to measure the distance displayed and not the distance expected!
4. **Record the measured distance on the Data Sheet.**
5. **Graph the measurements on the vertical distance accuracy Graph Sheet.**

Procedure: Distance Accuracy, Horizontal Test

1. **Scan the horizontal row of pins nearest the transducer.**
2. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the horizontal distance measurement.**
3. **Freeze the image and measure the distance between the selected pins.**
   • Be careful to measure the distance displayed and not the distance expected!

4. **Record the measured distance on the Data Sheet.**
5. **Repeat for the horizontal row of pins farthest from the transducer.**
6. **Graph the measurements on the horizontal distance accuracy Graph Sheet.**

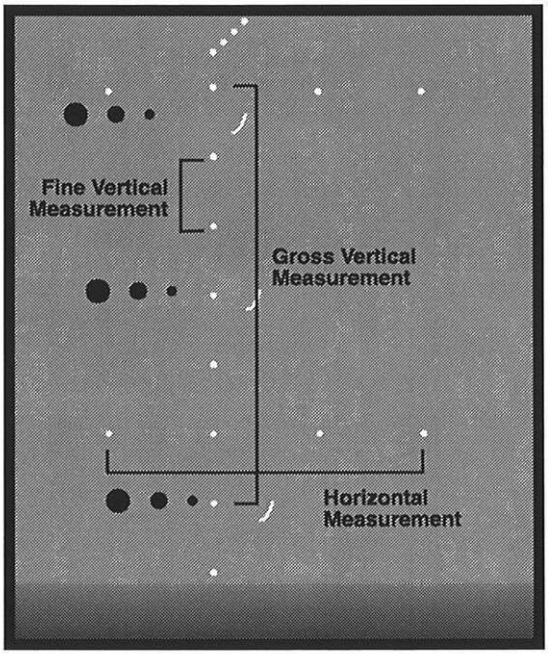


Fig. 3.2 Pin target patterns in the RMI 403 phantom used for the distance accuracy tests.

Action

Contact your service engineer if

- **Vertical measurement error exceeds the action level of 1.0% of the actual distance.**
- **Horizontal measurement error exceeds the action level of 2 mm or 2% of the actual distance, whichever is greater.**

Lateral Resolution

Lateral resolution describes the instrument's ability to distinguish small, adjacent structures perpendicular to the beam's major axis. Lateral resolution is approximately equal to beam width and varies with depth, the transducer focusing characteristics, and the system's gain and sensitivity settings. Objects smaller than the ultrasound beam are displayed with a width equal to the width of the ultrasound beam at that depth. The lateral resolution of transducers with a fixed focus will vary noticeably with depth. Systems with multiple focal zones or "dynamic focus" may produce more uniform lateral resolution over a wider range of depths. Lateral resolution is typically affected by the loss of transducer elements or by problems in the system's beam-forming circuits.

Method

Lateral resolution is measured indirectly by measuring the width of pin targets at depths corresponding to the transducer's near, mid, and far field zones.

Procedure

1. **Adjust the control settings to the values on the Data Sheet.**
2. **Obtain a clear image that shows as many of the vertical pin targets as possible.**
3. **Freeze the image.**
   • For baseline tests, select three pins at depths representing the near, mid, and far field zones of the transducer. Record these depths on the Data Sheet.
4. **Measure the width of the three pin images with the calipers and record on the data sheet.**
   • Always measure the pin width from edge-to-edge as shown in Figure 3.3.
5. **Graph the measurements on the lateral resolution Graph Sheet.**

Action

Although minor variations are normal, the pin width should remain relatively constant (within 1 mm) over time.

• Call your service engineer if the beam width changes by more than 1 mm for 2 successive test periods.

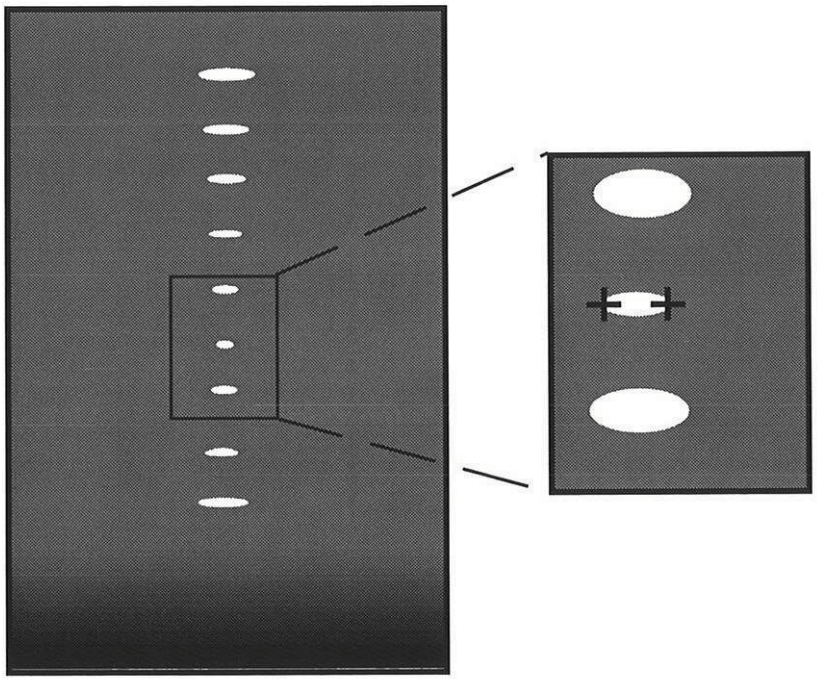


Fig. 3.3 The lateral resolution at a particular depth is determined by measuring the width of the pin target at that depth.

Axial Resolution

Axial resolution describes the scanner's ability to detect and clearly display closely spaced objects that lie on the beam's axis. Axial resolution depends on the transducer's spatial pulse length or pulse duration, which depend on the center frequency and damping factor.

Method

The phantom's axial resolution targets contain pin targets with decreasing vertical spacing. Each pin target is offset horizontally by a small distance to avoid shadowing. The system's axial resolution is determined by locating the two pin targets with the smallest vertical separation.

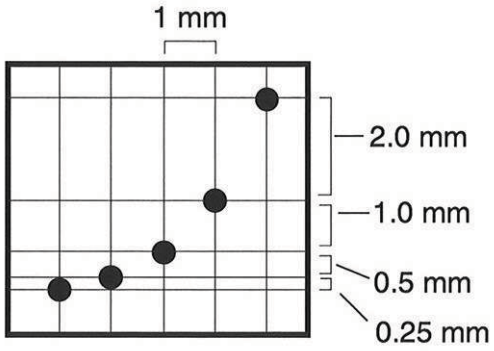


Fig. 3.4 Dimensions and locations of the pin targets in the RMI 403 axial resolution target groups.

Be careful with targets whose images overlap vertically. The targets are resolved only if a horizontal line can be drawn between the targets as shown below.

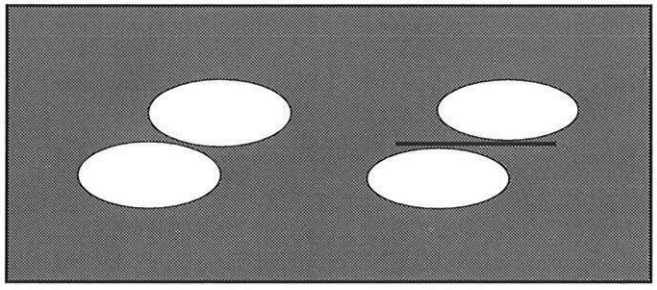


Fig. 3.5 Pin targets are resolved axially if an imaginary horizontal line can be drawn between the targets without touching either target. The targets on the left are not resolved. The targets on the right are resolved

Procedure

For each axial resolution target group (near, mid and far depths):

1. **Adjust the focal zone and depth controls to the value listed on the Data Sheet.**
2. **Scan the target group.**
3. **Freeze the image and make a hard copy.**
4. **Determine the axial resolution by finding the two pin targets with the smallest vertical spacing that are visible as distinct objects and have no vertical overlap. Record the resolution on the Data Sheet.**
5. **Repeat for the other target groups.**
6. **Graph the measurements on the axial resolution Graph Sheet.**

Note: Pin targets larger than 0.15 mm in diameter may produce a doubling artifact for transducer frequencies ≥ 5 MHz.

Action

Axial resolution should remain stable over time:

- **Contact your service engineer if you observe any changes.**

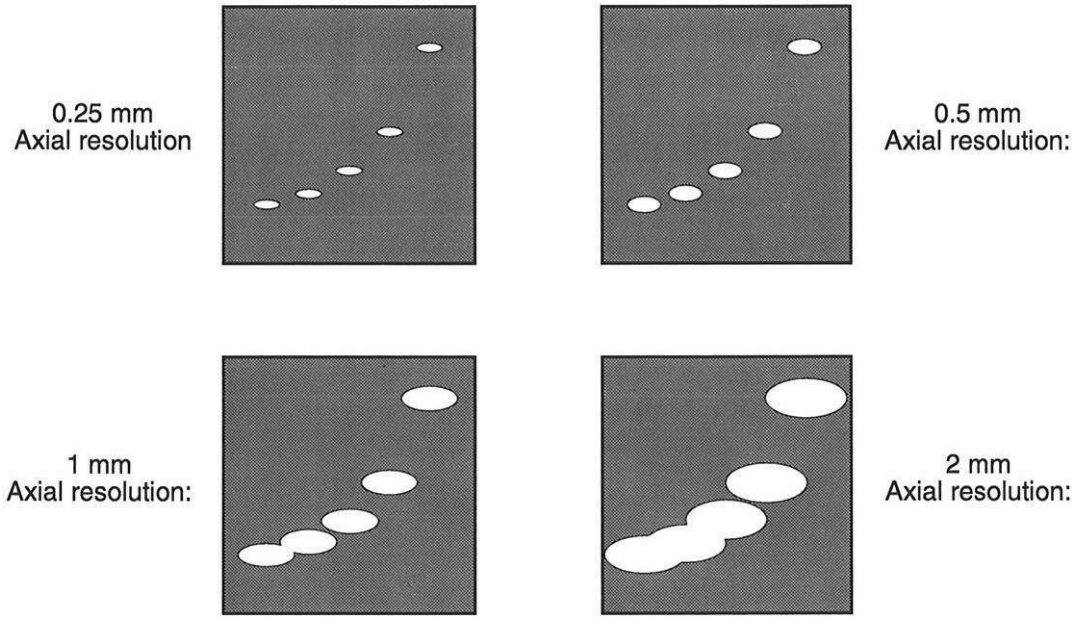


Fig. 3.6 Examples of the appearance of the pin targets at different degrees of axial resolution. Notice the minor vertical overlap of the targets in the 0.5, 1.0 and 2.0 mm examples.

Image Uniformity

Ultrasound systems can experience various image artifacts and nonuniformities. Image nonuniformities are a serious problem because they can mask subtle variations in tissue texture and increase the risk of false negatives. Major non-uniformities should be corrected immediately. Even though one can often "work around" minor non-uniformities, these defects should be seen as a potentially large problem and should also be corrected if consistently present.

Nonuniformities may be caused by hardware malfunctions such as bad transducer elements or poor electrical contacts in cables or circuit boards. Failures in the image processing circuitry and/or software bugs can also introduce nonuniformities. Poor acoustic coupling between the patient and transducer may also introduce reverberations and other artifacts.

Method

Image uniformity is assessed by scanning a uniform region of the tissue mimicking phantom that is relatively free of targets and identifying any deviations from the expected smooth tissue texture.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet.**
2. **Scan the region of the phantom with the fewest targets. For most RMI phantoms, this is the area opposite the cysts.**
3. **Freeze the image and make a hard copy.**
4. **On a scale from 1 to 3, grade the image for each of the categories on the Data Sheet. Refer to baseline hard copy image for reference.**

   1 = none
   2 = noticeable nonuniformities
   3 = serious nonuniformities
5. **Record the scores and graph the ratings on the image uniformity Graph Sheet.**

Action

Contact your service engineer if

- **any serious non-uniformities (rating of 3) are scored.**
- **any noticeable non-uniformities (rating of 2) are scored for two consecutive test periods.**

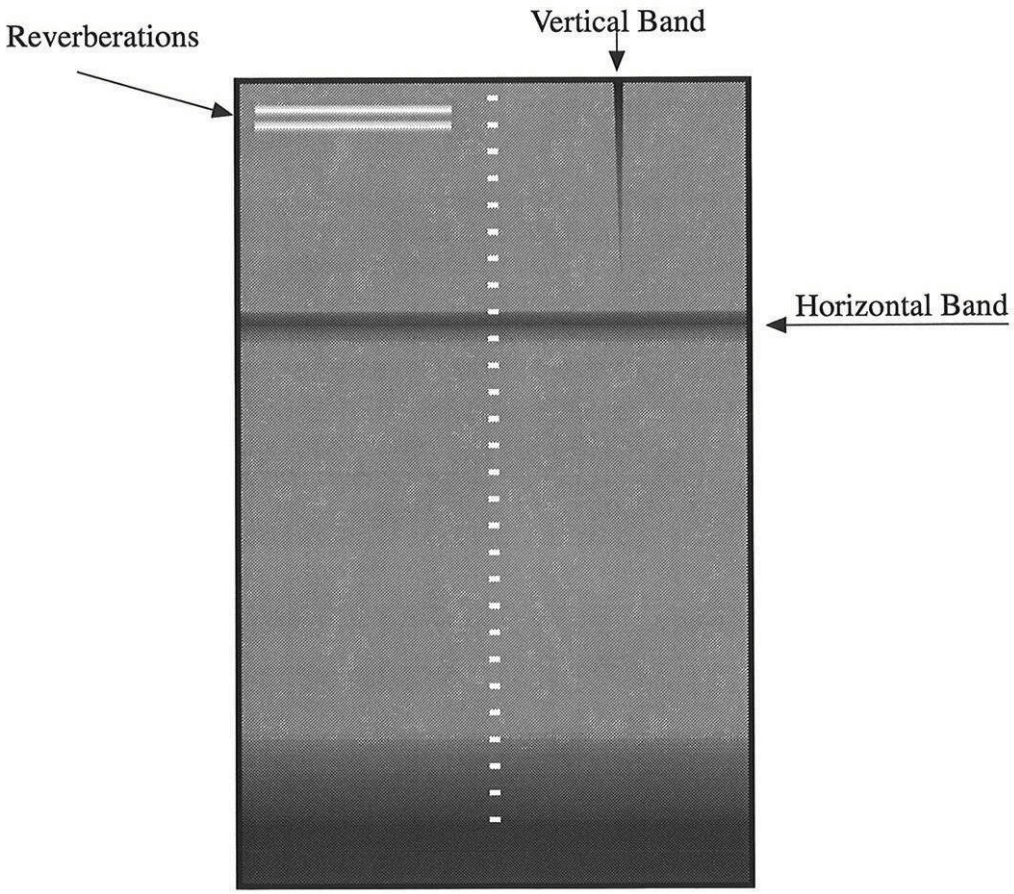


Fig. 3.7 Examples of common nonuniformities. Horizontal bands are often caused by circuitry problems while vertical bands indicate a damaged transducer element.

Dead Zone

The dead or "ring down" zone is the portion of the image directly under the transducer where image detail is missing or distorted. The dead zone is the result of reverberations in the transducer and adjacent tissue and the scanner's attempts to compensate for these problems. Although many of today's instruments are normally free from noticeable dead zones, damage to the transducer or poor acoustic coupling may produce this defect.

Method

The dead zone is measured by identifying the depth of the pin target nearest the transducer.

Procedure

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet for the dead zone measurement.**
2. **Scan the dead zone target group.**
3. **Freeze the image and determine the closest pin which can be imaged and record its depth on the Data Sheet.**
4. **Graph the measurements on the dead zone Graph Sheet.**

Action

Contact your service engineer if

- **the dead zone depth increases from the baseline value.**

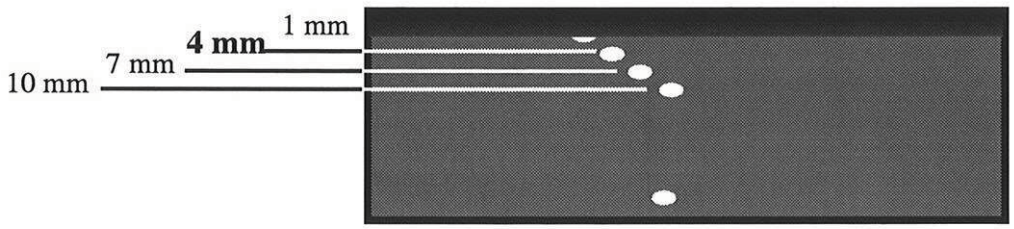


Fig. 3.8 The depth of an instrument's dead zone is determined by identifying the shallowest pin target that can be clearly visualized. In this example the dead zone is 4 mm deep.

Cyst Imaging

The cyst imaging test looks at the system's ability to accurately display a round, negative contrast object. This test combines aspects of contrast resolution and image uniformity into a single test. Cyst image quality can be affected by electrical noise, side lobes in the transducer beam and problems in the image processing hardware.

Method

Evaluate the smallest cyst in each cyst group that can be easily seen in the image and grade the image with the following criteria. Because this test is subjective, images from previous tests should be used for comparison.

Cyst Image Characteristics

Shape: Measure the height and width. The two measurements should be equal.

Edge: The edge of the cyst should be sharply defined.

Texture: The cyst interior should be echo free.

NOTE: Bright spots at the top and bottom of the cysts are specular reflections and are normal for some systems.

Procedure

For each cyst group:

1. **Adjust the focal zone and depth controls to the values listed on the Data Sheet. Obtain a clear image of the group.**
2. **Freeze the image and make a hard copy.**
3. **For the largest cyst target, rate the three image characteristics on a scale from 1-3. Use the baseline image as a reference for grading.**

   1 = No Distortion
   2 = Minor Distortion
   3 = Major Distortion

4. **If your phantom has cysts of different sizes, determine the smallest visible cyst at near, mid and far depths. Keep the final image stored on the monitor for the next test.**
   - For baseline tests, record the minimum visible diameter on the Data Sheet.
   - For standard tests, compare the current minimum with the baseline minimum. Note changes in event log.
5. **Record and graph the scores on the cyst imaging Data and Graph Sheet.**

Action

Contact your service engineer if

- **any major distortions (rating of 3) are detected.**
- **minor distortions (rating of 2) are observed for two consecutive tests.**

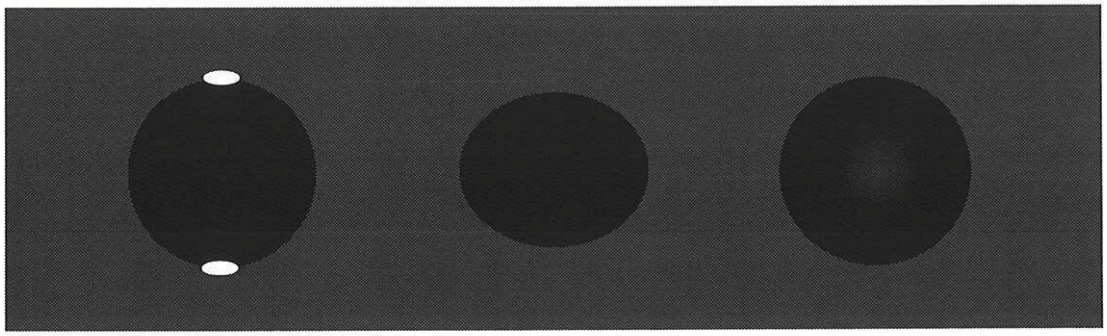


Fig. 3.9 (Left) The normal appearance of a low scatter "cyst" target. Notice the sharp edges, clear black appearance and round shape. Bright artifacts at the top and bottom are normal specular reflections. (Center) Flattened cyst indicates geometric distortion. (Right) Echoes inside the cyst may be the result of system noise or side lobe contamination.

Image Recorder Tests

Drift in the alignment and gray values can cause distortions in the hard copy images. These problems may be the result of failures in either the ultrasound system or the image recorder. Film processors can also introduce distortions and should also be closely monitored with a separate QA program.

Method

Hard copy images of the phantom are generated and checked for their similarity to the video monitor image. Geometric distortion is detected by physically measuring and comparing the displayed distances on the monitor screen with the hard copy images.

Procedure

1. **Inspect the hard copy images of the cyst imaging and depth of penetration tests.**
2. **Compare the hard copy image from the cyst imaging test to the monitor image. Check that the brightest and darkest image features are similar on the hard copy image and monitor. Record the result on the Data Sheet.**
3. **Repeat the depth of penetration test on the phantom and freeze the image. Check that the depth at which echo data disappears on the hard copy is the same as on the monitor. Record the result on the Data Sheet.**
4. **Check that the number of gray bars on the hard copy image and the video monitor are equal. Indicate the number of gray bars on the Data Sheet.**

Action

Contact your service engineer if

- **any artifacts are observed.**
- **the difference between the measured depth of penetration on the video monitor and hard copy images exceeds 3 mm.**
- **the number of gray bars on the monitor image and hard copy are not equal.**

Chapter Four
Using the Image Quality Test Data

Graphing the Test Data

Plot the image quality data on the Graph Sheets as soon as the tests have been completed. Graphical representations of the data are more useful than columns of numbers for identifying changes and trends in the image quality indicators.

Good notation and a little color can improve the legibility of your graphs. For example,

- The upper and lower action levels can be identified by coloring those lines with a yellow highlighting marker.
- The data point corresponding to a significant event can be identified by a box or circle.
- Data points that reach or exceed an action level are circled. When the cause of the defect has been corrected, the indicator is remeasured and a box is drawn around the new data point to indicate that it is a corrected value. Connecting the points with a line can also help to visually associate them.

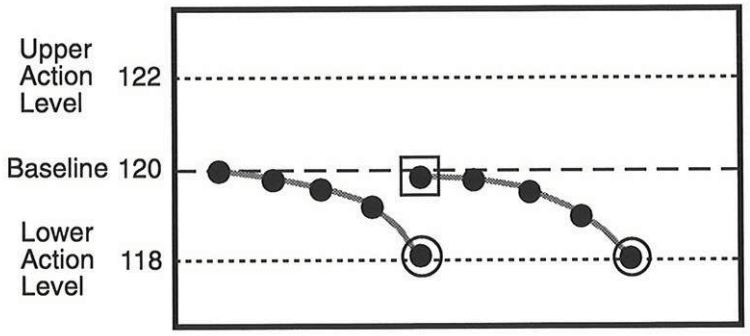


Fig. 4.1 Identifying significant data points makes it easier to assess overall system performance.

Using the Event Logs

The event logs help improve your perception of the significance of events that may contribute to image quality changes in the future. In many cases a minor event will mark the beginning of an unrecognized trend. For example, the failure of an air conditioner in a lab might not cause an immediate system failure, but the higher room temperature combined with other factors might cause electronic components to fail at a later date. "Useful parameters for assessing potential damage are shown below.

Image Quality Indicator	What To Look For:
Dead Zone	Increased dead zone depth or reverberation artifacts
Horizontal Distance	Increased measurement errors
Axial Resolution	Resolution loss
Lateral Resolution	Resolution loss
Depth of Penetration	Reduced depth of penetration
Image Uniformity	Erroneous echoes

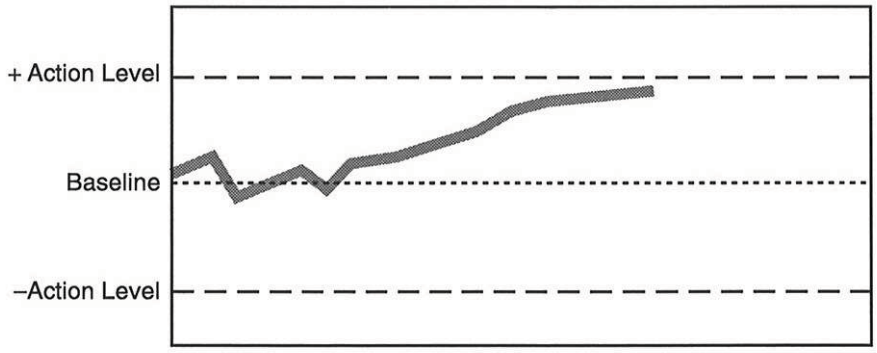
Fig. 4.2 An instrument can be evaluated for damage by measuring the following image quality indicators.

Evaluating the Service Program

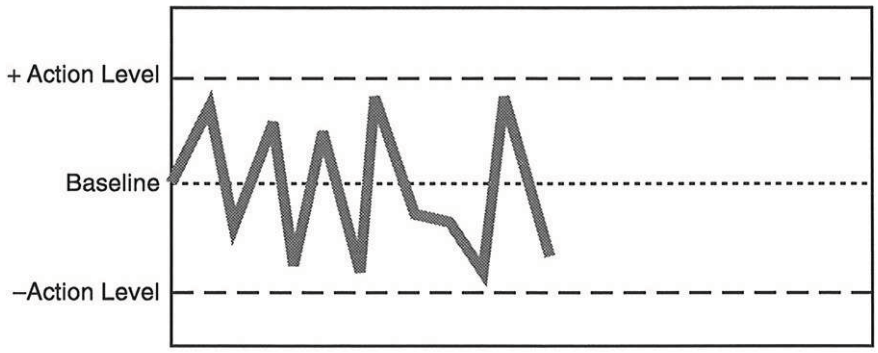
Recording the dates of service visits on the event log gives you the ability to compare the effect on image quality for each visit. This information can illustrate the effectiveness of the preventive maintenance/repair program and help you identify ways to improve it.

Looking At the Data

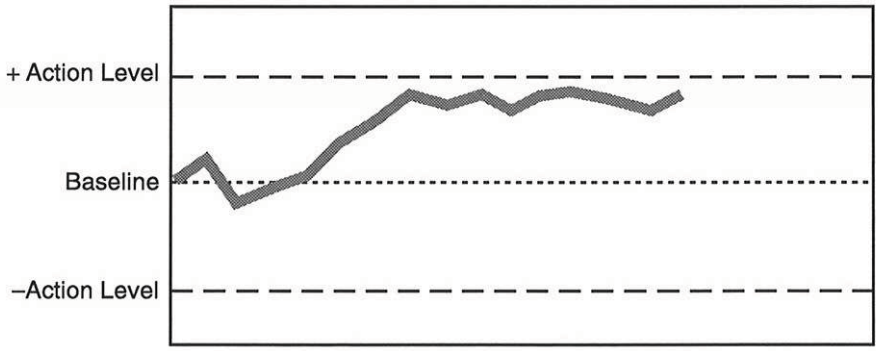
In addition to taking corrective action whenever an action level is exceeded, you should also watch for other signs of potential problems. For example, data will normally have a certain amount of random movement around the baseline value. You should consult your service engineer if the image quality test data demonstrates any of the trends shown on the next page.



- **A consistent movement in one direction towards an action level.**



- **Wide, regular oscillation from one side of the baseline to the other, frequently approaching the action levels.**



- **Flat spots in the data curve that come close to the action level.**

Adjusting Tolerances and Action Levels

You may wish to adjust the tolerance and action levels for a particular image quality indicator to reflect the demands of your applications. For example, the recommended error limit for horizontal distance measurements is 3 mm or 3%. If your lab is documenting changes in tumor size following radiation or chemo-therapy, you might decrease the limit to 2 mm or 2% with a corresponding decrease in the action levels.

You may also need to increase the values of the action levels to accommodate the variations in the test data caused by experimental error. If the image quality levels are relatively stable over five to ten test periods and the occaisional "spike" has no apparent correlation with events (from the event logs) or a particular operator, then increase the action level to let the spike pass. In cases like this, experience with the performance of your instruments, good test data and the advice of a trusted physicist and service engineer are your best guides.

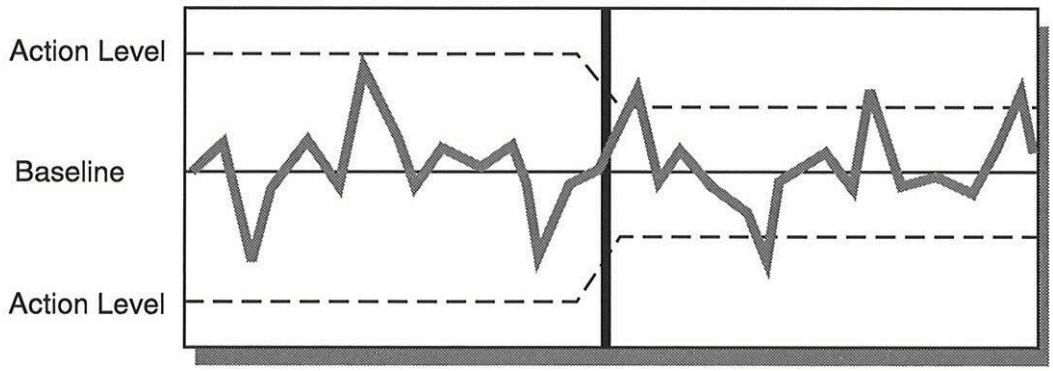


Fig. 4.3 Normal fluctuations in data that are acceptable for the action levels on the left will trigger corrective actions for the action levels on the right.

Archiving the Data

It's a good idea to retain the Data Sheets for the life of the instrument. If the instrument is sold or performance questions arise, the Data Sheets are valuable evidence that the machine was carefully maintained. Documentation can also support your claims if you feel that the system is a "lemon". The Graph Sheets are especially valuable for the long term because they provide a quick visual summary

of the instrument's performance over time. To save storage space, old Graph and Data Sheets can be reduced to half or quarter size with a photocopier.

If your department or facility has a quality committee, a periodic summary of the quality activities performed in the ultrasound lab should be added to the official 'minutes' of the committee meetings.

Where To Go For Help

Many health care organizations now have a quality manager or quality assurance committee than can provide valuable ideas and support in the development of your quality assurance program. Many radiology/oncology departments have a physicist on staff or employed as a consultant. You may want to seek the advice of this individual regarding the implementation and interpretation of your quality tests.

Operator error is a frequent cause of poor image quality. Take advantage of the expertise of the manufacturer's applications specialists in producing high quality clinical images. Getting the service engineer involved in your quality program will provide you with useful experience and advice in interpreting your results. In addition, your experience can provide valuable feedback to help the manufacturer improve the reliabilty and performance of their products.

A wide variety of written material is available on general and specific quality issues. The Appendix provides a short list of recommended resources. Remember, simply being aware of image quality will have a positive effect on the quality of medicine.

Appendix

- Selecting a Phantom
- Suggested Readings
- Data & Graph Sheets

Selecting A Tissue Mimicking Phantom

A tissue mimicking phantom is a required tool for every ultrasound QA program. Image quality tests must be performed with the ultrasound beam operating in an environment that is acoustically similar to the patient's body. Because the acoustic characteristics of the phantom will affect the accuracy of your tests, it is important to choose your phantom wisely.

Phantom Selection Checklist

The following features are important in a tissue mimicking phantom.

- ❑ Speed of sound: 1540±10 m/s at 22 °C with a temperature dependence of less than 2 m/s/°C.

- ❑ Attenuation coefficient 0.5 or 0.7 dB/cm/MHz for typical operating frequencies and be approximately proportional to frequency.
  Note: Specifications should state the frequency at which the attenuation was measured.

- ❑ Vertical Column of pin targets with spacing of 2 cm or less.

- ❑ Horizontal Row of pin targets with spacing of 3 cm or less.
  Several rows at various depths are useful for assessing geometric accuracy.

- ❑ Axial Resolution pattern with minimum spacing of 0.5 mm or less.
  Note: Many users prefer multiple resolution target groups.

- ❑ Diagonal "dead zone" or "ring down" pin target group with a minimum spacing of 3 mm.
  Note: Although the dead zone is less of an issue on newer systems, the dead zone targets are useful for very near field lateral resolution tests.

- ❑ Low scatter cylinder, diameter of 4 to 6 mm.
  Groups of cylinders with diameters from 1 to 6 mm are useful.
  Groups at several depths can show the effect of depth on performance.

A Discussion of Phantom Characteristics

Speed of Sound

To calculate distances, ultrasound scanners normally assume an average speed of sound in the patient of 1540 m/s. To properly measure distance accuracy, the material in the phantom must provide the same speed of sound. The recommended speed of sound for phantoms is 1540±10 m/s at 22°C.

The correct speed of sound is essential for accurate focusing of the ultrasound beam, particularly for phased array transducers. An incorrect speed of sound may cause the ultrasound beam to focus at the wrong point in space and may produce misleading lateral resolution measurements.

Phantoms with incorrect speed of sound values attempt to compensate by adjusting the spacing of targets to fool the scanner. Although this may yield correct distance measurements, it fails to address the beam focus phenomenon and can produce unreliable results.

Attenuation

Sound waves are attenuated as they pass through tissue. The attenuation coefficient describes the amount of signal loss per unit distance of tissue traveled. Attenuation coefficients are commonly expressed in decibels per centimeter (dB/cm). Attenuation in tissue is approximately proportional to frequency. In practice, this means that a 4 MHz ultrasound beam will experience roughly four times the decibel signal loss of a 1 MHz beam for the same tissue path.

Because the beams generated by "broad band" and "multi-frequency" transducers contain a wider range of component frequencies, accurate measurements of penetration and axial resolution require that all frequencies (not just the center frequency) be properly attenuated. For example, excessive high frequency attenuation will result in reduced depth of penetration for high frequency probes and degraded axial resolution.

Echogenicity and Speckle Texture

The phantom should be scanned with the same power and gain settings normally used on patients. For this reason, the tissue mimicking material in the phantom should have an echogenicity or 'brightness' that is similar to commonly scanned soft tissue such as liver parenchyma. To highlight image artifacts and

nonuniformities, the tissue mimicking material should produce a smooth, even speckle texture throughout the phantom .

Phantom Components

Tissue Mimicking Materials

The heart of the phantom is the tissue mimicking material. Tissue mimicking materials based on water, foam, oil, hydrogels, and rubber-like materials have been developed and described in the literature. To date, only graphite/hydrogel-based materials have achieved the acoustic characteristics and repeatability necessary for reliable performance testing.

Phantom Targets

A phantom for standard ultrasound image quality tests requires certain target types and configurations. Although large numbers of targets are impressive the experienced users tend to prefer phantoms with fewer targets to increase the area of unobstructed phantom material for depth of penetration and image uniformity tests.

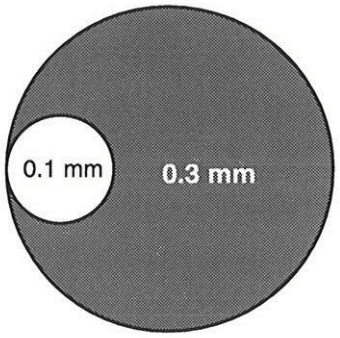
Contrast Cylinders

Cylinders of hypoechoic or 'low scatter' material are useful for observing geometric distortion and nonuniformities in a more complex shape. To ensure good propagation of the ultrasound pulse, the cylinder should have the same speed of sound characteristics as the surrounding tissue mimicking material. Because the target mimicks a fluid-filled cyst, a low attenuation coefficient (~0.05 dB/cm-MHz) is common.

A single cylinder with a diameter of 4-6 mm is enough to get the job done. Many users prefer several sets of cylinders with a range of diameters and depths to look at the effect of target depth on image quality. Target diameters between 1 and 6 mm are most useful. Target depths corresponding to near, mid and far-field depths (3, 8, 14 cm) are popular because they minimize the beam interference caused by numerous targets.

Pin Targets

Pin targets are small diameter rods that function as point reflectors. Although steel has been used in the past, nylon is the most popular target material. Pin targets are arranged in rows and columns for distance accuracy tests and in various patterns for axial and lateral resolution tests. For systems with transducers operating below 5 MHz, a pin diameter of 0.3 mm is acceptable. However, the 0.3 mm pins may experience reverberations at frequencies above 5 MHz, making a 0.1 mm pin diameter more appropriate for high performance systems.



The smaller cross section of the 0.1 mm diameter pin target eliminates the doubling artifacts commonly experienced by higher frequency transducers with 0.3 mm diameter pin targets.

Scanning Surfaces

Phantoms are currently available in both single and multiple scanning surface designs. Experienced users tend to choose single scanning surfaces design for convenience and durability. Single surface phantoms allow the user to scan all of the targets from one position, thereby reducing the amount of gel and cleanup required. In addition, single scanning surface phantoms have less surface area and will last longer. Additional viewing angles of the targets can be achieved by scanning through the walls of the phantom.

Suggested Readings

Quality Assurance in Ultrasound

- AIUM Standard Methods for Measuring Performance of Pulse Echo Ultrasound Equipment. American Institute of Ultrasound in Medicine, 1990.
- Instrument Quality Assurance (Chapter 6), James Zagzebski, Textbook of Diagnostic Ultrasonography, edited S. Hagen Ansert, C.V. Mosby, St. Louis, 1989.
- Understanding Ultrasound Physics, Sidney Edelman.
- Physics in Medical Ultrasound, Report 47, The Institute of Physical Sciences in Medicine, 1986.
- Essential Physics of Medical Imaging, Stewart C. Bushong, William and Wilkins, Baltimore, 1993.

Quality in Healthcare

- JCAHO Accreditation Manual for Hospitals
- Curing Health Care: New Strategies for Quality Improvement, Donald Berwick, M.D., Jossey Bass Publishers, 1990

General Quality

- Juran's Quality Control Handbook - Fourth Edition, J.M. Juran, Editor, McGraw Hill, 1988
- Quality is Free, Philip Crosby, Mentor, 1980
- The Memory Jogger, Goal/QPC, Muethen MA, 1988
- Juran on Leadership for Quality, Joseph M. Juran, The Free Press, 1989
- Out of the Crisis, W. Edwards Deming

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St. Jude Medical
2375 Morse Ave.
Irvine, CA 92614 USA
Tel 949 769 5000
Fax 949 769 5144

April 11, 2014

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

RE: (b) (4) [redacted]

To Whom It May Concern:

(b) (4) [redacted]

If there are questions regarding this submission, please contact either, Kellie Stefaniak, Manager, Regulatory Affairs, at 949-769-5059 or myself below.

Sincerely,

Jennifer Correa

Jennifer Correa
Regulatory Affairs Specialist II
St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

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ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

St. Jude Medical
2375 Morse Ave.
Irvine, CA 92614 USA
Tel 949 769 5000
Fax 949 769 5144

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St. Jude Medical, Inc.
2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5053
Fax: 855-482-7739
E-mail: jcorrea05@sjm.com

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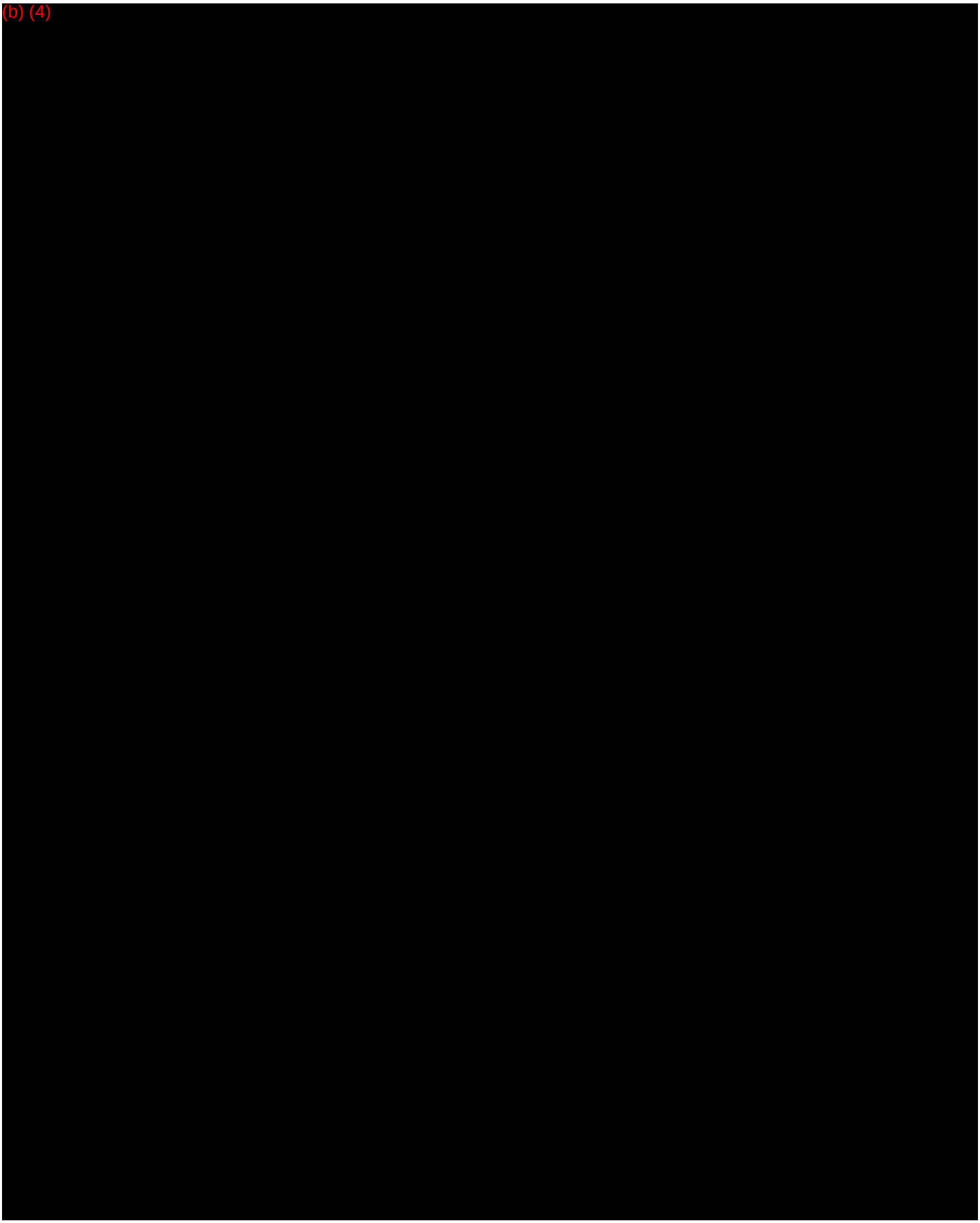

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