Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016 1(62)82623

CONFIDENTIAL

510(k) SUMMARY

FEB 25 2009

General Information

Submitted by:

Televere Systems
1611 Center Avenue
Janesville, WI 53545

Phone: 800-385-9593
Fax: 608-314-1084

Contact Person:

Barbara Deay
471 Stage Road
Charlton, NY 12019

Phone: 800-385-9593 x128
Fax: 408-762-2760
Email: barb@tigerview.com

Date Prepared: August 29, 2008

Device Name

Trade Name: Visix Imaging
Common Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp. (purchased by Televere Systems)	TigerScan/TigerView	K955237

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

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Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card, or SCSI card.

Intended Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Technological Comparison

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Visix Imaging has been demonstrated to perform as intended.

Conclusions

Visix Imaging is substantially equivalent to legally marketed Picture Archiving and Communications Systems.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2009

Televere Systems
% Ms. Barbara Deay
Technical Support and Writing
Televere Systems
471 Stage Road
CHARLTON NY 12019

Re: K082623
Trade/Device Name: Visix Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2009
Received: January 14, 2009

Dear Ms. Deay:

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

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

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

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

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

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

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

INDICATIONS FOR USE

510(k) Number (if known): K082623

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082623

August 29, 2008

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2009

Televere Systems
% Ms. Barbara Deay
Technical Support and Writing
Televere Systems
471 Stage Road
CHARLTON NY 12019

Re: K082623
Trade/Device Name: Visix Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2009
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Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

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21 CFR 892.xxx	(Radiology)	(240) 276-0120
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Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

INDICATIONS FOR USE

510(k) Number (if known): K082623

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
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Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiologic[illegible]
510(k) Num[illegible] K082623 August 29, 2008

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 9 2009

Ms. Barbara Deay
Technical Support and Writing
Televere Systems
471 Stage Road
CHARLTON NY 10219

Re: K082623
Trade Name: Visix Imaging
Dated: December 12, 2008
Received: December 15, 2008

Dear Ms. Deay:

We have reviewed your December 12, 2008 letter sent to us in response to our December 04, 2008 Letter in which we requested additional information from you for your 510(k) premarket notification submission K082623, Visix Imaging. After reviewing your response, we have determined that there is still information needed before we can determine if your device is substantially equivalent to a legally marketed predicate device. To complete the review of your submission, we require the following information.

(b)(4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled "A Suggested Approach to Resolving Least Burdensome Issues" located at http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

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

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If you have any questions concerning the contents of the letter, please contact Charles F. Myers at (240) 276-3657. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

David S. Buckles, PhD., FACC
Chief, Radiological Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(Please include 510(k) number here: K 082623/S001)

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 DRARD
D.O.

Final: kjh 1.7.2009

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
470	Buckles	1/9/09						

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 2008

Ms. Barbara Deay
Technical Support and Writing
Televere Systems
471 Stage Road
CHARLTON NY 12019

Re: K082623
Trade Name: Visix Imaging
Dated: August 20, 2008
Received: September 29, 2008

Dear Ms. Deay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

(b)(4) Deficiencies

[redacted]

57

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

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If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Charles F. Myers at (240) 276-3657. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

David S. Buckles, PhD., FACC
Chief, Radiological Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

September 29, 2008

TELEVERE SYSTEMS
471 STAGE RD.
CHARLTON, NEW YORK 12019
UNITED STATES
ATTN: BARBARA DEAY

510k Number: K082623
Received: 9/23/2008
Product: VISIX IMAGING

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

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

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"
tp://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely yours,

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

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 09, 2008

TELEVERE SYSTEMS
471 STAGE RD.
CHARLTON, NY 12019
ATTN: BARBARA DEAY

510(k) Number: K082623
Received: 09-SEP-2008
User Fee ID Number: (b)(4) [redacted]
Product: VISIX IMAGING

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Office of Device Evaluation
Center for Devices and
Radiological Health

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

RA/DRARD
Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

CONFIDENTIAL

K082623

August 29, 2008

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

SEP - 9 2008

RE: 510(k) Submission for Visix Imaging

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, two copies of this 510(k) Notification are being submitted at least 90 days prior to the date when Televere Systems proposes to introduce this product into interstate commerce for commercial distribution. One copy of this 510(k) Notification is a paper copy.

This is the electronic copy of the 510(k) submission for Visix Imaging. Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, this electronic copy is an exact duplicate of the original paper submission that accompanies it.

A copy of each page of the 510(k) submission that requires a signature (in sections 003, 006 and 016) is included with the electronic copy with an original signature on each. A scanned copy of each signature page is included with the pdf file for that section.

The proposed product is a modification (an expansion of the indications for use) of the TigerView Professional product that was developed by Televere Systems.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: System, Image Processing, Radiological

   Common/Usual Name: Picture Archiving and Communications System

   Trade/Proprietary Name: Visix Imaging

2. The registration number for Televere Systems is 2954358.

3. Picture archiving and communications systems have been classified as Class II (special controls) devices under 21 CFR 892.2050. Panel designation for similar devices is under Radiology, with Product Classification Code: LLZ.

KIO

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

4. No mandatory performance standards under Section 514 have been developed by the FDA for picture archiving and communications systems.

5. Proposed labeling for Visix Imaging is described in Section 13.

6. Visix Imaging is substantially equivalent to other marketed devices previously cleared under Section 510(k). These include:

Manufacturer	Product Name	510(k) Number
Televere Systems	TigerView Professional	K061035
Televere Systems	TigerView Classic	K955237
Patterson Dental	Patterson EagleSoft (formerly known as EagleSoft ChairSide)	K982422

7. Table of Contents
The header on each page indicates the 510(k) section on the left and the page within the section on the right. The additional section, Certification of Compliance With Clinical Trials listed in the Device Advice document "How To Prepare a Traditional 510(k)" located at http://www.fda.gov/cdrh/devadvice/3143.html has been placed between section 2 and section 3.

Section 1.0 Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2.0 CDRH Premarket Review Submission Cover Sheet
Section 2X Certification of Compliance With Clinical Trials
Section 3.0 510(k) Cover Letter
Section 4.0 Indications for Use Statement
Section 5.0 510(k) Summary
Section 6.0 Truthful and Accuracy Statement
Section 7.0 Class III Summary and Certification
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Section 11.0 Device Description
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Section 15.0 Biocompatibility
Section 16.0 Software
Section 17.0 Electromagnetic Compatibility and Electrical Safety
Section 18.0 Performance Testing – Bench
Section 19.0 Performance Testing – Animal
Section 20.0 Performance Testing – Clinical

Should you have any questions or require further information, please feel free to contact me at phone number (800) 385-9593 x128, or at the following address: 471 Stage Road, Charlton, NY 12019.

August 29, 2008

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Sincerely,

Barbara Deay

Barbara Deay
Technical Writer, Televere Systems

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

CERTIFICATION OF COMPLIANCE WITH CLINICAL TRIALS

This new section (included per instructions on the FDA web site) does not apply since no clinical studies were necessary to support this 510(k) submission.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Medical Device User Fee Cover Sheet

Site: null Page 1 of 1

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TELEVERE SYSTEMS LLC 1611 Center Ave. Janesville WI 53545 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 752692534	2. CONTACT NAME Jill Davieswhite 2.1 E-MAIL ADDRESS jill@tigerview.com 2.2 TELEPHONE NUMBER (include Area code) 800-3859593 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 408-7624441

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:	3.1 Select one of the types below
[X] Premarket notification(510(k)); except for third party	[X] Original Application
[ ] 513(g) Request for Information	Supplement Types:
[ ] Biologics License Application (BLA)	[ ] Efficacy (BLA)
[ ] Premarket Approval Application (PMA)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Modular PMA	[ ] Real-Time (PMA, PMR, PDP)
[ ] Product Development Protocol (PDP)	[ ] 180-day (PMA, PMR, PDP)
[ ] Premarket Report (PMR)	
[ ] Annual Fee for Periodic Reporting (APR)	
[ ] 30-Day Notice	

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

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

[X] NO, I am not a small business

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

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

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

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

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

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

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

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted] 14-Aug-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?ordnum=6038023 8/26/2008

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
8/29/08	(b)(4) [redacted]	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Televere Systems	Establishment Registration Number *(if known)* 2954358		
Division Name *(if applicable)*	Phone Number *(including area code)* 1-800-385-9593		
Street Address 1611 Center Avenue	FAX Number *(including area code)* 1-608-314-1084		
City Janesville	State / Province Wisconsin	ZIP/Postal Code 53545	Country USA
Contact Name Barbara Deay			
Contact Title Technical Support and Technical Writing	Contact E-mail Address barb@tigerview.com		

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

Company / Institution Name Televere Systems			
Division Name *(if applicable)*	Phone Number *(including area code)* (800) 385-9593 x128 or (518) 384-2052		
Street Address 471 Stage Road	FAX Number *(including area code)* (408) 762-2760		
City Charlton	State / Province NY	ZIP/Postal Code 12019	Country USA
Contact Name Barbara Deay			
Contact Title Technical Support and Writing	Contact E-mail Address barb@tigerview.com		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
PSG Media Arts (301) 443-2454 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

☐ Other Reason *(specify)*:

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

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LLZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K061035	1	TigerView Professional	1	Televere Systems
2	K955237	2	TigerScan/TigerView	2	Televere Systems
3	K982422	3	EagleSoft ChairSide Software Application	3	EagleSoft, A Patterson Co.
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Image Processing System (PACS)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Visix Imaging	1	
2		2	
3		3	
4		4	
5		5	

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

1 K955237	2 K061035	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

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

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: LLZ

C.F.R. Section *(if applicable)*: 21 CFR 892.2050

Classification Panel: Radiology

Device Class

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

Indications *(from labeling)*

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

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

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 2954358	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Televere Systems		Establishment Registration Number 2954358		
Division Name *(if applicable)*		Phone Number *(including area code)* 800-385-9593		
Street Address 1611 Center Avenue		FAX Number *(including area code)* 608-314-1084		
City Janesville		State / Province WI	ZIP/Postal Code 53545	Country USA
Contact Name Barbara Deay	Contact Title Technical Support and Technical Writer		Contact E-mail Address barb@tigerview.com	

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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August 29, 2008

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: 510(k) Submission for Visix Imaging

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, two copies of this 510(k) Notification are being submitted at least 90 days prior to the date when Televere Systems proposes to introduce this product into interstate commerce for commercial distribution. One copy of this 510(k) Notification is a paper copy. Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

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The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: System, Image Processing, Radiological

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    Trade/Proprietary Name: Visix Imaging

2. The registration number for Televere Systems is 2954358.

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4. No mandatory performance standards under Section 514 have been developed by the FDA for picture archiving and communications systems.

5. Proposed labeling for Visix Imaging is described in Section 13.

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

6. Visix Imaging is substantially equivalent to other marketed devices previously cleared under Section 510(k). These include:

Manufacturer	Product Name	510(k) Number
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Televere Systems	TigerView Classic	K955237
Patterson Dental	Patterson EagleSoft (formerly known as EagleSoft ChairSide)	K982422

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Section 2.0 CDRH Premarket Review Submission Cover Sheet
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Section 15.0 Biocompatibility
Section 16.0 Software
Section 17.0 Electromagnetic Compatibility and Electrical Safety
Section 18.0 Performance Testing – Bench
Section 19.0 Performance Testing – Animal
Section 20.0 Performance Testing – Clinical

Should you have any questions or require further information, please feel free to contact me at phone number (800) 385-9593 x128, or at the following address: 471 Stage Road, Charlton, NY 12019.

Sincerely,

Barbara Deay

Barbara Deay
Technical Writer, Televere Systems

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes. It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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510(k) SUMMARY

General Information

Submitted by: Televere Systems
1611 Center Avenue
Janesville, WI 53545

Phone: 800-385-9593
Fax: 608-314-1084

Contact Person: Barbara Deay
471 Stage Road
Charlton, NY 12019

Phone: 800-385-9593 x128
Fax: 408-762-2760
Email: barb@tigerview.com

Date Prepared: August 29, 2008

Device Name

Trade Name: Visix Imaging
Common Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp. (purchased by Televere Systems)	TigerScan/TigerView	K955237

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card, or SCSI card.

Intended Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Visix Imaging has been demonstrated to perform as intended.

Conclusions

Visix Imaging is substantially equivalent to legally marketed Picture Archiving and Communications Systems.

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that as a responsible representative of Televere Systems, I believe, to the best of my knowledge and understanding, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Randall Quaal
General Manager
Televere Systems
8/20/2008

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PREMARKET NOTIFICATION

CLASS III SUMMARY AND CERTIFICATION

This section does not apply as the proposed device is classified as Class II (special controls) under 21 CFR 892.2050.

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PREMARKET NOTIFICATION

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

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PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section does not apply since declaration of conformances to recognized standards are not being provided.

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EXECUTIVE SUMMARY

1.1 Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., brighten, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging utilizes the same programming routines to capture the images as TigerView Professional (K061035). The minimum computer requirements for the Visix Imaging software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher Hard Drive: 70MB or more of free space for the program Monitor: 1024x786 setting minimum Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, black and white laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology. Microsoft. Network speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database and images

Visix Imaging is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card or SCSI card. Examples of capture devices that are compatible are the ScanX scanner from Air Techniques, the Expression 1680 Pro Scanner from Epson, and the Acclaim camera from Air Techniques.

Visix is comprised of five (5) main areas: Patients, Images, Acquire, Mount, and View. Additionally, there is an Export Image function and a Print function.

Visix includes software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

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Patients

The Patients window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

Images

The Images bar displays the images that belong to the currently open patient. Images are stored in date order with the newest image at the top.

Acquire

Images are acquired into Visix through one of the devices listed in the Acquire area. The input methods consist of x-rays, video, flatbed scanning, and imported digital images.

The optional settings for the attached hardware device are displayed in settings windows. The following is an overall list of options available to the user to fine-tune the images. Not every option is available for every hardware device.

Optional Device Settings

- Edge Enhancement
- Smoothing
- Brightness
- Contrast
- Gamma / Gray Shift
- Trim
- Film Mask
- Auto Flip
- Auto Re-arm
- Timeout Value
- Advanced Settings
- Allow Scan Edit
- Auto Optimize
- Auto-Segment
- DEMS
- Image Orientation
- Prompt for Date
- Display Size
- Image Resolution
- Network Settings
- Shared / Exclusive Use

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- X-ray
  Various x-ray devices (e.g. ScanX scanner, Accent sensor) are compatible with Visix Imaging. Associated with x-ray acquisition are a number of options, such as the scan setting and exposure mode, which are specific to the attached hardware device, plus automatically mounting acquired images.

- Video
  Still pictures from video camera devices are acquired in the Acclaim window. Video options include such things as the specific video camera device from which to capture images, where the input is coming from, the size the live input is displayed at, the option to change device-specific video camera settings, and automatically mounting acquired images.

- Laser Fluorescence Caries Detection
  Still pictures from laser fluorescence caries detection devices are acquired in the Spectra window. Options include detection (of caries) and analysis (of plaque), and automatically mounting acquired images.

- Flatbed Scanning
  Images from a flatbed scanner are acquired in the Scan Film window. Flatbed scanner options include such things as selecting the appropriate TWAIN driver that matches the connected scanner, storing the image with a date specified by the user, and automatically mounting acquired images.

- Import
  Digital images and documents may be acquired through the import of various file types in the Import window. The user specifies the location of the files, and then selects the specific files to import. Import options include such things as automatically mounting the imported images.

Mount

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing photographs in a cardboard mat that has multiple openings. Mounted images are viewed, printed, exported, or otherwise manipulated together as one image. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function which automatically places newly acquired images into an existing mount.

View

The View window may be used to examine, manipulate, measure, and place notes on an image. The View window provides advanced image manipulation tools and

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has the capability for viewing multiple images at once. Various tools are available to the user in the View window such as:

- Zoom In and Out
- Full Screen
- Reset Zoom
- Rotate
- Flip
- Reset Orientation
- Automatically Arrange Images
- Manually Arrange Images
- Measure
- Annotate
- Magnifying Glass
- Print Image
- Negate
- Colorize Image
- Pseudo 3D
- Sharpen Image Edges
- Reset Original Image
- Brightness and Contrast
- Gray Shift (Gamma)

Export

Images are exported in a user selected file type of bitmap, jpeg or tiff in the Export function.

Print

A predefined report containing images and data prints in the Print function.

Dynamic Exposure Monitoring System (DEMS)

Dynamic Exposure Monitoring System is an aid to the user in quickly identifying images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data available in the image to render the object being imaged. The amount of data (measured in terms of bits acquired from the hardware device) required to meet the criteria for determining these status colors is specific to each hardware device supported by Visix Imaging based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software displays a yellow or red light that prompts the user to check the image and possibly

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retry image acquisition. Each hardware device has threshold bit levels set by default on installation. Whether the image displays a green (good) light or a yellow or red light, the user makes the decision to either accept the image or change imaging hardware settings and reacquire the image.

1.2 Indications for Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic imaging devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes and measurements.

Visix Imaging is intended to acquire, display, edit (e.g. adjust brightness and contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

1.3 Technological Comparison

Visix Imaging is substantially equivalent to TigerView Pro (K061035), EagleSoft ChairSide Software Application (K982422) and TigerScan/TigerView Classic (K955237). Visix Imaging, TigerScan/TigerView Classic, TigerView Pro and EagleSoft ChairSide are each software applications that have similar indications for use and overall functions, and perform in a similar manner with respect to image processing systems (i.e. PACS). Visix Imaging is compatible with similar types of hardware devices (e.g. scanners, digital sensors, digital video cameras, etc.) and has similar options for displaying, editing, and printing/sending images as the predicate devices.

A comparison of the features and performance of these devices is provided in the following table.

Parameters	**Visix Imaging Televere Systems**	**TigerView Pro Televere Systems K061035**	**TigerScan/TigerView Tau Corp. (Televere Systems) K955237**	**EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422**
Patient/Image Management	Yes	Yes	Yes	Yes
Acquire Images				
X-Ray	Yes	Yes	Yes	Yes
Video	Yes	Yes	No	Yes
Photos	Yes	Yes	No	Yes
Laser	Yes	No	No	No

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Fluorescence Detection Documents Import	Yes Yes	Yes Yes	No Yes	Yes Yes
Display Images	Yes	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes	Yes
Print/Send/Export Images	Yes	Yes	Yes	Yes
Enhance Images	Yes	Yes	Yes	Yes

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1.4 Performance Testing

(b)(4)

[redacted]

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INDICATIONS FOR USE AND DEVICE DESCRIPTION

11.1 Indications for Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes and measurement data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

11.2 Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging utilizes the same programming routines to capture the images as TigerView Professional (K061035). The minimum computer requirements for the Visix software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher Hard Drive: 70MB or more of free space for the program Monitor: 1024x786 setting minimum Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, black and white laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology, Microsoft, network speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database and images

Visix Imaging is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card or SCSI

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card. Examples of capture devices that are compatible are provided in the table below.

Devices that attach to the computer in the following manner:	Device Examples
USB Port	Phosphor plate scanners such as the ScanX from Air Techniques
	Video cameras such as the Acclaim Intra-oral camera from Air Techniques
	Digital cameras such as the M305 digital camera from HP
	Flatbed scanners such as the Epson 1680
	Sensors such as the Accent from Air Techniques
	Laser fluorescence caries detection devices such as the Spectra from Air Techniques
Parallel Port	Phosphor plate scanners such as the ScanX from Air Techniques
S-video port on a video capture card	Video cameras such as the Acclaim Intra-oral camera from Air Techniques
SCSI Card	Various flatbed scanners such as the Perfection 4870 Photo Scanner from Epson Expression 1680 Pro Scanner from Epson ScanMaker 9800XL Scanner from Microtek

Visix Imaging is comprised of five (5) main areas: Patients, Images, Acquire, Mount, and View. Additionally, there is an Export Image function and a Print function.

Visix Imaging includes software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

11.2.1 Patients

The Patients window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

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11.2.2 Images

Images on the Image bar are displayed based on their age, i.e., the newest image will be displayed first. Images can be deleted, opened in the View window for viewing and manipulation, mounted, or printed.

Additionally, by right clicking on a specific image, the user will be able to copy an image, archive an image, export an image, print a report, view/designate the anatomical region of the image, add/delete keywords, flip the image, rotate the image, and view image properties such as where the image is stored and how large it is.

Exported image files save to the local hard drive or a network hard drive as a jpeg, bitmap or tiff image file (the type of file is selected by the user).

11.2.3 Acquire

Images are entered into Visix through one of the devices listed in the Acquire area. The input methods consist of x-rays, video, photos/documents/images acquired by a flatbed scanner, and imported digital images.

<u>Optional Software Settings for Devices</u>
The following is an overall list of options available to the user to fine-tune images. Not every option is available for every hardware device.

- Advanced Settings
  Advanced settings are specified by the device manufacturer.

- Allow Scan Edit
  When enabled, this option permits the user to draw selection boxes around images, or edit the selection boxes Visix Imaging draws automatically if the Auto-Segment option is enabled. Allow Scan Edit is only available for flatbed scanners.

- Auto-Flip
  When an image is Auto Flipped the view is as though the user is sitting on the other side of the item being x-rayed looking toward the x-ray head.

- Auto-Optimize
  This option is only available for flatbed scanners. When enabled, Auto-Optimize is used to make a flatbed scanner image a true 8-bit image with its greater range of grayscale values. See section 11.2.7 for more detail.

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- Auto Re-arm
  When enabled, as soon as one x-ray is taken, the device (typically a sensor) will automatically become ready to take another x-ray.

- Auto-Segment
  When enabled, Visix attempts to recognize separate items on a scanner bed as separate images. For example, when scanning standard size negatives, a green box is placed around each negative indicating that the area within the box is recognized as a standard size negative. A blue box is placed around an item that is not recognized as a standard size negative but is recognized as a separate item to scan.

- Brightness
  Raises or lowers the lightness of every pixel in the image.

- Contrast
  Makes white areas whiter and black areas blacker in an image. This has the effect of making details more noticeable in the image.

- DEMS
  Allows specification of threshold values for the Dynamic Exposure Monitoring System. See section 11.2.8 for more detail.

- Display Size
  This option is only available for video cameras. Display size allows the user to determine how large the image from the camera displays on the screen.

- Edge Enhancement
  When Edge Enhancement is enabled, edges within an image will appear more defined. Edge Enhancement tends to give an image a "salt and pepper" look.

- Extra-oral Settings
  Extra-oral images are much larger images than intra-oral images. Extra-oral settings are the same settings as intra-oral settings except that they are applied against larger images.

- Film Mask
  A Film Mask is a black border around the image similar to a mat around a photograph. The border can make the edges of the image appear sharper.

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- Gamma / Gray Shift
  Raises or lowers the lightness of the mid-range grayscale values without changing the whitest or blackest values on an image.

- Image Orientation
  This option lists each size of phosphor plate and sensor along with the default acquisition orientation - vertical or horizontal - for each size. The user may change image orientation at any time before or after acquisition.

- Image Resolution
  Image resolution (e.g. very high, high, standard) determines the amount of detail that an image will have. Selecting a high or very high resolution will result in a greater amount of detail in the resulting image. It will also save a larger digital image file that requires more hard drive space. For most images, a standard resolution is acceptable.

- Network Settings
  Some devices may be controlled by computers other than the computer the device is physically connected to. Network settings identify the computer and the ports used to acquire images from these devices.

- Prompt for Date
  If enabled, the user is prompted to specify the date the image was taken. If disabled, the current date is used as the image date.

- Reset
  Restores the default settings that came with Visix Imaging.

- Shared / Exclusive
  If more than one computer can control a device, the device can be set to either Shared mode or Exclusive mode. When in Shared mode, multiple computers can acquire images from the device. When in Exclusive mode, only one computer can acquire images from the device.

- Smoothing
  Smoothing attempts to remove any extra “noise” (miscellaneous black dots) from the image that was caused by applying edge enhancement.

- Timeout Value

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Timeout Value specifies how much time a sensor should wait before placing itself in low energy mode.

- Trim
  Removes extraneous black dots from the outside edges of the image.

Software enabled setting options for the different types of hardware devices vary and are listed in the following Device Specific Settings chart:

Device Specific Settings	Phosphor Plate scanners such as the ScanX	Video Cameras such as the Acclaim	Sensors such as the Accent	Flatbed Scanners	Laser Fluorescence devices such as the Spectra
Advanced Settings		x			x
Allow Scan Edit				x	
Auto Flip	x		x		
Auto-Optimize (Adaptive Image Processing or AIP)				x	
Auto Rearm			x		
Auto-Segment				x	
Brightness	x		x	x	
Contrast	x		x	x	
DEMS	x			x	
Display Size		x			
Edge Enhancement	x		x		
Extra-oral Settings	x				
Film Mast	x			x	
Gamma / Gray Shift	x		x	x	
Image Orientation	x		x	x	
Image Resolution	x		x		
Network Settings	x				
Prompt for Date				x	
Shared / Exclusive Use	x				
Smoothing	x		x		
Timeout Value			x		
Trim	x				

Chart 1

Image activities after an image has been acquired into Visix

- Auto or Manual Mounting
  When enabled, the auto-mount function automatically places acquired images into a previously created mount in the order in which they are acquired. Alternatively, images may be manually placed in mounts through dragging and dropping the desired images into image placeholders on a mount. See section 11.2.4 below for more information.

- Image Buttons
  After images have been acquired, single or multiple images may be selected and then deleted, viewed, or saved.

- Open an Image into the View window
  Images may be opened into the View window by:
  - Double-clicking on one image
  - Single clicking on one or more images and then clicking on the View button
  - Single clicking on one or more images and then right clicking once on one of the selected images and selecting View from the Right Click Menu

  See section 11.2.6 below for more information on the View window.

- Print an Image Report
  The Image Report may be printed from the main Visix window, the View window or the Right Click Menu. See section 11.2.5 below for more information.

- Right-Click Image Menu
  Some image manipulation functionality is available via the right-click image menu, including:
  - Mounting an image
  - Opening an image into the View window
  - Printing an image
  - Deleting an image
  - Copying an image to the clipboard
  - Moving an image to a user specified archive location
  - Exporting an image outside of Visix Imaging
  - Moving an image to a different patient
  - Specifying the anatomical region of the image
  - Assigning keywords to an image
  - Changing the orientation of an image (flip or rotate)
  - Viewing image properties

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11.2.3.1 Acquire X-ray Images

Various x-ray devices, such as the ScanX scanner and the Accent sensor, are compatible with Visix Imaging. X-rays from phosphor plate scanners such as the ScanX are acquired in the ScanX window, and x-rays from sensors such as the Accent are acquired in the Accent window. See the Device Specific Settings chart (Chart 1) above for user specified device settings for each.

11.2.3.2 Acquire Video Images

Various video cameras, such as the Acclaim intra-oral camera, are compatible with Visix Imaging. Video images from video camera devices are acquired in the Acclaim window using the Freeze function and the Save function. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, video options include the specific video camera device from which to capture images and the specific type of input such as S-Video.

11.2.3.3 Acquire Laser Fluorescence Images

Laser fluorescence images are acquired in the Spectra window (a laser fluorescence caries detection device) using the Freeze function and the Save function. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, options include Detection (of caries) and Analysis (of plaque).

11.2.3.4 Acquire images from a Flatbed Scanner

Images from a flatbed scanner are acquired in the Scan Film window. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, the only option for Flatbed Scanning is selecting the appropriate TWAIN driver that matches the scanner that is connected to the computer.

11.2.3.5 Acquire Imported Images

Digital images, documents, and photos may be acquired through the import of various file types in the Import window. The only import option is the user specified name and location of the file to import.

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11.2.4 Mount Window

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing photographs in a cardboard mat that has multiple openings. Mounted images can be viewed, printed, exported, or otherwise manipulated together as one image. The images contained in the mount can also be viewed and manipulated individually. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function that automatically places newly acquired images into an existing mount.

Using the right-click menu on an image holder in the mount, the user is able to perform the following functions:

- Automatically assign a specific anatomical region to the image that is moved to that mount location
- Automatically assign specific keywords to the image that is moved to that mount location
- Change the image holder orientation from vertical to horizontal or from horizontal to vertical
- Automatically flip any image placed in that image holder
- Delete the image holder

Using the right-click menu on an image in an image holder, the user is able to perform the following functions:

- Open the image into the View window
- Place a copy of the mounted image in the area below the Mount box
- Copy the image to the clipboard
- Show or hide any annotations that have already been placed on the image
- Remove the image from the Mount

Additionally, basic image manipulation functionality is available via the Right Click Menu, including copying, archiving, exporting, assignment of an anatomical region, addition of keywords, image flip, rotation, viewing of properties, and printing.

11.2.5 Print

A predefined report that includes one or more images accompanied by patient, practice, and provider information will print. A sample of the report appears on the last page of this section.

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11.2.6 View Window

The View Window may be used to examine, manipulate, and place measurements and annotations on an image. The View Window provides the capability of manipulating multiple images at once. Various tools are available for use in the Viewer Window:

- Zoom
  Narrows or broadens the view of an image. Zooming in (enlarging) focuses on a specific area of an image that has been enlarged. Zooming out (reducing the size of an enlarged image) broadens the view until the image is returned to its original size.

- Full Screen
  Fills the Viewer Window with the selected image.

- Reset Zoom
  Resets the image to its original size.

- Rotate
  Allows the image to be turned by either 90º or 180º at a time.

- Flip
  Allows flipping of the image, either left-to-right or top-to-bottom.

- Reset Orientation
  Returns the image to the original orientation.

- Automatically Arrange Images
  Places images in the View window in the position they occupied when the View window was originally opened.

- Manually Arrange Images
  Allows images to be manually moved to any position in the View window. Also allows the image size to be manually adjusted.

- Measure
  Allows the measurement of the distance between points or the angle between intersecting lines. For some devices, calibration is required before measurements are made. Measurement lines may remain on the image and be displayed, may remain on the image and be hidden from sight, or may be deleted.

- Annotate

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Provides tools with which to add, edit or delete annotations on the image, including text, shapes, lines, arrows, freehand drawing, and options to customize each of these including size, font, and color. Annotations may remain on the image and be displayed, may remain on the image and be hidden from sight, or may be deleted.

- Magnifying Glass
  Permits closer visual inspection of a particular region of an image using different-sized areas and shapes of magnification, different magnification amounts, and the application of effects such as increased contrast, inversion, or colorization.

- Print Image
  Opens the Microsoft Print window in order to print the image in a pre-setup report that includes the image plus some patient, provider and practice information.

- Negate
  Converts image areas that are black to white, and areas that are white to black.

- Colorize Image
  Substitutes colors for grayscale values in an image.

- Pseudo 3D
  Applies a 3-D effect to the image.

- Sharpen Image Edges
  Increases contrast on edges in the image, causing the edges to be more easily seen.

- Reset Original Image
  Resets the image to its original state when the View Window was opened.

- Remove From Viewer
  Removes the image from the View window. This function does not delete the image from Visix Imaging.

- Brightness and Contrast
  Changes the brightness and contrast levels of the image.

- Gray Shift (Gamma) Slide Bar
  Leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker.

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11.2.7 Adaptive Image Processing (AIP) / Auto-Optimize

Flatbed scanners cannot properly interpret what should be pure white or pure black, since the film being scanned is not completely transparent or opaque in these areas. Auto-Optimize, the flatbed scanner version of AIP, takes the lightest white and makes it pure white, and the darkest black and makes it pure back. It then adjusts the grayscale values of the image to fall between those values, increasing the sharpness of the image and using a full 8-bit grayscale that would otherwise be lost by the scanner.

For x-ray images, Adaptive Image Processing (AIP) takes into account the medical use of the image and removes unnecessary information to reduce the size of the image file. For example, Visix Imaging removes image information relating to the cheek in front of the teeth being x-rayed.

11.2.8 Dynamic Exposure Monitoring System (DEMS)

The Dynamic Exposure Monitoring System is an aid to the user in quickly identifying x-ray images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data available in the image to render the object being imaged. The amount of data (measured in terms of bits) required to meet the criteria for determining these status colors is specific to each hardware device supported by Visix Imaging based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software prompts the user to retry image acquisition. Each hardware device has threshold bit levels set by default on installation, and users are advised not to change these values without consulting a Visix Imaging representative.

The DEMS system of indicator lights is not intended to serve as a diagnostic tool, but rather provide a quick visual to the user that an image may need to be retaken. Threshold values affect how many warnings a user may receive during image acquisition; higher thresholds will require higher quality images that may prompt the user to reacquire images more frequently. Lower thresholds may not prompt the user to reacquire an image frequently enough.

Whether prompted or not, the user makes the decision to accept the image or change the x-ray hardware settings and reacquire the image.

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Visix

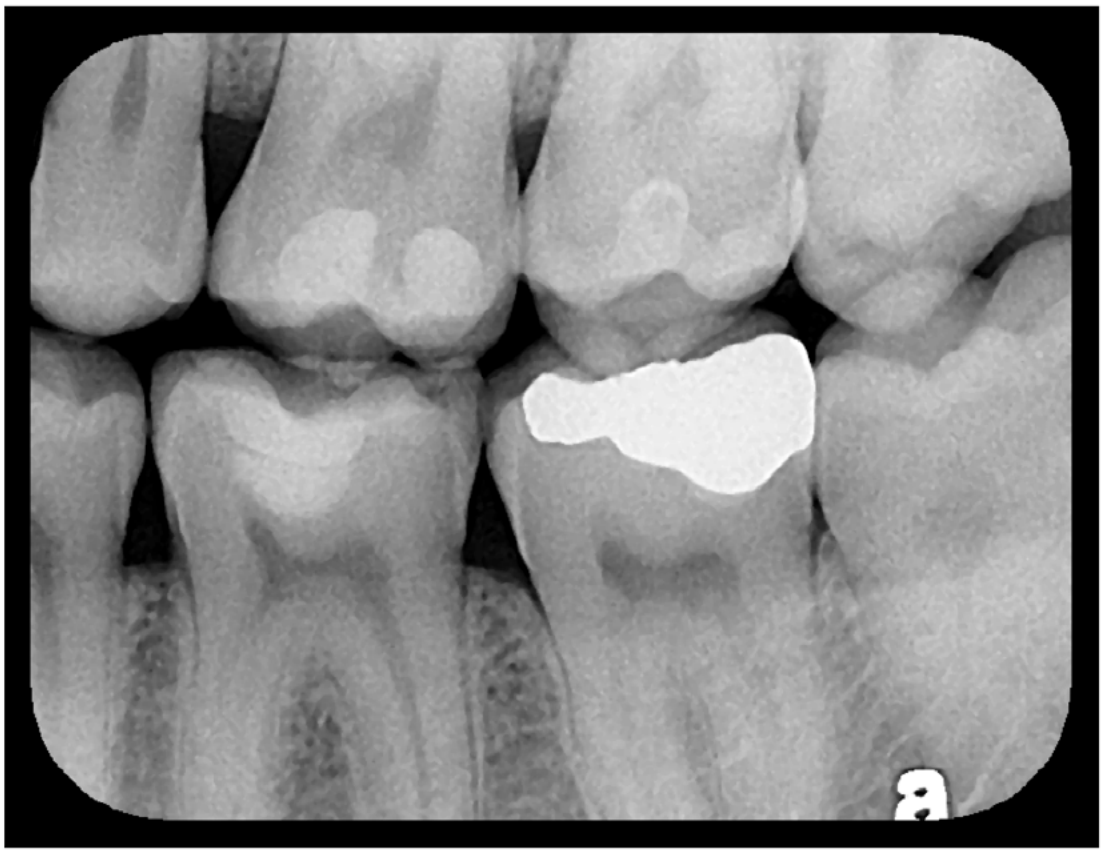
Sample Reports

Image Report

(b)(4)

[redacted]

Visix Imaging



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

[redacted]

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SUBSTANTIAL EQUIVALENCE AND PREDICATE COMPARISON

Visix Imaging is substantially equivalent to the following predicate devices:

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
Tau Corp. (Televere Systems)	TigerScan/TigerView	K955237
EagleSoft	EagleSoft ChairSide Software Application	K982422

This conclusion is based on the following aspects:

Indications for Use:

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic imaging devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes and measurements.

It is intended to acquire, display, edit (e.g., adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison:

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS). Visix Imaging is compatible with similar types of hardware devices (e.g. scanners, digital video camera, etc.) and has similar options for displaying, editing, and printing images as the predicate devices.

A more detailed comparison of the features and performance of these devices is provided in the following table.

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Indications for Use	Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes and measurements. It is intended for use by radiologists, clinicians, and physicians to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images	TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data. It is intended for use by radiologists, clinicians, and physicians to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store,	Uses of TigerScan and TigerView in the dental industry include the following: - Scanning of film and archival storage for on-line access by patient - Electronic transmission of digital radiographs with insurance claims. - Radiograph viewing and manipulation for diagnostic purposes, patient education and consultation, and insurance claims adjudication. - Electronic transmission	EagleSoft's ChairSide is a clinical software program that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audio recordings, and clinical exam data. In addition, it also offers an imaging module for image acquisition, editing, and storage of digital images. It is designed to be a single-source solution for a dentist's software needs for clinical and diagnostic use when serving the general public. Images can be acquired from standard dental imaging devices including Digital Radiographic Devices, Digital Video Capture Devices, and Generic Image

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
	using standard PC hardware.	print, and distribute images using standard PC hardware.	of radiographs to specialists for consultation.	Devices such as scanners. Non-diagnostic images can then be edited (i.e. resized, contrast, cropped, etc.). Images can also be easily imported and exported.
Patient/Image Management	Yes	Yes	Yes	Yes
Acquire Images				
X-ray (i.e., Phosphor Plate, Digital Sensor, Digital Panaromic)	Yes	Yes	Yes	Yes
Laser Fluorescence Caries Detection	Yes	No	No	No

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Video	Yes	Yes	No	Yes
Photos	Yes	Yes	No	Yes
Documents	Yes	Yes	No	Yes
Import	Yes	Yes	Yes	Yes
Display Images	Yes	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes	Yes
Produce Reports	Yes	Yes	Yes	Yes
Print/Export Images	Yes	Yes	Yes	Yes

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Enhance Images:				
Brightness	Yes	Yes	Yes	Yes
Contrast	Yes	Yes	Yes	Yes
Colorize	Yes	Yes	Yes	Yes
Crop	No	Yes	Yes	Yes
Rotate	Yes	Yes	Yes	Yes
Zoom In/Out	Yes	Yes	Yes	Yes
Invert	Yes	Yes	Yes	Yes
Sharpen	Yes	Yes	Yes	Yes
Measure	Yes	Yes	Yes	Yes
Over/Under	Yes	Yes	Yes	Yes

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Exposure Annotate	Yes	Yes	Yes	Yes
Run on standard PC-compatible computers	Yes	Yes	Yes	Yes

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PRODUCT LABELING

The labeling for the proposed device, Visix Imaging, follows this page. The labeling includes:

Part 1 This document, 1 page
Part 2 Visix Imaging Manual, 157 pages
Part 3 Visix Imaging Administration Manual, 27 pages
Part 4 Visix Imaging CD label, 1 page
Part 5 A web site about Visix Imaging with the documents printed from that web site, 22 pages
Part 6 A Visix Imaging marketing document, 1 page

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Perfecting Your Practice…

Visix Imaging Manual

Dental Imaging Software

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Indications for Use

Visix is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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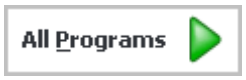
How To Open Visix

On your desktop, double click on the Visix icon.

Or

On your desktop, click on the Start button

Go to All Programs 

Select Visix Imaging

Then select Visix again.

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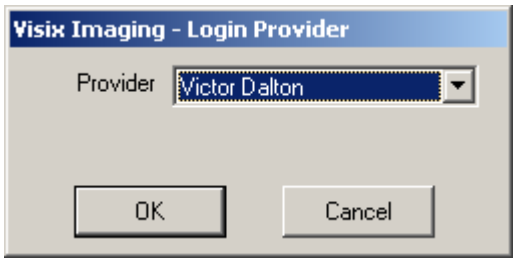
Select a Provider

The first Visix window that opens is the Select Provider Window.



A provider is a doctor. If the name that displays is the correct provider click on the Login button. Otherwise, click on the User Name down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, click on the cancel button to exit Visix then open Visix Administration and enter a new provider. For instructions on how to use Visix Administration, please refer to the Visix Administration manual.

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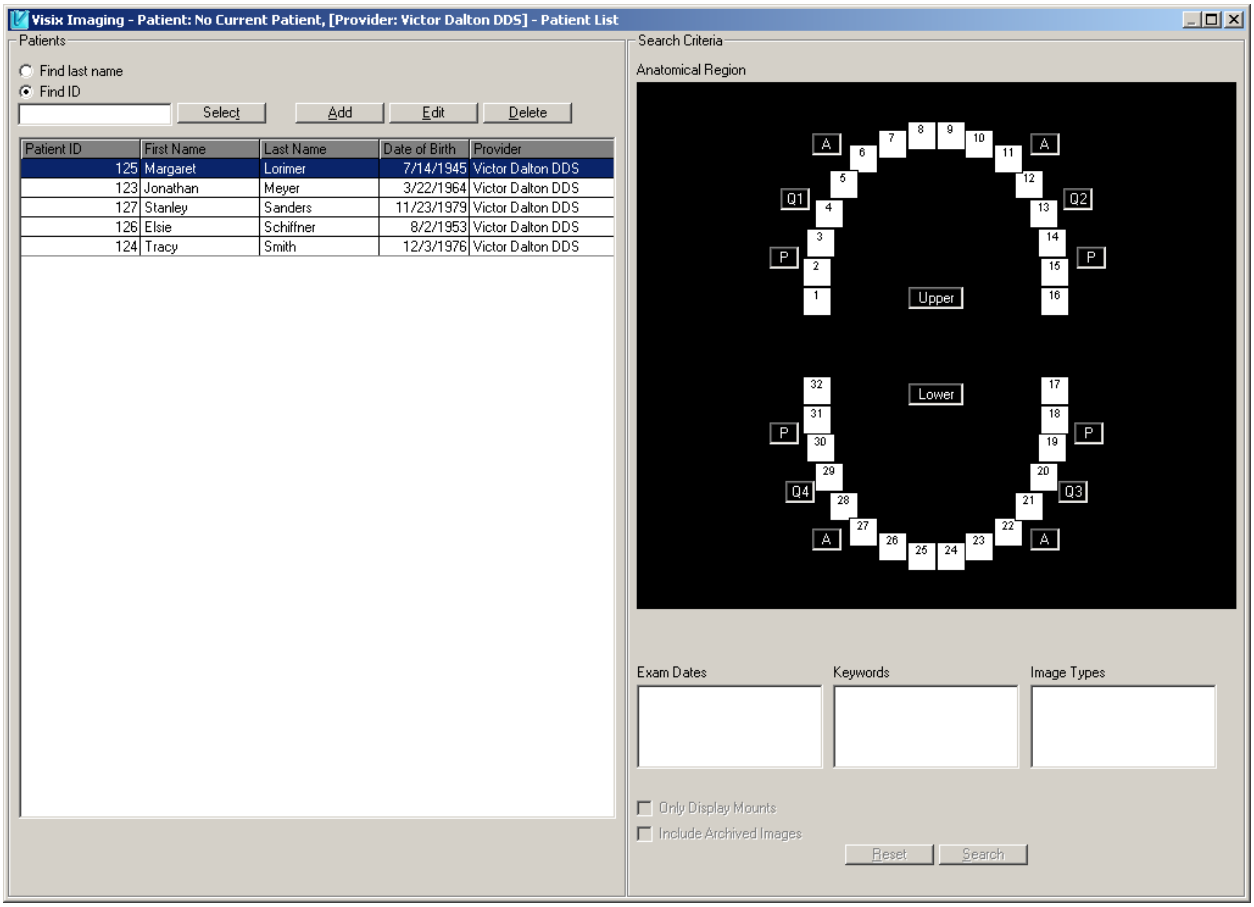
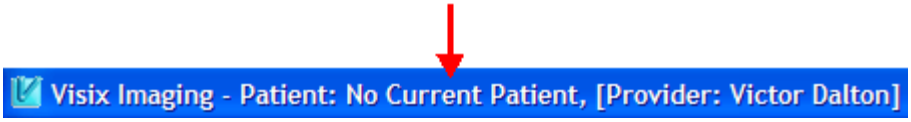
Patients Window



The Patient window is broken up into two sections: a Patients area where a patient is selected, added, deleted, or has his information edited, and a Search Criteria area which is used to locate specific images.

Patients Area

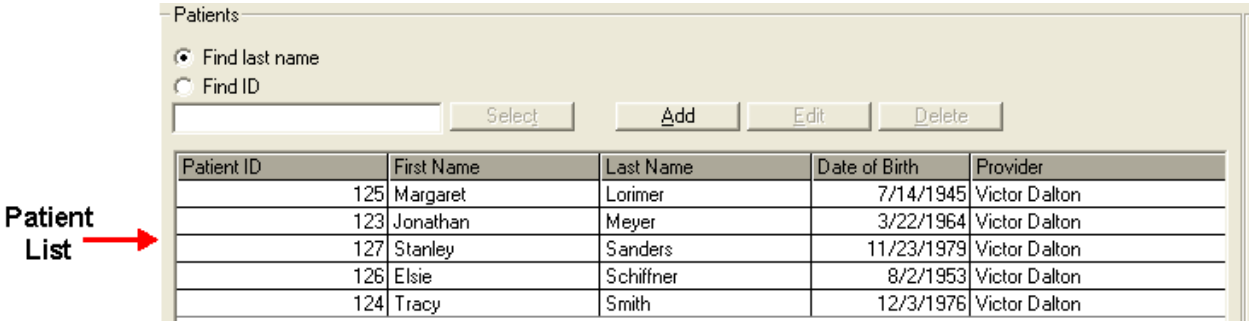
The Patient window initially opens without a patient selected. Notice on the top bar of the window where the provider, Visix icon, and Visix name display, the message “No Current Patient” also displays.



After a patient is selected the patient's name will display here.

Always check this area of the screen to make sure that the correct patient is selected before starting an activity in Visix.

Display Existing Patients

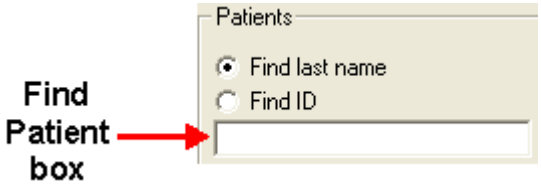


Patient ID	First Name	Last Name	Date of Birth	Provider
125	Margaret	Lorimer	7/14/1945	Victor Dalton
123	Jonathan	Meyer	3/22/1964	Victor Dalton
127	Stanley	Sanders	11/23/1979	Victor Dalton
126	Elsie	Schiffner	8/2/1953	Victor Dalton
124	Tracy	Smith	12/3/1976	Victor Dalton

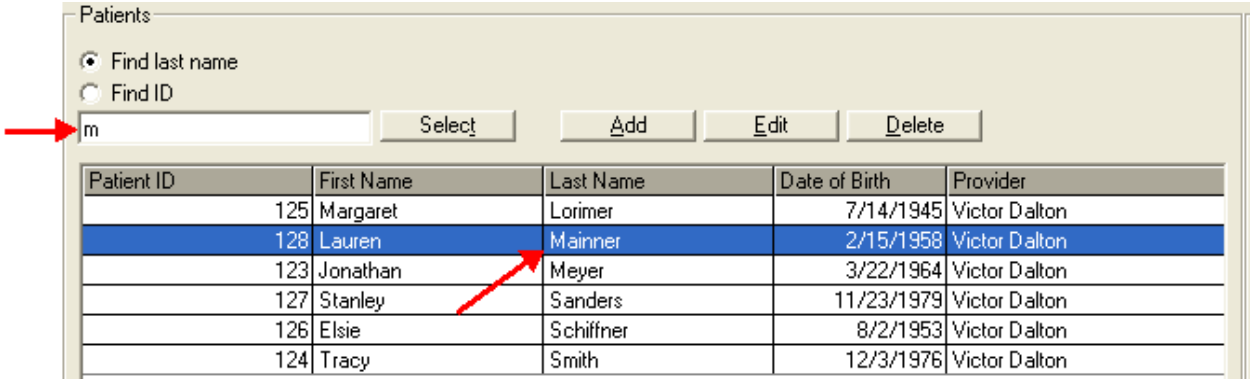
In the Patient List inside Visix, patients are listed in alphabetical order by last name.

Find a Patient

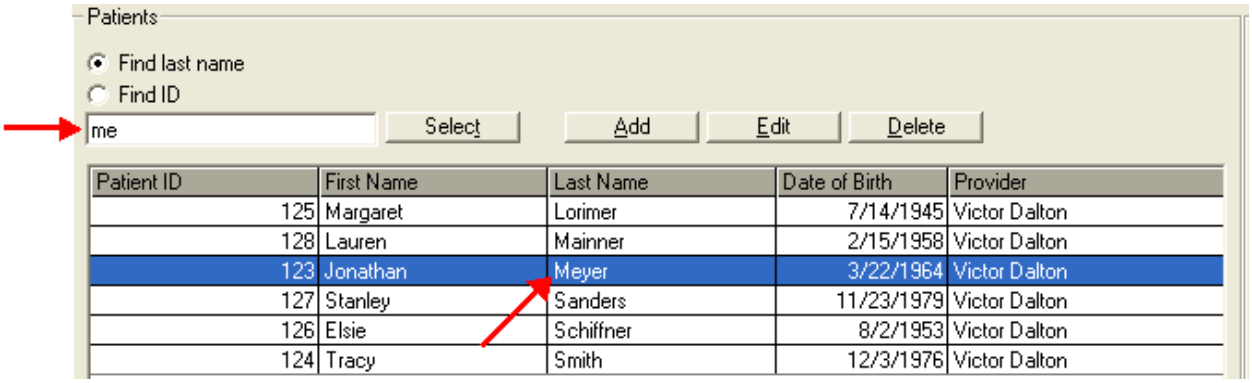
Click on the Find Last Name radio button to find patients by their last name, or on the Find ID radio button to find patients by their ID, then enter either the patient's last name or ID into the Find Patient box.



As information is entered into the Find Patient box, Visix will advance through the list of patients, moving to the first patient whose last name or ID is the same as the entry in the Find Patient box.



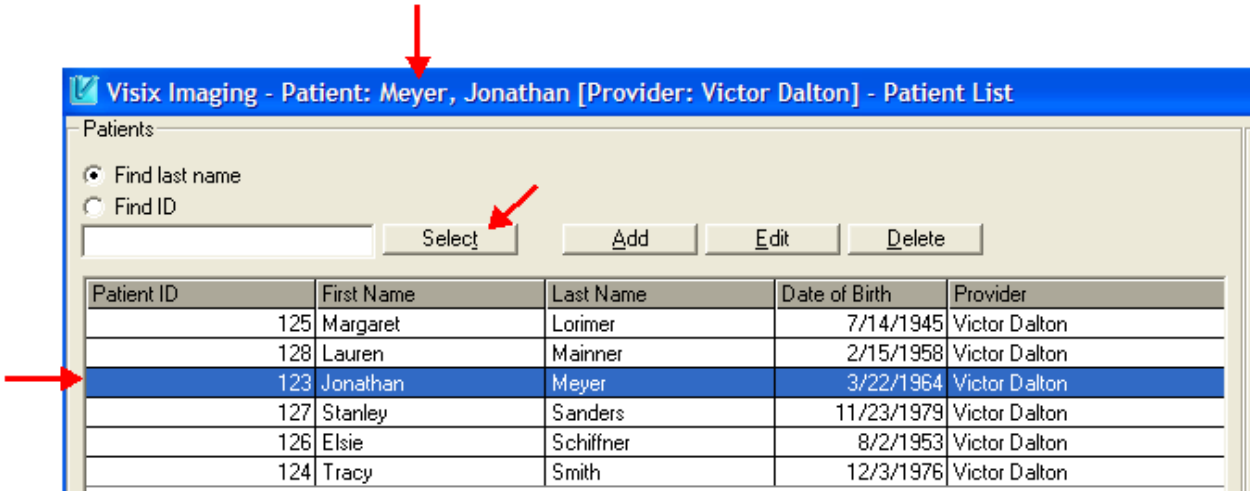
In the example above, the patient is being found by their last name and the letter “m” was entered into the Find Patient box. Visix moved to the first patient in the Visix Patient List whose last name begins with the letter “m”.



In this second example, the letters “me” were entered into the Find Patient box. Visix moved past “Mainner” whose second letter is an “a” to “Meyer” whose second letter is an “e” which matches the Find Patient criteria.

Select a Patient

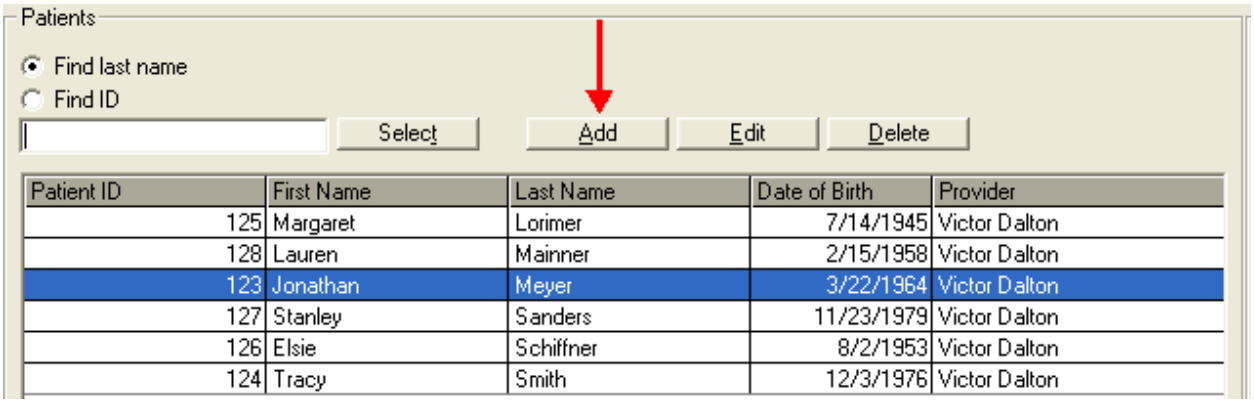
To select a patient, double click anywhere on the patient’s information in the patient list (Patient Name, ID, Date of Birth, or Provider) or click on the Select button. The patient’s name will display in the top bar of the Visix window letting you know which patient has been selected.



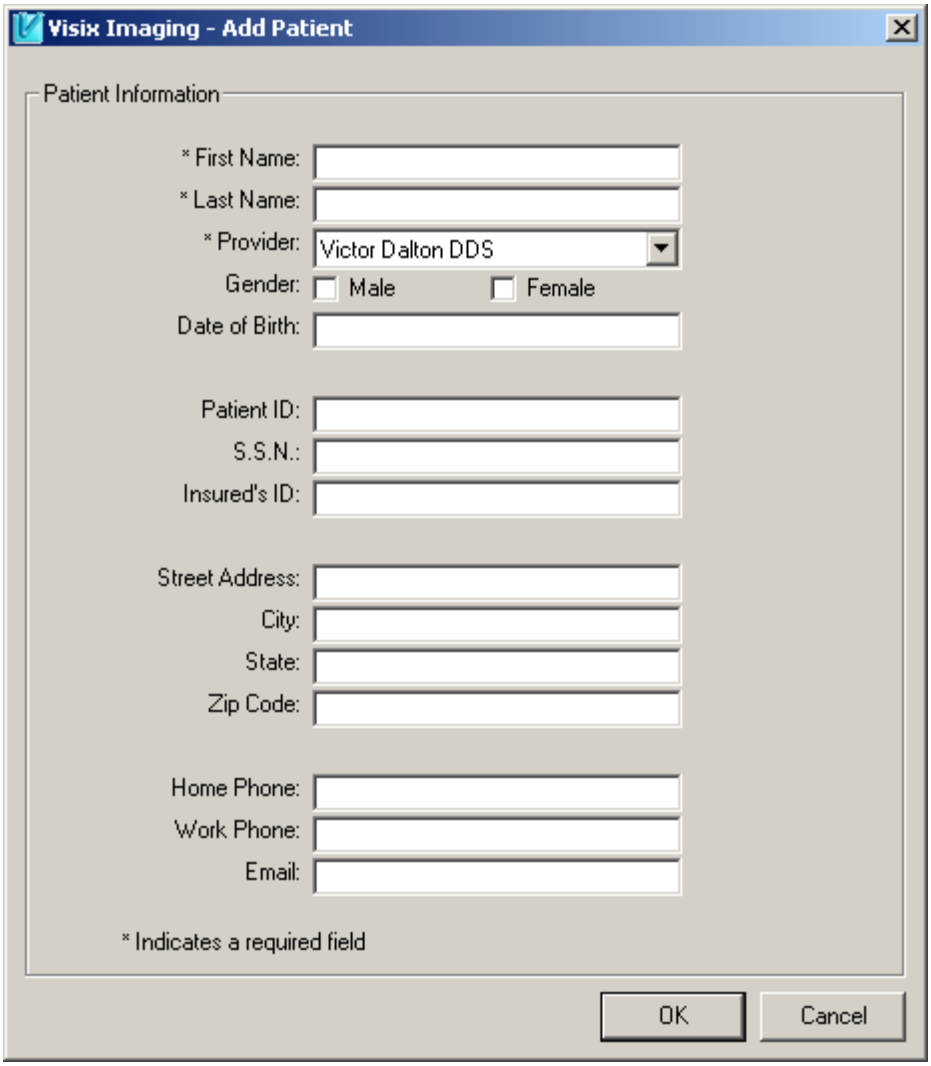
Once the patient has been selected, the main Visix window appears with the patient's images displayed on the right hand side in the Images window.

Add a Patient

To add a new patient, click on the Add button at the top of the Patients window.



The Add Patient window will display.



First Name

Enter the first name of the patient. This is required to save the record.

Last Name

Enter the last name of the patient. This is required to save the record.

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Provider

Select the correct provider from the drop down box. This is required to save the record.

Gender

Select Male or Female to specify the gender of the patient.

Date of Birth

Enter the date the patient was born. Include slashes as a separator and a four-digit year. (ex. 11/23/1985)

Patient ID

Enter the ID this patient will use in Visix.

S.S.N.

Enter the patient's Social Security Number. All X's can be substituted.

Insured's ID:

If applicable, enter the ID for the Insured party for the patient.

Street Address

Enter the street address of the patient.

City

Enter the city the patient lives in.

State

Enter the state the patient lives in.

Zip Code

Enter the zip code the patient lives in.

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Home Phone

Enter the home phone number of the patient. If you would like the phone number to display with separators for ease of viewing, such as dashes, enter them.

Work Phone

Enter the phone number where the patient works. If you would like the phone number to display with separators for ease of viewing, such as dashes, enter them.

Email

Enter the e-mail address the patient uses.

OK

Click on the OK button

at the bottom of the Add New Patient window to save the patient record. The patient record can be saved at any point after the patient's name and providers' name have been entered. Once saved, the patient record will appear in its alphabetical position by last name.

Cancel

Click on the Cancel button

at the bottom of the Add New Patient window to close the window without any further saving.

Edit a Patient

To change information in a patient record, left click once on the patient in the Patient List, and then click on the Edit button at the bottom of the Patients section of the Patients window.

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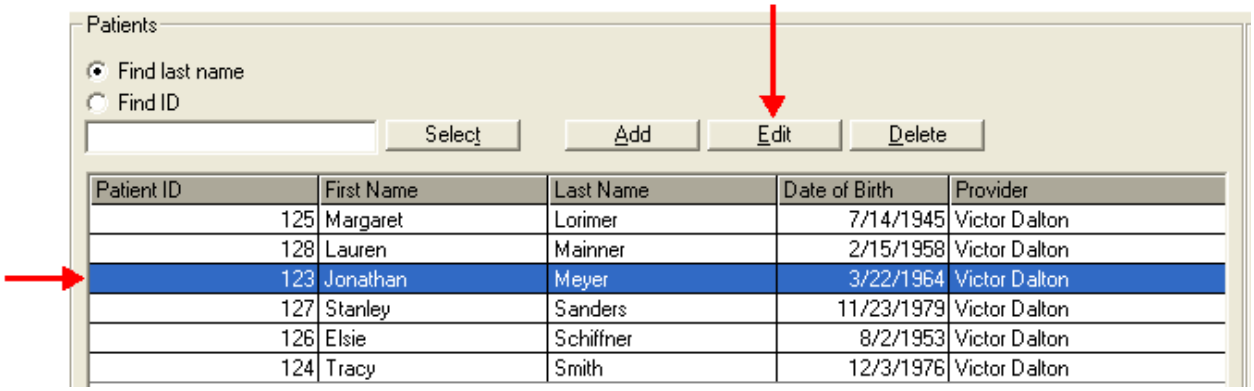
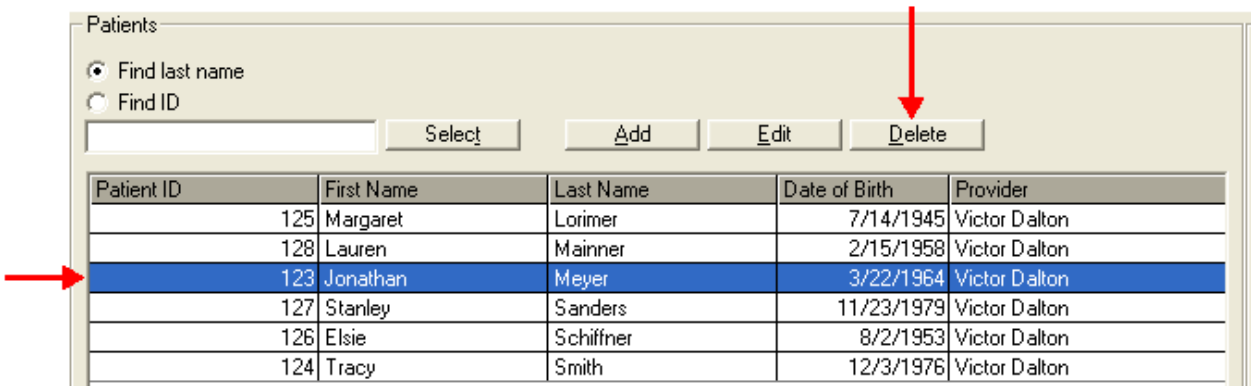


The Edit Patient Info window will display. The Edit Patient Info window contains the same information fields as the Add New Patient window. For an explanation of each entry please refer to the Add A Patient section of this manual.

Delete A Patient

To delete a patient, left click once on the patient in the Patient List, and then click on the Delete button at the bottom of the Patients section of the Patients window.



A window that asks if you are sure that you want to delete the patient <u>and all of the patient's images</u> will appear. Check the patient name at the top of the Visix window to make sure this is the correct patient before proceeding.

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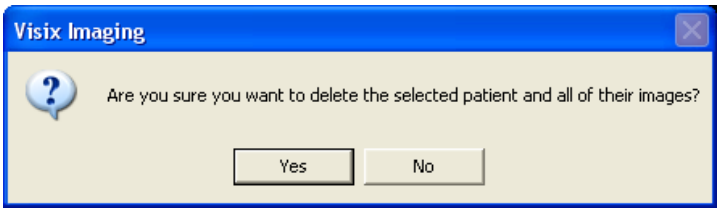
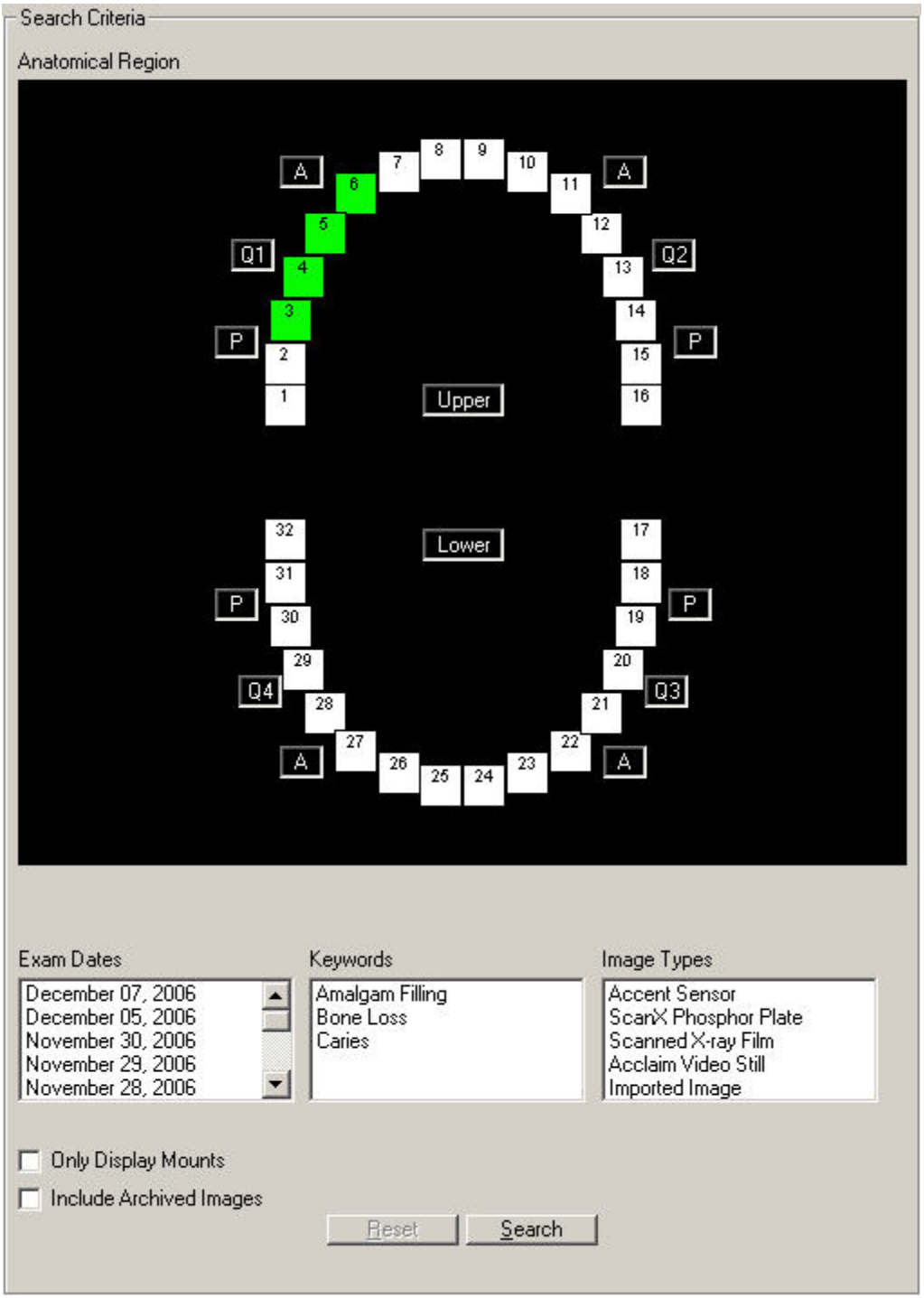


Click on yes if you are sure that you want to delete the currently selected patient with all of his or her images. Click on No if you are not sure.

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

Patients Window



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

Search Criteria Area

The Search Criteria section of the Patient window is used to find a specific image, or group of images, from among a potentially large number of images.

The search decision involves the information that is displayed in the Anatomical Region, Exam Dates, Image Types, and Keywords list boxes in the Search Criteria section of the Patients window. Click on any information in each list box that can be used to narrow the image search.

The anatomical region diagram allows you to search for images that have the selected teeth displayed in the image. If any images have anatomical information specified, the Anatomical Region diagram will color the corresponding teeth green. To search for images of a specific tooth or teeth, click on the green teeth to turn them blue. To search for standard sets of teeth click on “A” for anterior, “P” for posterior, “Q1”, “Q2”, “Q3” and “Q4” buttons for a quadrant, and “Upper” and “Lower” buttons for all teeth in either the Upper or Lower Arch.

When “Only Display Mounts” is checked, clicking the Search button will filter out all single images and display only mount images.

Click on the Include Archived Images check box if there are any archived images that should also be searched.

Double-clicking on the patient’s name in the Patient List will over-ride the search criteria and display all of the patient’s images.

For example, referring to the Search Criteria window section pictured above, a search could be narrowed to only those images that have teeth with amalgam fillings where the x-ray was taken on 11/28/2006 or 12/7/2006 using a ScanX Phosphor Plate. To do this, the Amalgam Filling entry in the Keywords list box would be clicked on, the ScanX Phosphor Plate entry in the Image Types list box would be clicked on, and the 11/28/2006 and 12/7/2006 dates in the Exam Dates list box would be clicked on. When the Search button is then clicked, only those images that were of an Amalgam Filling that were taken on 11/28/2006 and 12/7/2006 using a ScanX would display.

The anatomical region for an image can be assigned using the Right Click Image Menu (see the Right Click On An Image section of this manual) or by assigning an anatomical region to a mount hole in the Mount window (see the Mount Window section of this manual).

Keywords can be assigned to an image in the same ways the anatomical region can be assigned.

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

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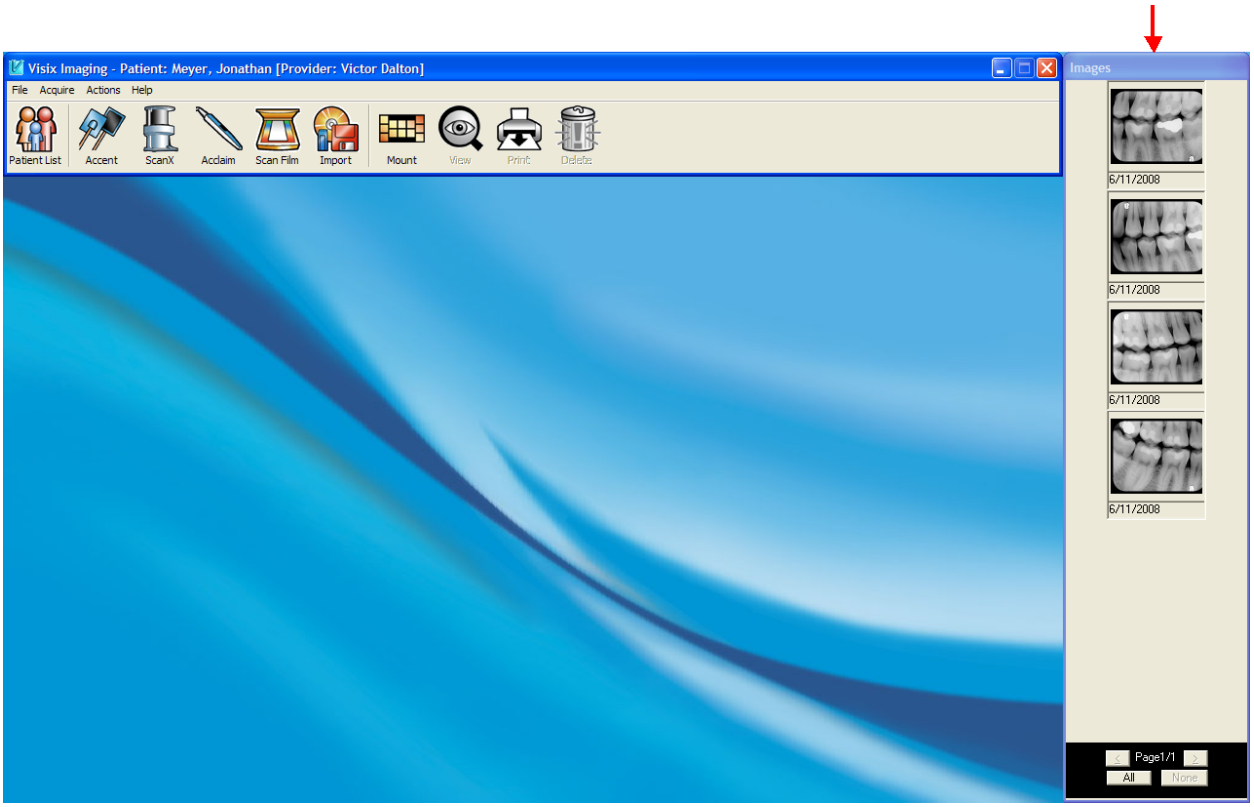
The information in the Exam Dates and Image Types list boxes in the Search Criteria area is automatically entered when the image is acquired.

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

Images Window



The Images window is the vertical window on the right side of Visix. The images displayed on the Images window belong to the patient whose name appears at the top of the Visix window. To learn how to change patients see the Select A Patient section of this manual.

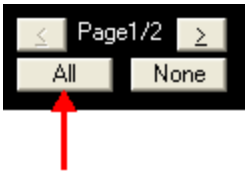
The images in the Image window will display based on their age. The newest images display first. Images can be deleted, exported, opened into the View window for viewing and manipulation, sent to the Mount window for viewing and mounting, or printed.

Select an Image

To manipulate an image in any fashion the image must be selected first.

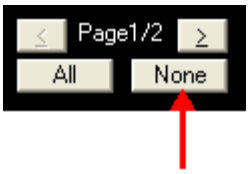
To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images, click on the All button at the bottom of the Images window.

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



Deselect an Image

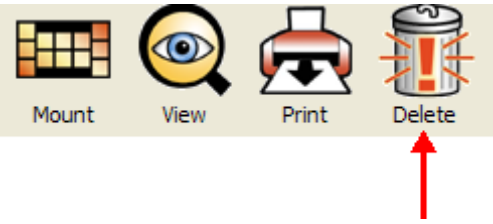
To deselect an image, click on it again. To deselect all of the selected images, click on the None button at the bottom of the Images window.



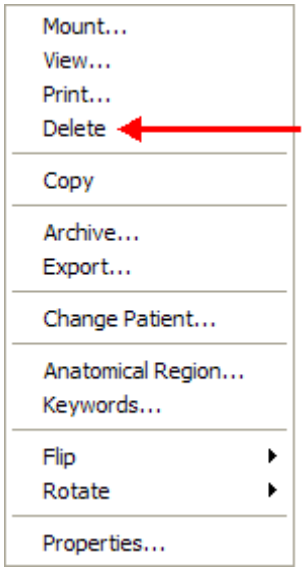
Delete an Image

To delete an image, first select the image or images to be deleted, and then perform ONE of the following steps:

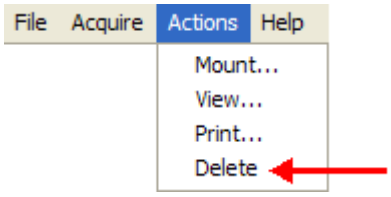
- Click on the Delete button on the top Visix toolbar.



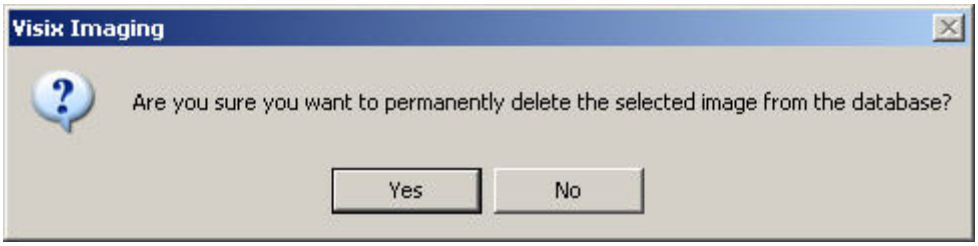
- Right click on one of the selected images and select Delete from the Right Click Menu that appears.



- Click on the Actions Menu on the top Visix toolbar and then select Delete from the drop down menu that appears.



Once the delete option is selected, the following window will open:



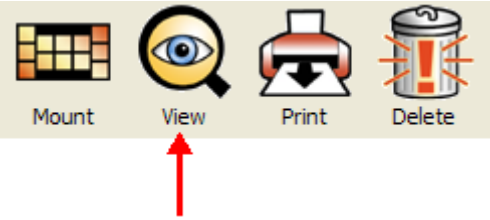
Note: If the Yes button is clicked, the image will be deleted. A deleted image is NOT recoverable.

View an Image

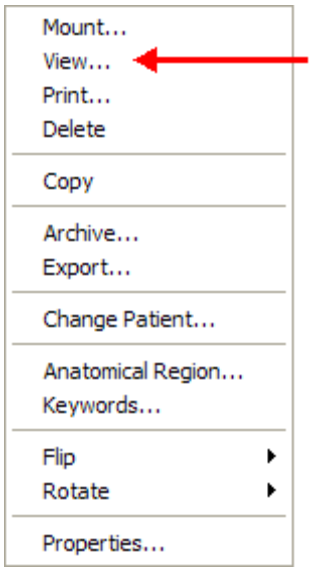
A single image may be opened in the View window by left clicking twice on it. To open multiple images in the View

window, first select the image or images to be viewed, and then perform ONE of the following steps:

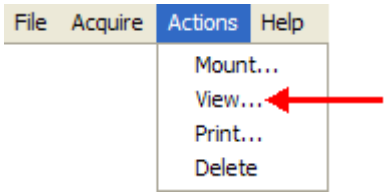
- Click on the View button on the top Visix toolbar.



- Right click on one of the selected images and select View from the Right Click Menu that appears.



- Click on the Actions Menu on the top Visix toolbar and then select View from the drop down menu that appears.

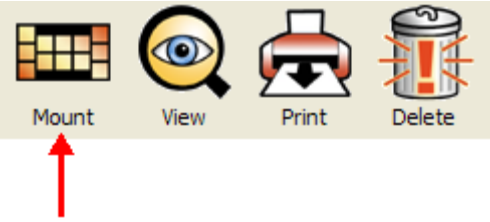


For instructions on how to use the View window, please refer to the View Window section of this manual.

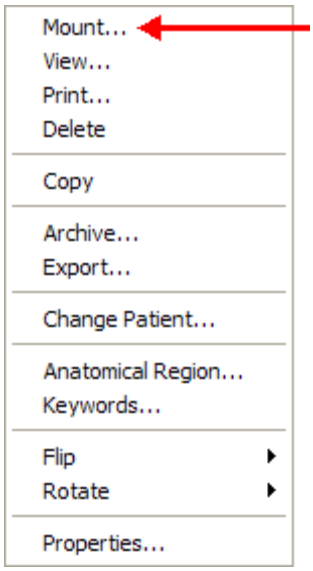
Mount an image

To mount an image or work with an already created mount, click on the mount and/or images that are needed then perform ONE of the following steps:

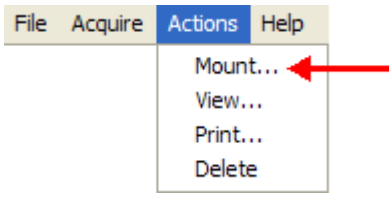
- Click on the Mount button on the top Visix toolbar.



- Right click on one of the selected images and select Mount from the Right Click Menu that appears.



- Click on the Actions Menu on the top Visix toolbar and then select Mount from the drop down menu that appears.

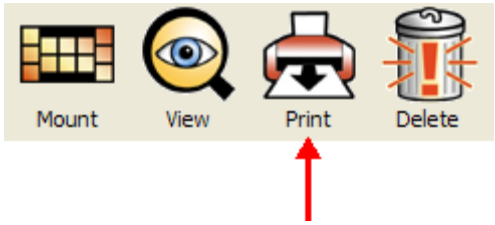


For instructions on how to use the Mount window, please refer to the Mount Window section of this manual.

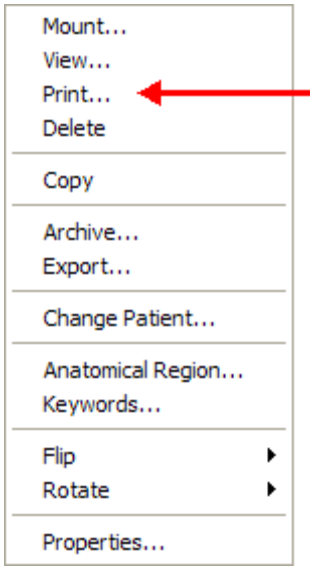
Print an Image

To print an image in a report, click on the image or images that need to be included then perform ONE of the following steps:

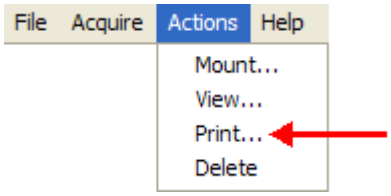
- Click on the Print button on the top Visix toolbar.



- Right click on one of the selected images and select Print from the Right Click Menu that appears.



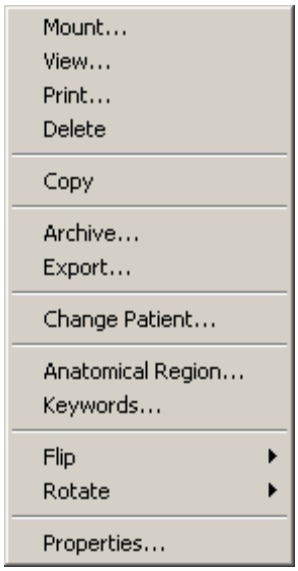
- Click on the Actions Menu on the top Visix toolbar and then select Print from the drop down menu that appears.



The Windows Print window will open to allow the user to select the printer to send the report to, the number of copies to print, etc. The report that prints will display patient, doctor and practice information in addition to the selected images.

Right Click on an Image Menu

When you right click on an image the Right Click Menu will appear:



Mount

The selected images will be opened in the Mount window. For instructions on how to use the Mount window, please refer to the Mount Window section of this manual.

View

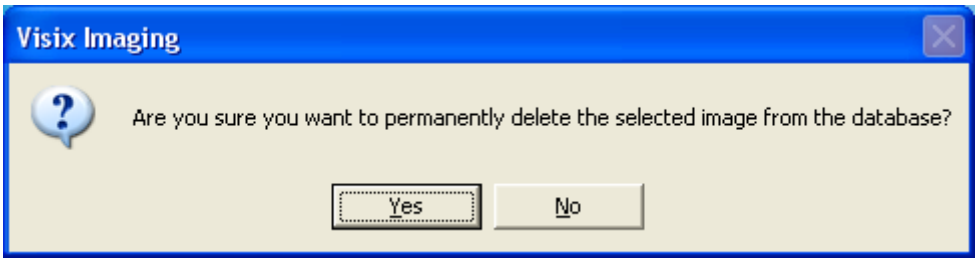
The selected images will display in the View window. For instructions on how to use the View window, please refer to the View Window section of this manual.

Print

The selected image or images will be printed along with the patient's name, ID, gender, and date of birth, the provider's name and phone number, the practice name, address and phone number and the date the image was taken.

Delete

When Delete is selected the following window will display:



Click on Yes to remove the image from Visix. Click on No to cancel the delete. A deleted image can not be recovered.

Copy

The selected image will be copied to the clipboard. The image can then be pasted into another program that uses the clipboard such as Microsoft Word.

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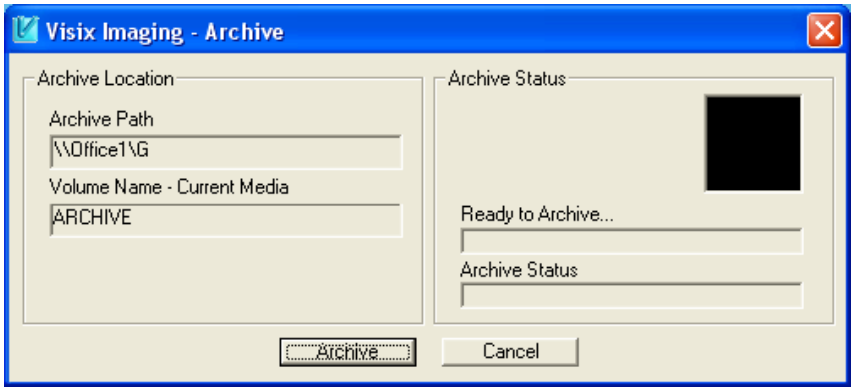
Archive



When an image is archived, the full size image is removed from Visix and placed in the archive location specified in Visix Administration. The thumbnail version of the image remains in Visix. The thumbnail version will not open in the View window. To restore an archived image, right click on the thumbnail version and select Restore.

Export

Exporting is the process by which an image is copied from within Visix to a file outside of Visix. When Export is selected the following window will display:

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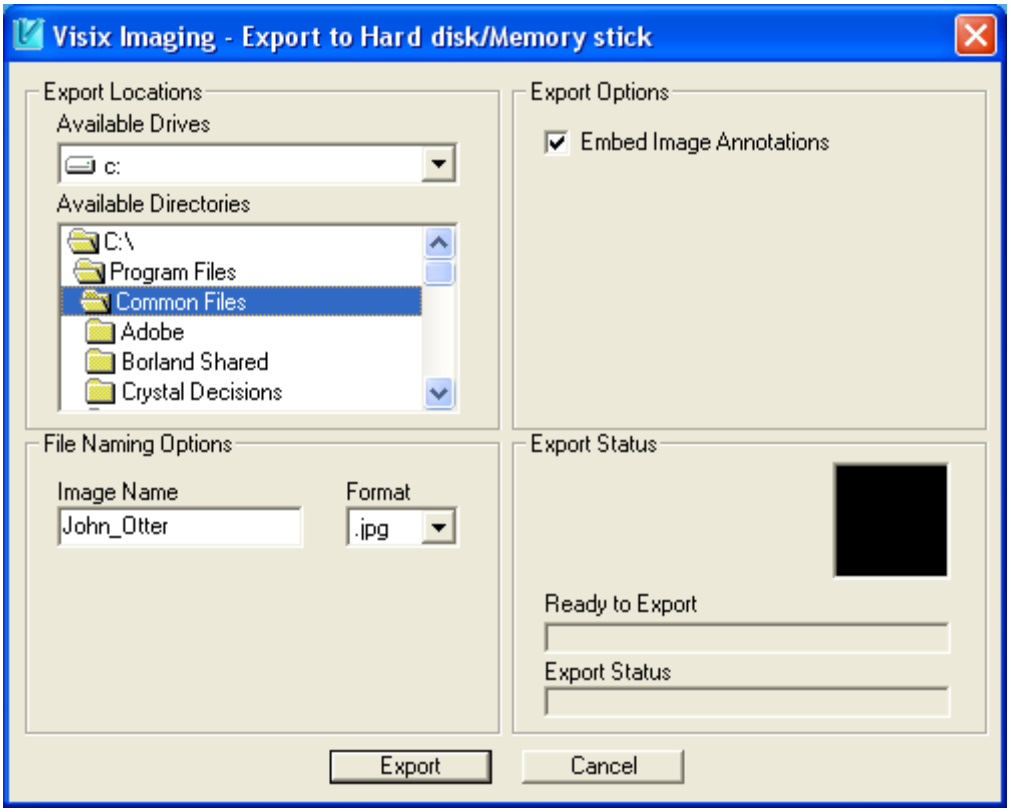
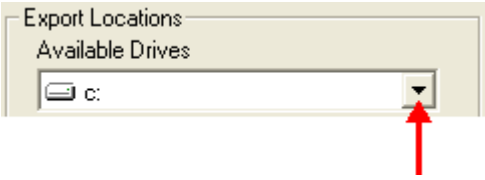
Export to Hard disk/Memory stick:



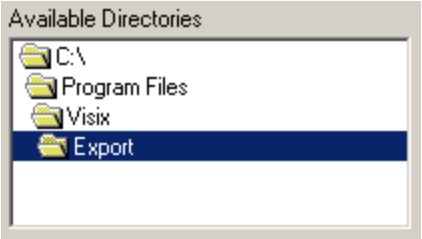
Export Location - Available Drives

To export the image to a hard drive or memory stick that is accessible by this computer, click on the Available Drives down arrow then select the drive from those displayed.



Export Location – Available Directories

The directories (also known as folders) within the selected drive will display. Double click on a folder to display any folders that might be within it.



Select the directory (folder) to copy the export file to.

File Naming Options

The default name for the exported file is the patient's name.

If multiple images are exported at the same time, a number that increases by 1 for each exported image will follow the image name. For example:

John_Smith1.jpg
John_Smith2.jpg
John_Smith3.jpg

Export Options

Click on Embed Image Annotations to place a check in the checkbox if the annotations on this image should be included with the exported image.

Export

Click on the Export button to export the file.

Change Patient (Move Images From One Patient To Another)

The ability to move an image from one patient to another patient is available only from the Right Click Image Menu.

To move an image from one patient to another, perform the following steps:

- Open the patient the image was incorrectly saved to
- Right click on the image to open the Right Click Menu
- Select Change Patient. The Change Patient window will open.

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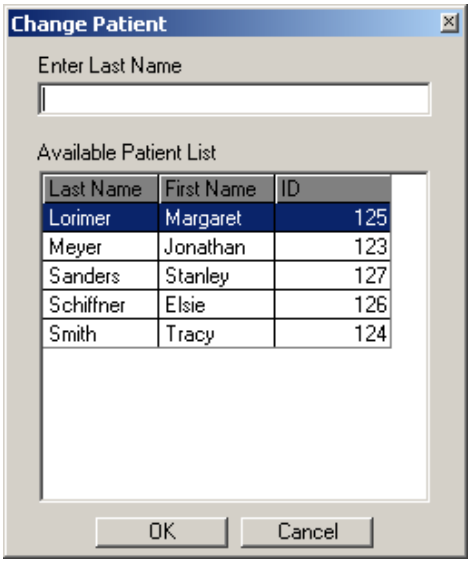
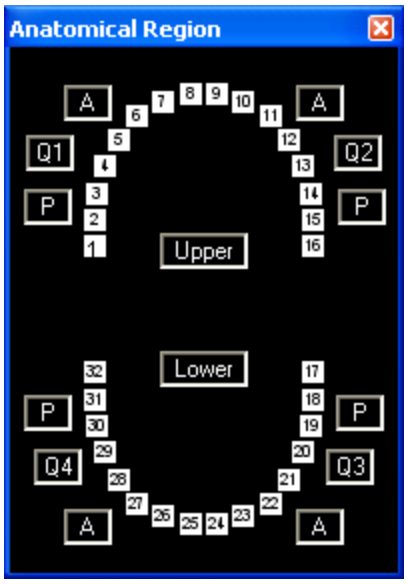


- Double left click on the name of the patient who should have received the image, or type in the last name of the patient who should have received the image for Visix to locate it for you
- Click on the OK button.

Anatomical Region

When Anatomical Region is selected the following window will display:

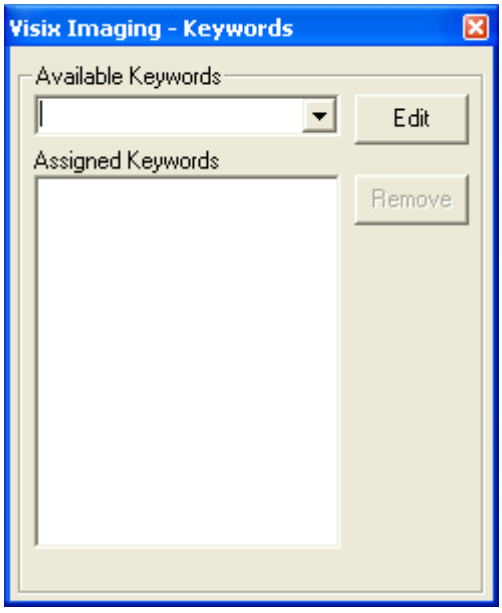


This is identical to the Anatomical Region section of the Patient Window. Select the teeth in the diagram that correspond with the teeth in the image by clicking on them. Clicking on “A”, “P”, “Q1”, “Q2”, “Q3”, “Q4”, “Upper” or “Lower” will select sets of teeth. Individual teeth can be selected by left clicking on each individual tooth. Clicking on selected teeth will un-select them. Changes to this window are saved when the window’s close button is clicked.

Saving the anatomical region allows this image to appear (or not appear) in response to a search by anatomical region. The search is performed on the Patient Window.

Keywords

When Keywords is selected the Keywords window will display:



The Keywords window allows two actions:

- Keywords can be added or deleted from the main Keywords List that supplies keywords to all of the images in Visix.
- Specific Keywords can be associated with the currently selected image

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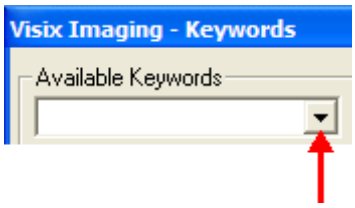
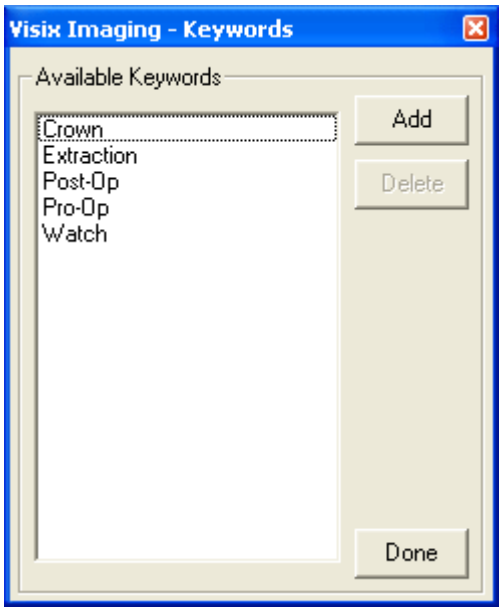
Add Keywords to the Main Keyword List

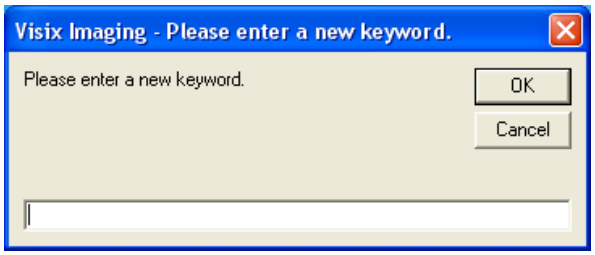
To add or delete Keywords from the main Keywords List, click on the Edit button on the right of the Available Keywords drop down box.



The following window will display:



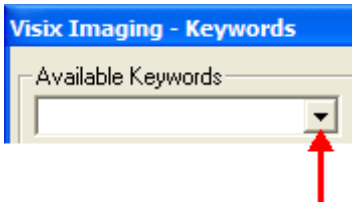
To Add a Keyword, click on the Add button at the top of the window then enter the keyword into the New Keyword window. Click on the OK button to save the new keyword.



Click on the Done button to close the Add Keyword window.

Assign a Keyword to an Image

To assign a keyword to a selected image, click on the down arrow of the Available Keywords drop down box

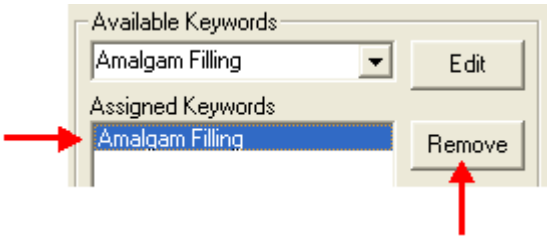


then select the keyword. The keyword must exist in the Main Keyword List before it can be assigned to an image.

Multiple Keywords can be assigned to an image. When all of the applicable Keywords have been assigned to the image, click on the window's Close button ☒ to close the Keywords window. Note: If the keyword to assign does not appear in the drop down box, add the keyword to the main Keyword List following the Add Keywords To The Main Keyword List instructions above.

Remove a Keyword from an Image

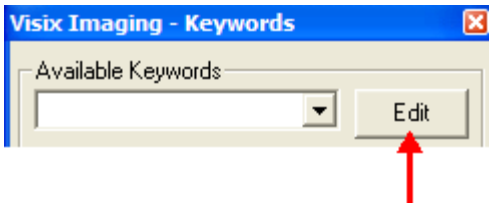
To Remove a Keyword that was assigned to an image, click on the Keyword then click the Remove Button.



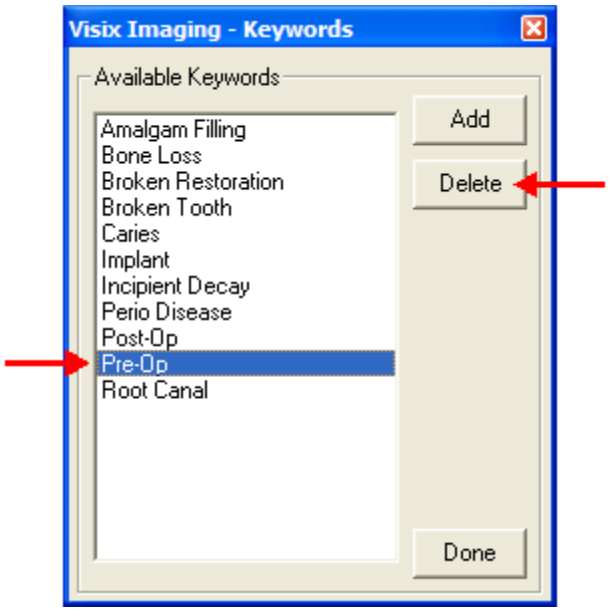
When finished, click on the window's Close button ☒ to close the Keywords window.

Delete a Keyword from the Main Keyword List

To Delete a Keyword from the Main Keyword List, click on the Edit button on the Keyword window.



In the window that opens click on the Keyword to delete, and then click on the Delete button.



Click on the Done button to close the Edit Keywords window then on the window's Close button ☒ to close the main Keywords window.

Flip

When Flip is selected the following window will display:

Left/Right

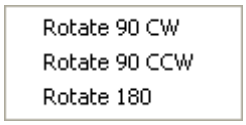
Selecting Left/Right will create a horizontally mirrored image. What was on the left side of the image will now be on the right side, and what was on the right side of the image will now be on the left side.

Top/Bottom

Selecting Top/Bottom will create a vertically mirrored image. What was on the top of the image will now be on the bottom, and what was on the bottom of the image will now be on the top.

Rotate

When Rotate is selected the following window will display:



Rotate 90 CW

Selecting Rotate 90 CW will cause the selected image to turn 90 degrees clockwise (CW).

Rotate 90 CCW

Selecting Rotate 90 CCW will cause the selected image to turn 90 degrees counter clockwise (CCW).

Rotate 180

Selecting Rotate 180 will cause the selected image to turn 180 degrees.

Properties

When Properties is selected the following window will display:

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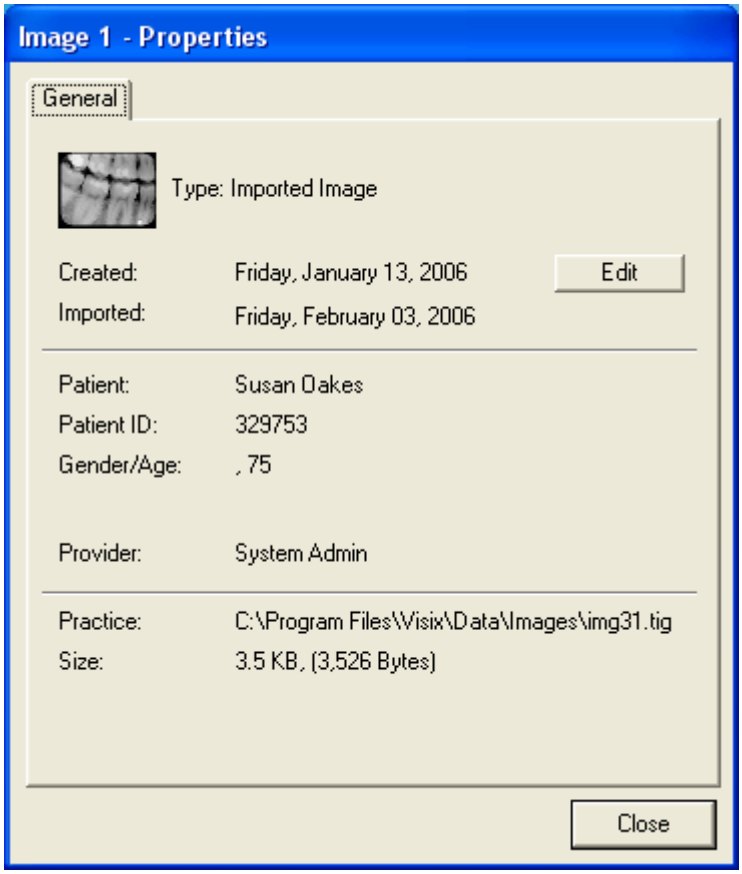

The information displayed on the General tab includes the type of equipment used to capture the currently selected image, the name, ID, gender, and age of the patient the image was taken of, the name of the provider for this patient, the date the image was acquired, where the image is stored, what the stored image is called, and how large the image is.

Change the Created Date for Images acquired from a flatbed scanner or imported

If the image was acquired from a flatbed scanner or imported, an Edit button Edit... will appear on the Properties window that will allow the Created Date for the image to be changed.

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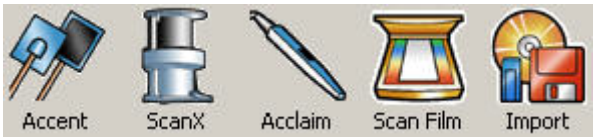
Acquisition Windows

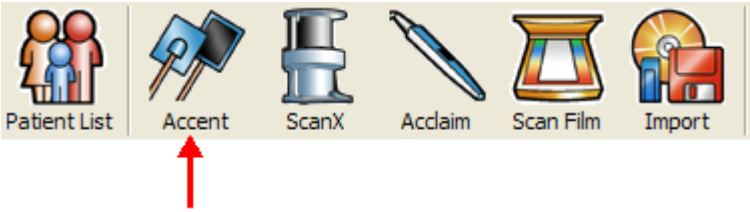
Accent Sensor

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.



Accent Acquisition Window

Click on the Accent button on the Visix toolbar to open the Accent Acquisition window.



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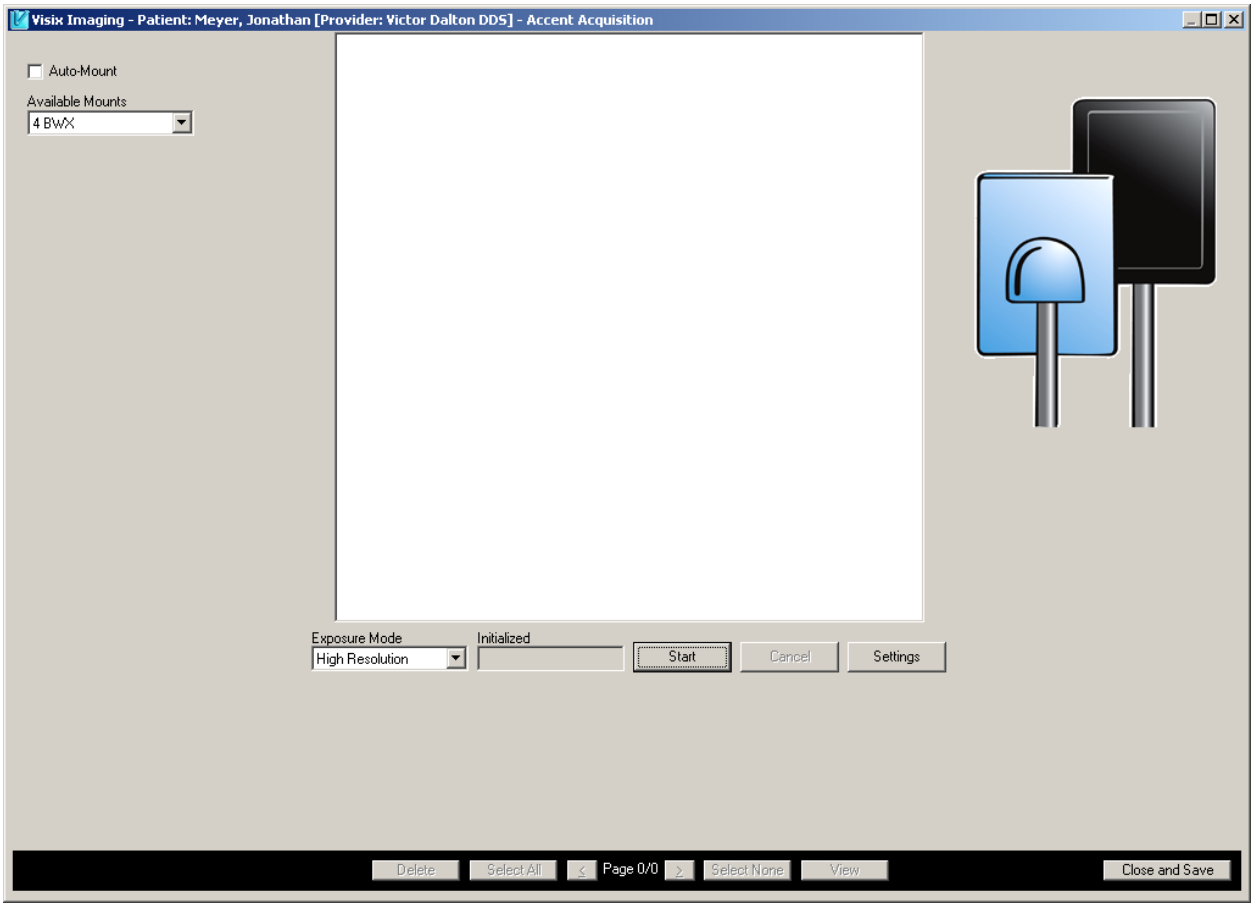

Acquiring Images from an Accent Sensor

When the Accent Acquisition window opens, the status bar will flash and then change to a solid green. This indicates the sensor has been initialized and is ready to acquire images.

Settings Button for an Accent Sensor

The Settings button will display windows that hold optional settings for the sensor that is connected to this computer. These settings are advanced and will apply to <u>all</u> of the future images acquired by this sensor.

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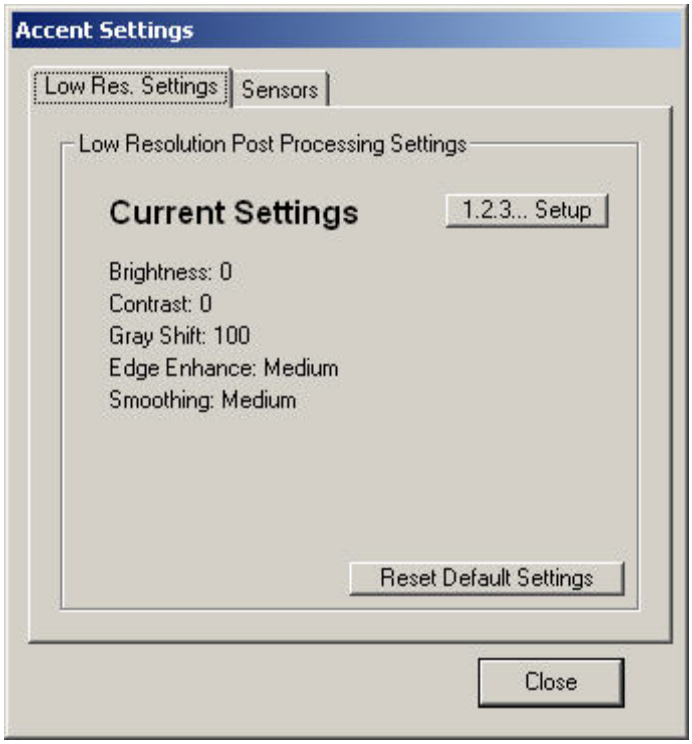
Settings Button – Low Res. Settings – Accent sensor



The current settings for the Accent sensor are displayed in the center of the Settings window under the heading "Current Settings". The settings for a low-resolution image will display if the last image taken was a low-resolution image. The settings for a high-resolution image will display if the last image taken was a high-resolution image.

1, 2, 3… Setup is a tool that will help obtain the best image quality possible. Click on the 1.2.3…Setup button to change the Brightness, Contrast, Gray Shift, Edge Enhancement, or Smoothing settings for future low-resolution or high-resolution images taken by this sensor. At least one image must be acquired before using the 1, 2, 3…Setup tool.

Clicking on the Reset Default Settings button [Reset Default Settings] will change the settings back to the original settings Visix came with.

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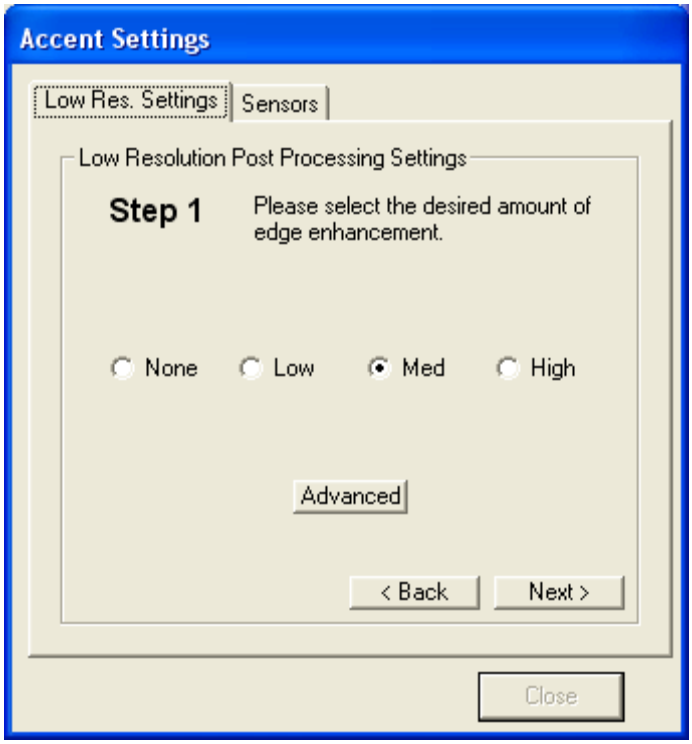
Settings Button – Accent sensor



1, 2, 3… Setup Step 1

Click on the amount of Edge Enhancement desired. Edge Enhancement will make the first few pixels on the dark side of an edge darker and the first few pixels on the white side of an edge whiter. This causes more contrast at the edges, which makes the edges more defined, giving them a sharper look.

As the level of Edge Enhancement is changed, the change is reflected on the last image that was acquired, allowing the user to decide the amount of Edge Enhancement that is appropriate.

The Advanced button should only be accessed by trained service personal. Changing its values may adversely affect image quality.

Click on the Back button to exit out of the 1, 2, 3…Setup tool. Click on the Next button to advance to the Step 2 window.

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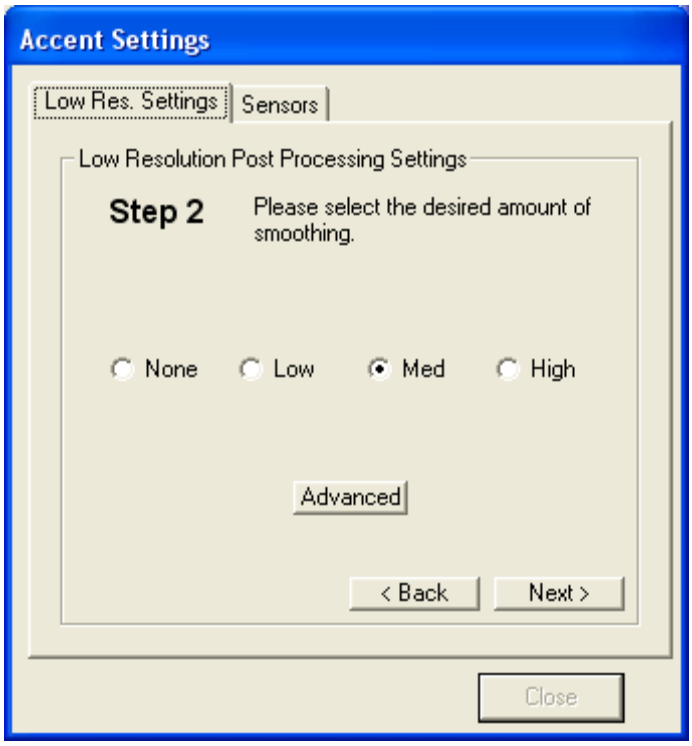
1, 2, 3… Setup Step 2



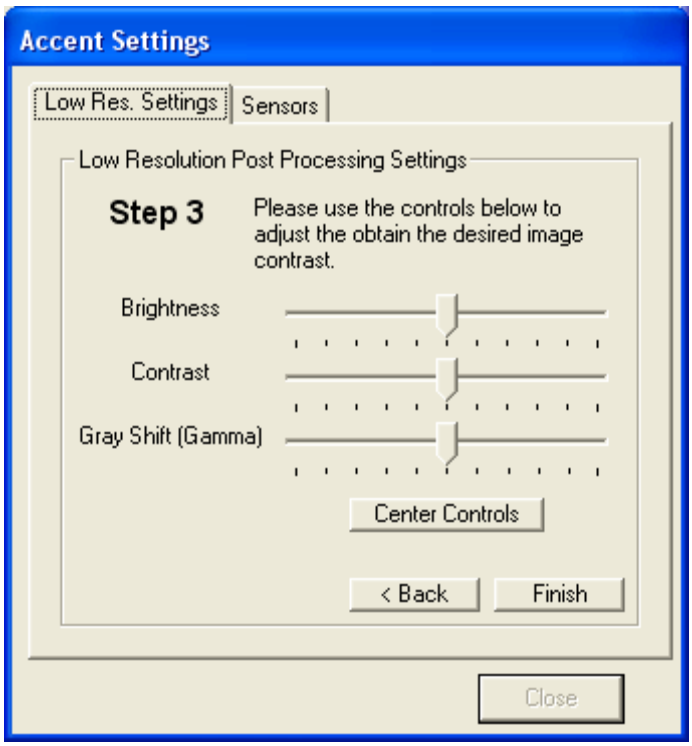
Click on the amount of Smoothing to apply to all future Low Resolution or High Resolution images. Smoothing attempts to remove any extra “noise” or graininess from the image caused by the Edge Enhancement applied in Step 1.

As the level of Smoothing is changed, the change is reflected on the last image that was acquired, allowing the user to decide the amount Smoothing that should be applied.

The Advanced button should only be accessed by trained service personal! Changing its values may adversely affect image quality.

Click on the Back button to return to Step 1, Edge Enhancement. Click the Next button to move to Step 3

1, 2, 3… Setup Step 3



Step 3 allows the user to set the amount of brightness, contrast and gray shift (also called gamma) that is applied to all future Low Resolution images.

The default values are shown in the screen shot above and can be set by clicking the Center Controls button below the sliders.

As the levels of brightness, contrast or gray shift are adjusted, the changes will be reflected on the last acquired image so that the user can determine which setting is appropriate.

Brightness

Changing the Brightness setting can make up for an x-ray device that takes images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

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Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gray Shift (Gamma)

A Gray Shift change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can result in an image that is very dark.

Back or Finish

Click on the Back button to return to Step 2, Smoothing. Click on the Finish button to complete the 1, 2, 3…Setup.

A summary of the new settings that will be applied to every Low Resolution or High Resolution image taken with the Accent sensor will appear on the first 1.2.3…Setup window under the heading “Current Settings”.

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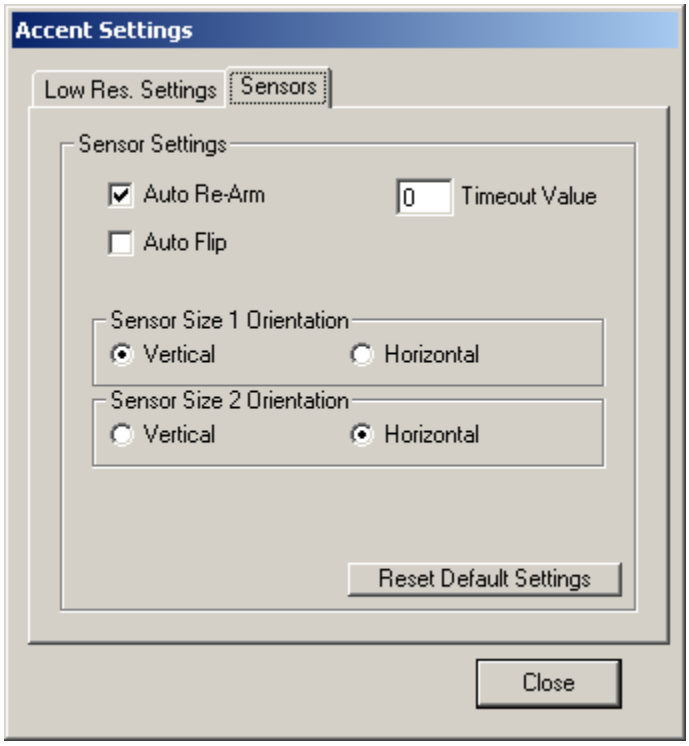
Settings Button – Sensors Window – Accent sensor



Sensors Tab Settings

Auto Re-Arm

Place a check in the Auto Re-Arm checkbox to have the sensor automatically reset itself for another picture as soon as the previous picture has been taken.

Auto Flip

By default, each image the sensor takes is viewed as if the viewer is on the outside of the mouth looking in. Place a check in the Auto Flip checkbox to change the view to look like the viewer is on the inside of the mouth looking out.

Timeout Value

The Timeout Value is the amount of time the sensor will wait for an x-ray to be taken before

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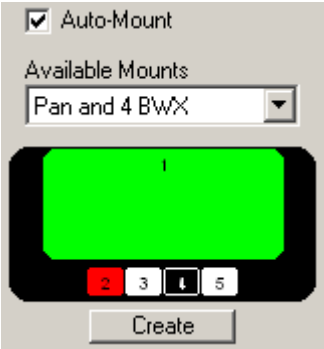
going into low power mode. The default value of 0 will cause the sensor to never time out.

Sensor Orientation

The Sensor Orientation lists each size of Accent sensor and whether the image taken by that sensor should be displayed in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order

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specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.

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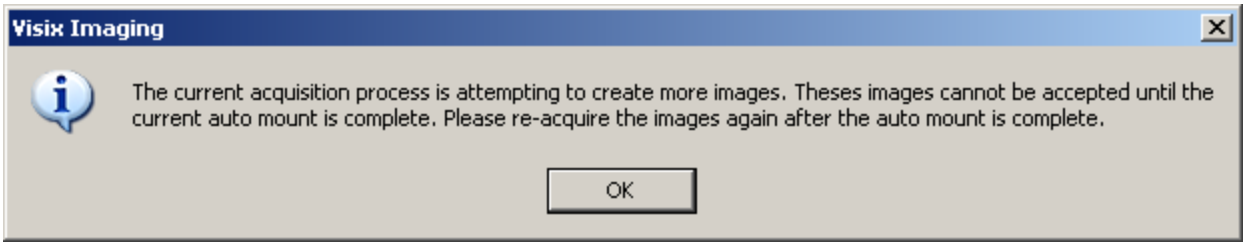

If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Sensor Indicator Bar

Once the Accent Sensor is ready to be used, the bar next to the Start button will display the word “Initialized” then will flash green and the words “Waiting for Exposure” will display. After the sensor button has been pressed to take the x-ray the bar will flash red and “Processing Image” will display.

During the Acquire Process

Visix will automatically capture the image from the sensor.

If the Cancel button

is clicked during the acquire process, the acquire process will be aborted.

After the Acquire Process

Once an image has been acquired it will appear in the area under the Start button as a thumbnail image.

To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the Close Window box in the upper right corner of the

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window and either continue acquiring images or move on to selecting the images and saving them into Visix.

If the image quality is not acceptable, close the View window, and reacquire the image. Once the image is acceptable, select the image then click on the Save button to save the image into Visix.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are <u>not</u> recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

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Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window.

Close and Save The images will save to the currently selected patient.

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Acquisition Windows

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

ScanX

The ScanX scanner uses small, flexible, reusable phosphor plates to acquire images instead of film. The ScanX can be setup in an office in two ways: Direct Connect Mode and Intelligent Track Control Mode.

Direct Connect Mode is the traditional method of setting up a ScanX. In Direct Connect Mode the ScanX is directly connected to one computer with a cable. Although all of the workstations on the network that have Visix installed on them can display saved ScanX images, only the copy of Visix on the computer the ScanX is directly connected to can acquire the images from the ScanX.

Intelligent Track Control Mode, also known as ITC mode, allows up to two workstations that have Visix installed to acquire images from the ScanX. The workstations will use the ScanX in either Exclusive or Shared Mode. In Exclusive Mode only one workstation will be allowed to acquire images from the ScanX. In Shared Mode, the tracks on the ScanX will be shared equally between two workstations allowing each workstation to independently acquire images from the plates that are fed into their assigned tracks.

Direct Connect Mode

Installation Overview

To use the ScanX in Direct Connect Mode install the ScanX and Visix on one workstation then use the Visix Administration program on that workstation to activate the ScanX. Install the remaining copies of Visix that were purchased on other network workstations. Each copy of Visix will request an activation code the first time it's opened. Please refer to the ScanX Drivers and Utilities cd for instructions about installing the ScanX. Refer to the Visix Installation instructions and the Visix Administration manual for instructions about installing Visix and activating Visix and the ScanX.

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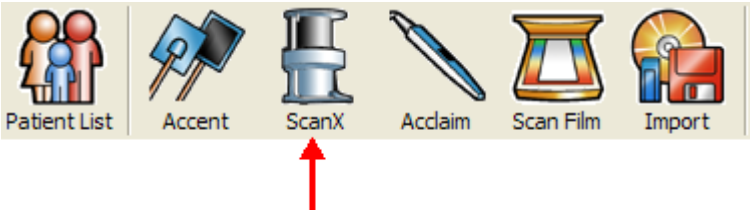
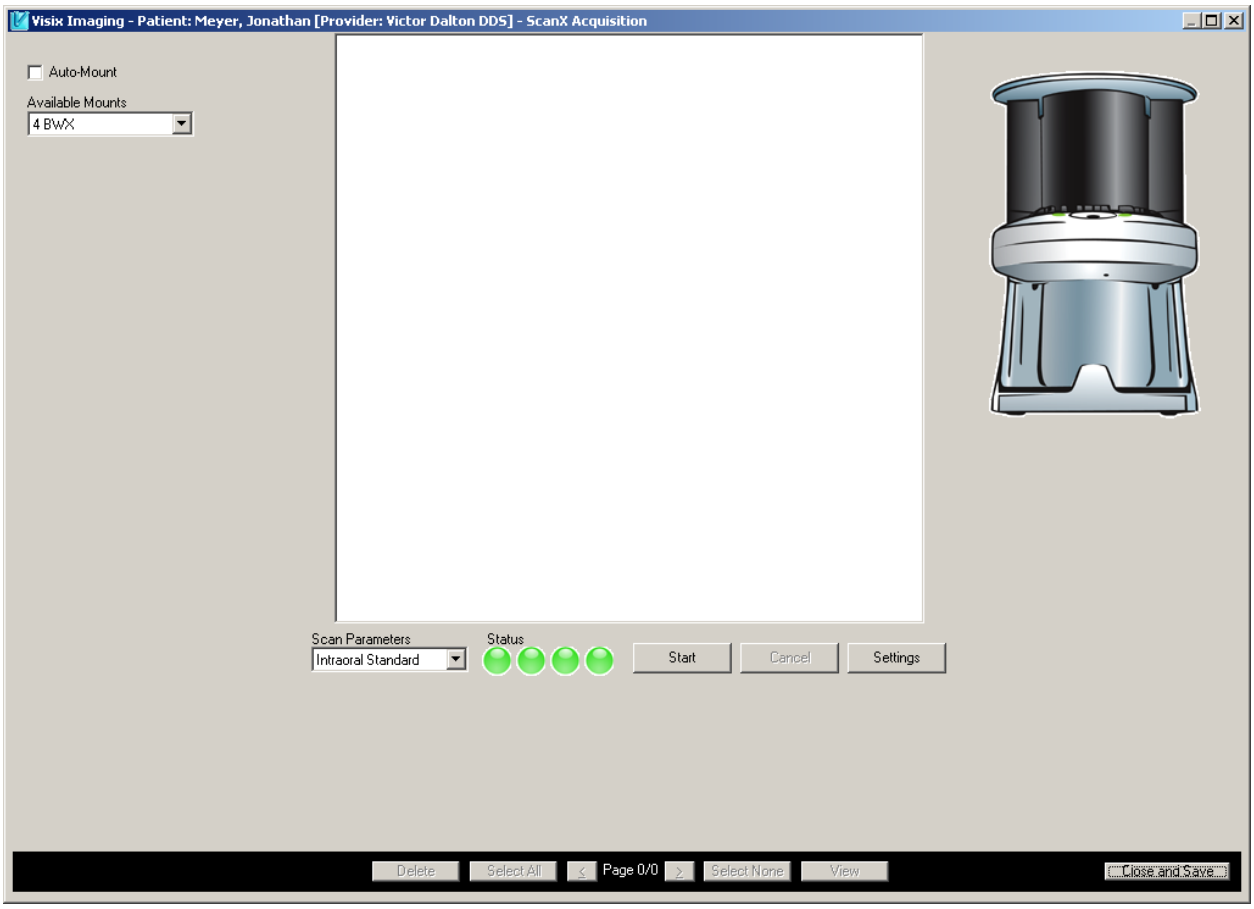
ScanX Acquisition Window

Click on the ScanX button on the Visix toolbar to open the ScanX Acquisition window.



ScanX Acquisition window when Direct Connect Mode is used



Scan Parameters

The Scan Parameters for the ScanX phosphor plate scanner specify the type of image being x-rayed and the resolution for the resulting digital image.

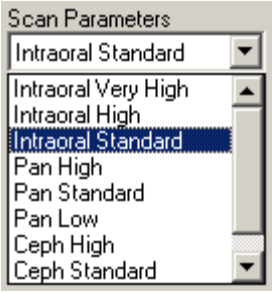
Image Type

Image types include:

- Intraoral, where a phosphor plate is placed inside the patient's mouth and an x-ray is taken of a small group of teeth.
- Pan, where a panoramic x-ray machine takes a picture of the patient's entire jaw.
- Ceph, where a cephalometric x-ray machine takes an x-ray of the side of the patient's head.

Resolution

Selecting a high or very high resolution will result in an image with a greater amount of detail along with a larger file size that requires more hard drive space. For most x-rays, a Standard resolution scan setting is appropriate.



Status Lights

Before beginning a scan check the color of the four Status lights. The four Status lights in Visix correspond to the four Track Status Lights on the ScanX.

If a track is available for use its Status light will be green. If a track is currently scanning a phosphor plate its Status light will be red. If the Status lights are gray, the computer has lost its connection to the ScanX. For connection issues please call Visix technical support.

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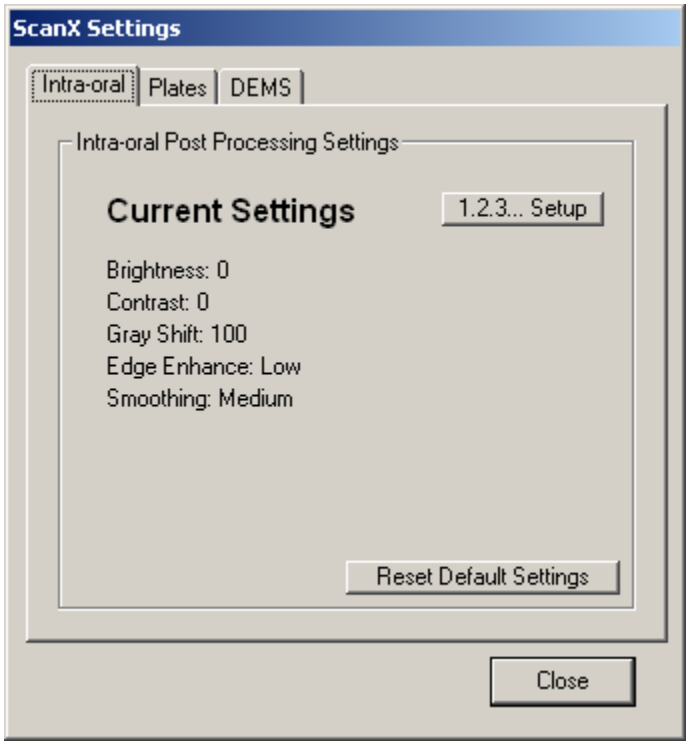
Settings Button for a ScanX Scanner

The Settings button will display windows that hold optional scan settings for the ScanX scanner. These settings are advanced and will affect the future images acquired by the ScanX scanner.

Settings Button – Intra-Oral Window – ScanX scanner



The Intra-oral settings window will display if the last image scanned was an intra-oral image. The intra-oral tab displays the Current Settings that are applied to every intra-oral phosphor plate that is scanned by the ScanX scanner. The default settings are displayed above. Clicking the “Reset Default Settings” button will return the settings on that window to the manufacturer’s default settings.

Intra-oral Window 1, 2, 3… Setup

1, 2, 3… Setup is a tool that will help determine the settings necessary for capturing the best image possible. At least one image must be scanned before using the 1, 2, 3…Setup tool. Changes

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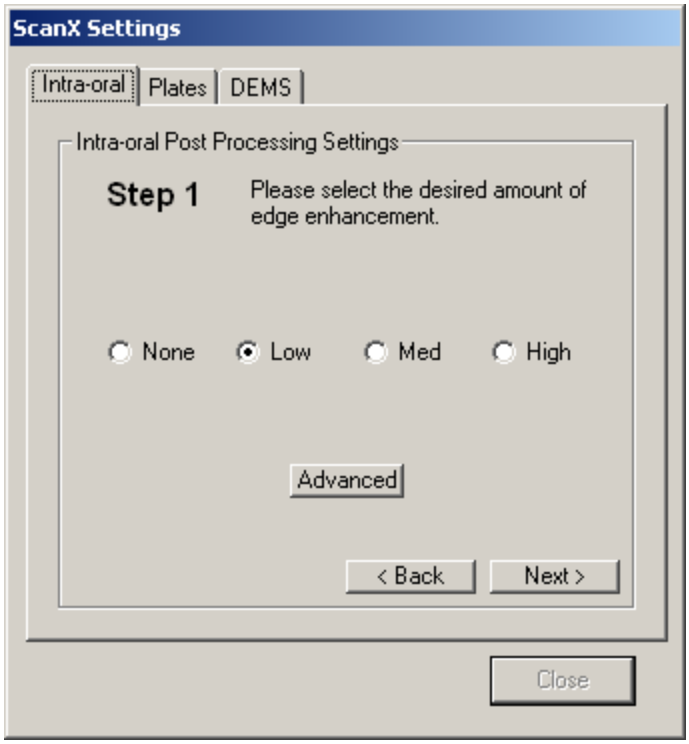
made in 1, 2, 3…Setup on the Intra-oral tab will affect all future intra-oral images.

Step 1



Step 1 determines the amount of edge enhancement that will be applied to an image, ranging from None to High. Edge enhancement increases the sharpness of the edges and structure of the teeth.

As different levels of edge enhancement are selected, the image displayed in the Waterfall window will change to show what the application of that level of edge enhancement will look like.

The Advanced button should only be accessed by trained service personnel! Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to exit out of the 1, 2, 3…Setup tool. Click the Next buttonto move to Step 2.

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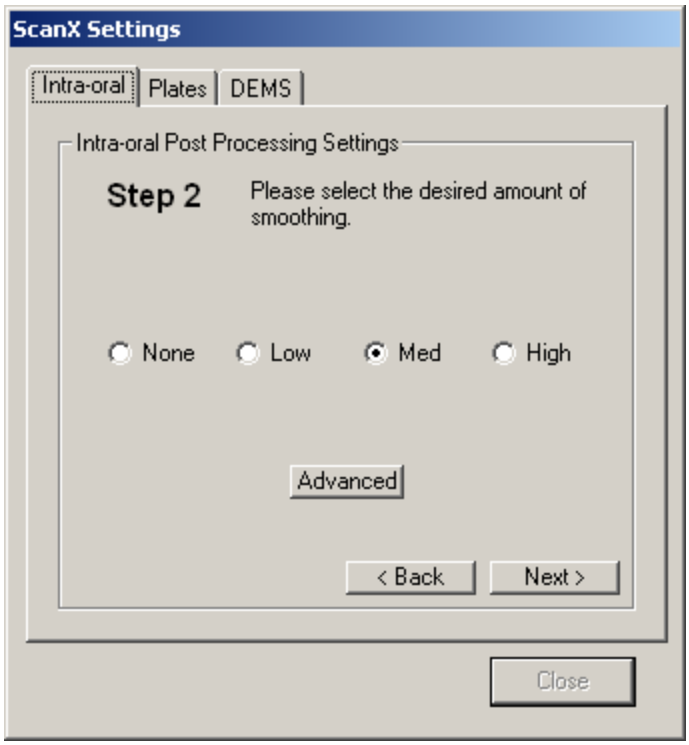
Step 2



Step 2 determines the amount of smoothing that should be applied to future images, ranging from None to High. Smoothing will attempt to remove any extra “noise” or graininess from the image caused by the edge sharpening applied.

As different levels of smoothing are selected, the image displayed in the Waterfall window will change to show what the application of that level of smoothing will look like.

The Advanced button should only be accessed by trained service personnel! Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to return to Step 1. Click the Next button to move to Step 3.

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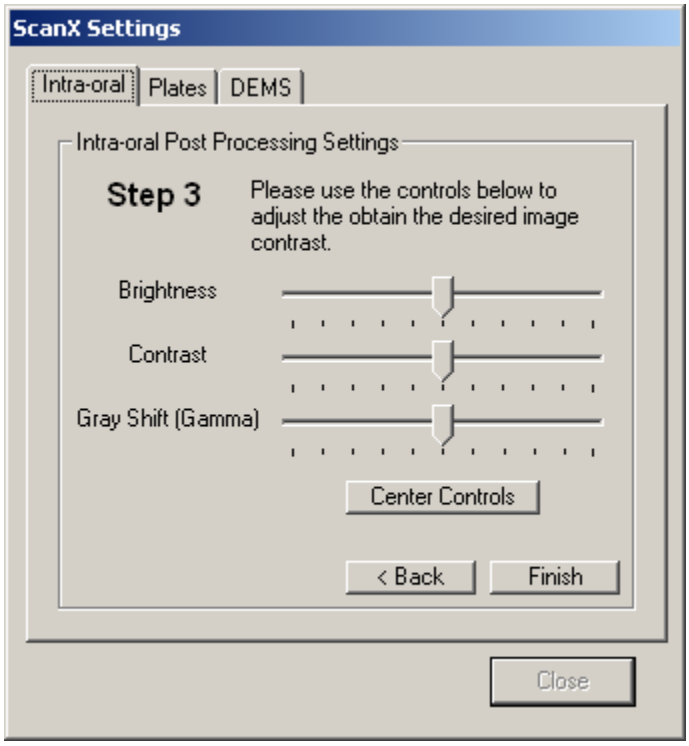
Step 3



Step 3 determines the amount of brightness, contrast, and gray shift (or gamma) that will be applied to future intra-oral images.

The default value for each slider is shown in the above window and can be set by clicking the Center Controls button Center Controls.

As the levels of brightness, contrast and gray shift are adjusted, the image displayed in the Waterfall window will change to reflect the adjustment.

Click the Back button to return to Step 2. Click the Finish button to move to complete the 1,2,3… Setup steps. The new settings will display on the Intra-oral window under the Current Settings heading.

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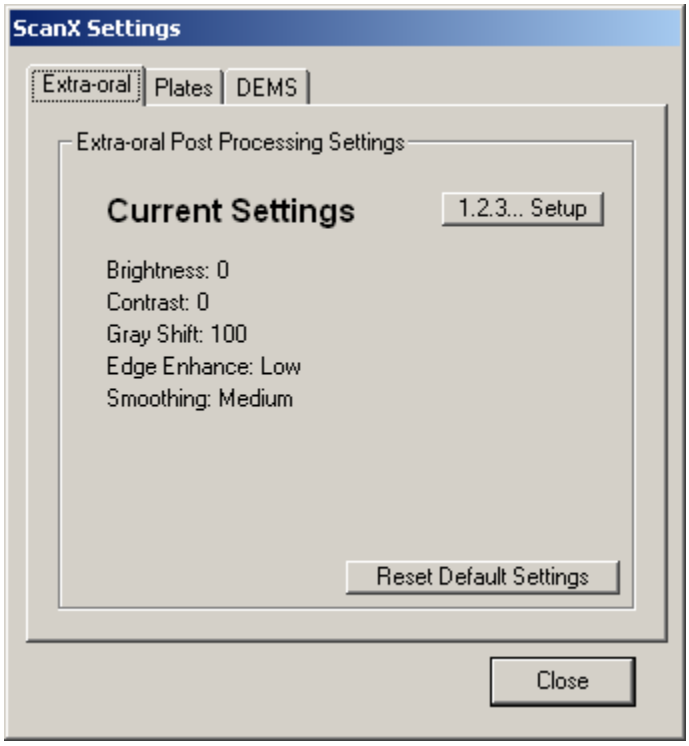
Settings Button – Extra-oral Window – ScanX scanner



Extra-oral Window 1, 2, 3… Setup

The Extra-oral settings window will display if the last image scanned was an extra-oral image. The Extra-oral settings are the same as the Intra-oral settings except that they refer to extra-oral images instead of intra-oral images. For an explanation of each setting please refer to the Intra-oral settings explanations listed before this section.

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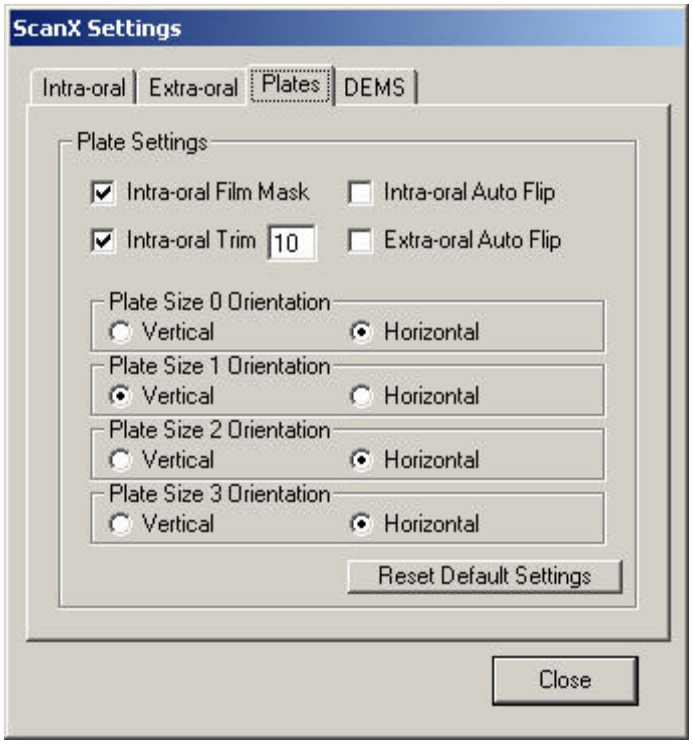
Settings Button – Plates Window – ScanX scanner



Intra-oral Film Mask

A Film Mask is a black border around an image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

Intra-oral Auto Flip

When an image is Auto Flipped the view is as though sitting on the tongue looking out at the x-ray head.

Intra-oral Trim

By default this option will be set to 10 which is the highest trim value. Instances where intra-oral trim would be used include cone-cut images and images that have “scatter” (extraneous black dots) around their edges. These types of images have

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white borders that the Intra-oral trim will delete, creating a cleaner image.

Extra-oral Auto Flip

When an extra-oral image is Auto Flipped, it's flipped left right.

Plate Orientation

The Plates window lists each size of intra-oral phosphor plates and whether it is to be displayed in Visix in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Reset Default Settings

Clicking the Reset Default Settings button will restore the original settings for this window.

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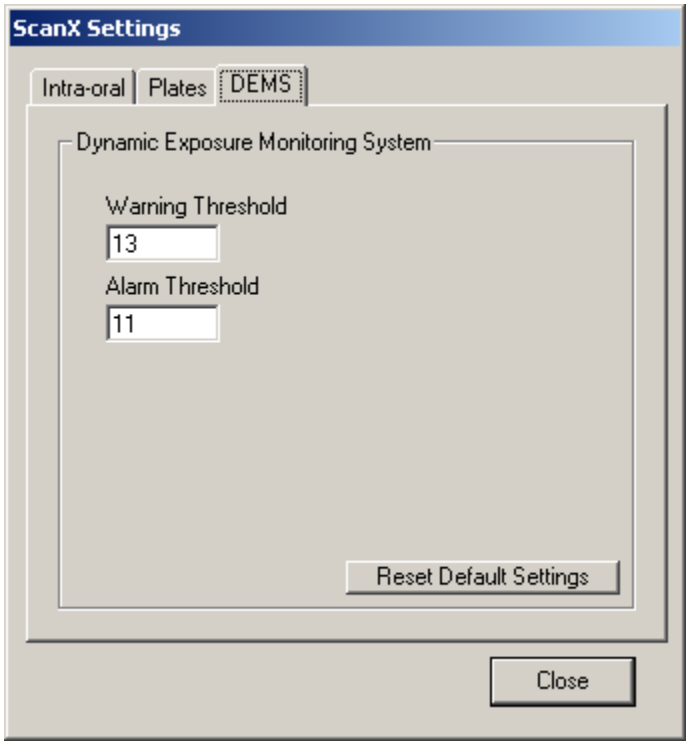
Settings Button – DEMS Window – ScanX scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset Default Settings button will restore the original settings.

The Dynamic Exposure Monitoring System lets the user know if the image being captured was shot with a less than optimum x-ray exposure setting.

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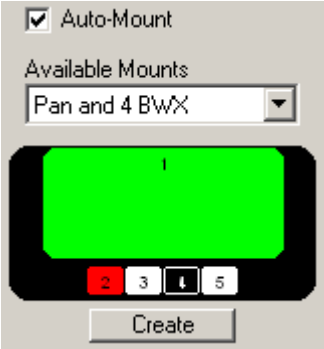
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

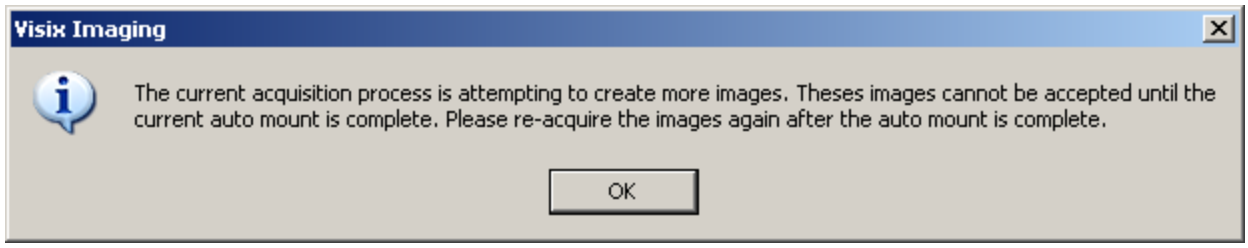
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Start button

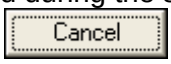
Click on the Start button

on the ScanX Acquisition window to tell Visix a scan is ready to begin.

At the ScanX Scanner

Load the phosphor plate or plates according to the manufacturer's directions into a ScanX track that displays a green light.

During the Scanning Process

Visix will automatically capture the image from the ScanX scanner. As the phosphor plate or plates advance through the ScanX scanner they will drop down the Visix Current Image box on the Acquisition window in a waterfall effect. As the plate is being scanned, the Status light on the ScanX and the corresponding light in Visix will turn red. A red light indicates that an image is being processed in that track. When a light turns green another phosphor plate can be inserted into that track to begin another scan. If the Cancel Button is clicked during the scanning process, the scan will be aborted. 

<u>Please note that the Current Image box (the waterfall) on the Acquisition Window is not a diagnostic quality image.</u> The Current Image box is only used to show the image's progression through the scanner.

After the Scanning Process

Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the ScanX window. A DEMS light on each image will be green if Visix is satisfied with the x-ray machine settings used to acquire this image, yellow if Visix thinks the x-ray settings

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could be slightly better, and red if Visix thinks the x-ray settings are poor and the image should be checked.

To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the Close Window box in the upper right corner of the window. If the image quality is not acceptable, close the View window and consider either rescanning the plate, if it hasn't been erased, or retaking the x-ray.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window. Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View

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button at the bottom of the Acquisition window.
View

Save an Image

To save images, click the Close and Save button at the bottom of the ScanX Acquisition window.
Close and Save The images will save, no matter what color their DEMS lights are, to the currently selected patient.

Intelligent Track Control Mode

Intelligent Track Control Setup Options

Intelligent Track Control Mode has three setup options that use different combinations of Visix workstations to control and acquire images from the ScanX.

Option 1	The ScanX is connected to a USB port on this workstation. The copy of Visix running on this workstation will acquire images from the ScanX.
Option 2	Although the ScanX is not physically connected to this workstation, the copy of Visix running on this workstation will acquire images from it.
Option 3	Although the ScanX is physically connected to this workstation, one or two other workstations will acquire images from it.

Installation Overview

To use the ScanX in ITC Mode, install the ScanX and Visix on one workstation first, then use the Visix Administration program on that workstation to change Visix to ITC Mode and to activate the ScanX. Next, install Visix on any additional workstations that will be acquiring images from the ScanX and use the Visix Administration program on those workstations to set Visix to ITC Mode. Finally install the remaining copies of Visix that were purchased on other network workstations. Each copy of Visix will request an activation code the first time it's opened. Please refer to the ScanX Drivers and Utilities cd for instructions about

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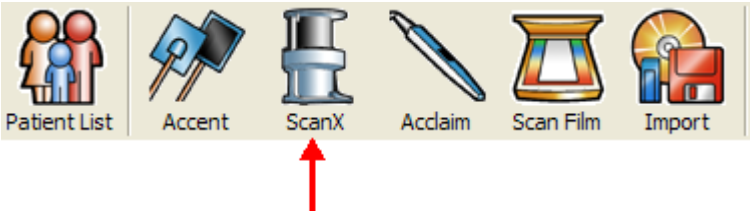
installing the ScanX. Refer to the Visix Installation instructions and the Visix Administration manual for instructions about installing Visix, changing to ITC Mode, and activating Visix and the ScanX.

ScanX Acquisition Window

Click on the ScanX button on the Visix toolbar to open the ScanX Acquisition window.



Intelligent Track Control – Setup Option 1 or 2

The copy of Visix running on this workstation will acquire images from the ScanX.

The ScanX Acquisition window looks the same when Visix is setup in ITC Mode and either Option 1 or Option 2 is selected to show where the ScanX will be located and which workstations will be acquiring images from it.

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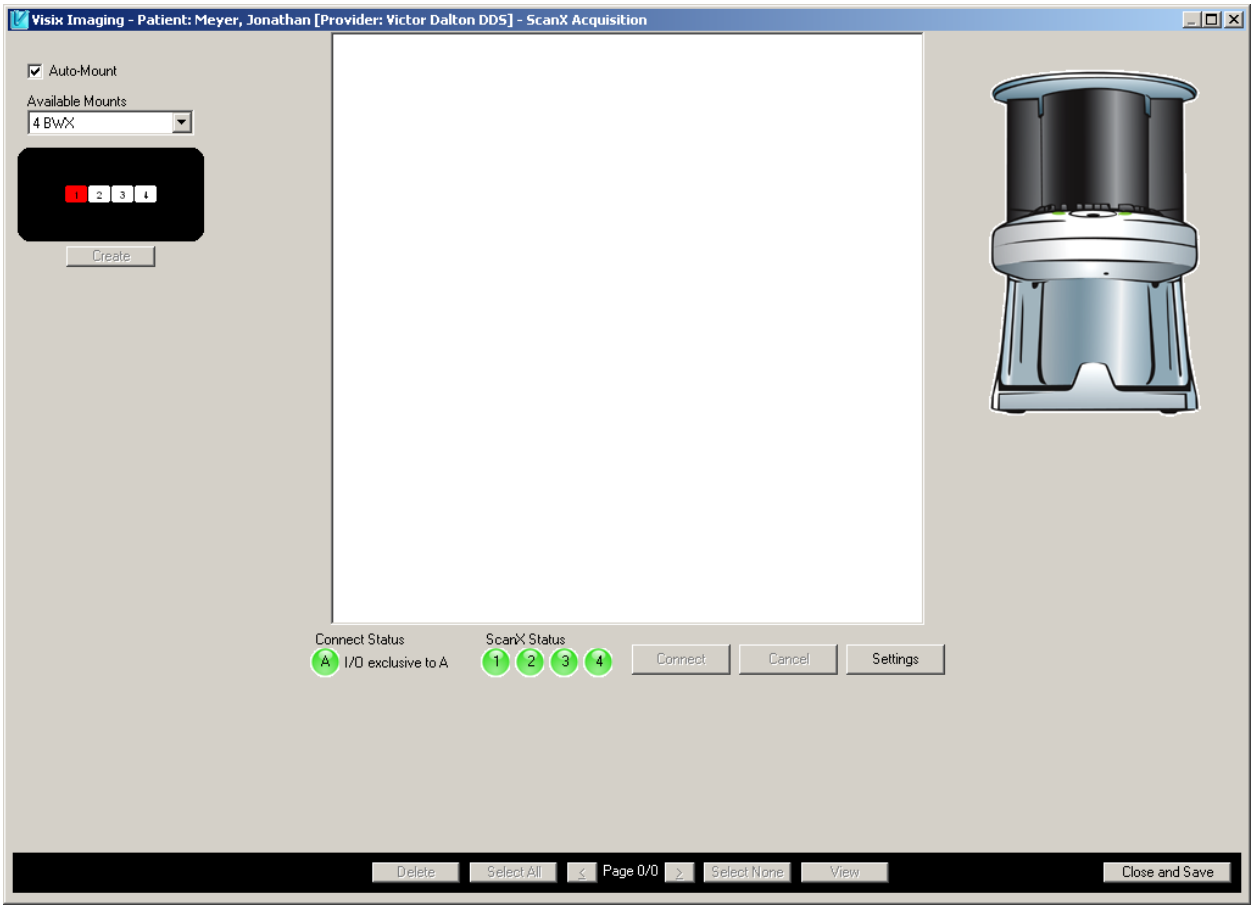
ScanX Acquisition window when Setup Option 1 or 2 of ITC Mode is selected:
The copy of Visix running on this workstation will acquire images from the ScanX



Connect Status

The Connect Status light will be green if this Visix workstation is currently connected to the ScanX scanner. The letter on the Connect Status light will indicate if the ScanX recognizes this Visix workstation as workstation A or workstation B.

The label next to the Connect Status light tells if the ScanX is being used in Shared mode or Exclusive Mode, and, if it's in Exclusive Mode whether workstation A or workstation B has control.

This is workstation A. Workstations A and B both acquire images from the ScanX.

This is workstation A. Only workstation B acquires images from the ScanX.

If this Visix workstation has failed to connect to the ScanX the Connect Status light will be red, and the Connect button will be available for use. Click on the Connect button to establish the connection to the ScanX scanner.

ScanX Status

Before beginning a scan, check the color of the four ScanX Status lights. The four ScanX Status lights in Visix correspond to the four Track Status Lights on the ScanX.

- If a track is available for use its corresponding Status light will be green.
- If a track is currently scanning a phosphor plate its Status light will be red.
- If half of the Status lights are gray, this Visix workstation is controlling the tracks that correspond to the green or red Status lights and the other Visix workstation that is sharing control of the ScanX computer is controlling the tracks that correspond with the gray Status lights.
- If all of the Status lights are gray, the Visix Controller has lost its connection to the ScanX. Please refer to the instructions in the ScanX Controller section of this manual to reconnect the ScanX Controller and the ScanX.

Settings Button for a ScanX Scanner

The Settings button will display windows that hold optional scan settings for the ScanX scanner. These settings are advanced and will affect the future images acquired by the ScanX scanner.

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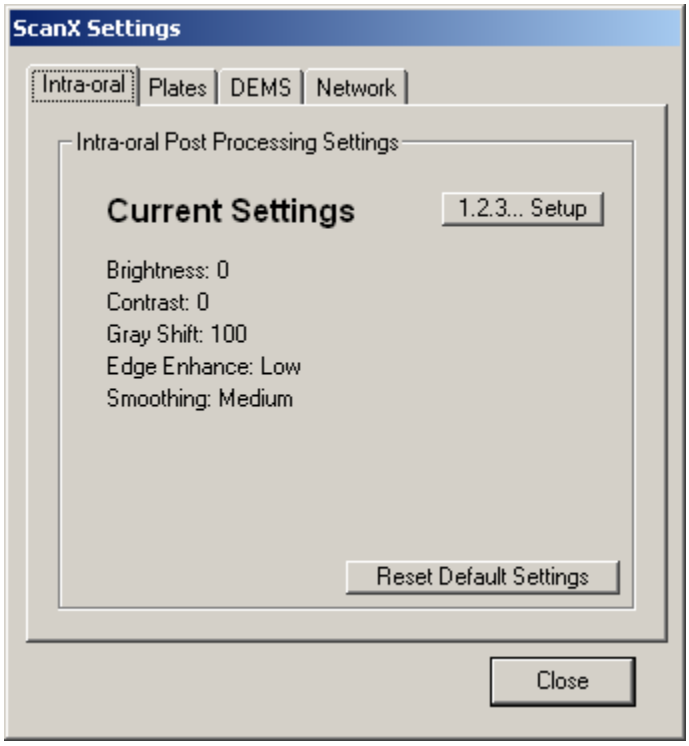
Settings Button – Intra-Oral Window – ScanX scanner



The Intra-oral settings window will display if the last image scanned was an intra-oral image. The intra-oral tab displays the Current Scan Settings that are applied to every intra-oral phosphor plate that is scanned by the ScanX scanner. The default settings are displayed above. Clicking the “Reset Default Settings” button will return the settings on that window to the manufacturer’s default settings.

Intra-oral Window 1, 2, 3… Setup

1, 2, 3… Setup is a tool that will help determine the settings necessary for capturing the best image possible. At least one image must be scanned before using the 1, 2, 3…Setup tool. Changes made in 1, 2, 3…Setup on the Intra-oral tab will affect all future intra-oral images.

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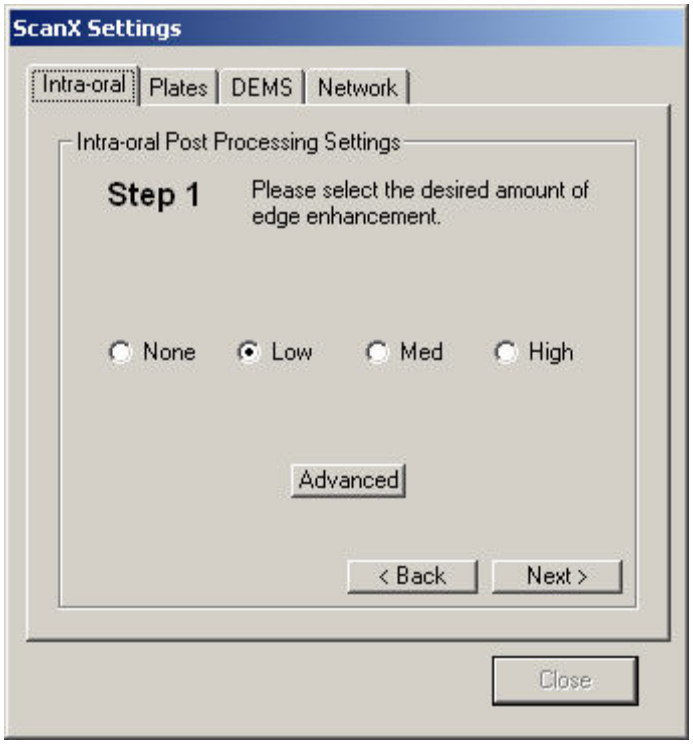
Step 1



Step 1 determines the amount of edge enhancement that will be applied to an image, ranging from None to High. Edge enhancement increases the sharpness of the edges and structure of the teeth.

As different levels of edge enhancement are selected, the image displayed in the Waterfall window will change to show what the application of that level of edge enhancement will look like.

The settings on the Advanced button should only be changed by trained service personnel. Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to exit out of the 1, 2, 3…Setup tool. Click the Next button to move to Step 2.

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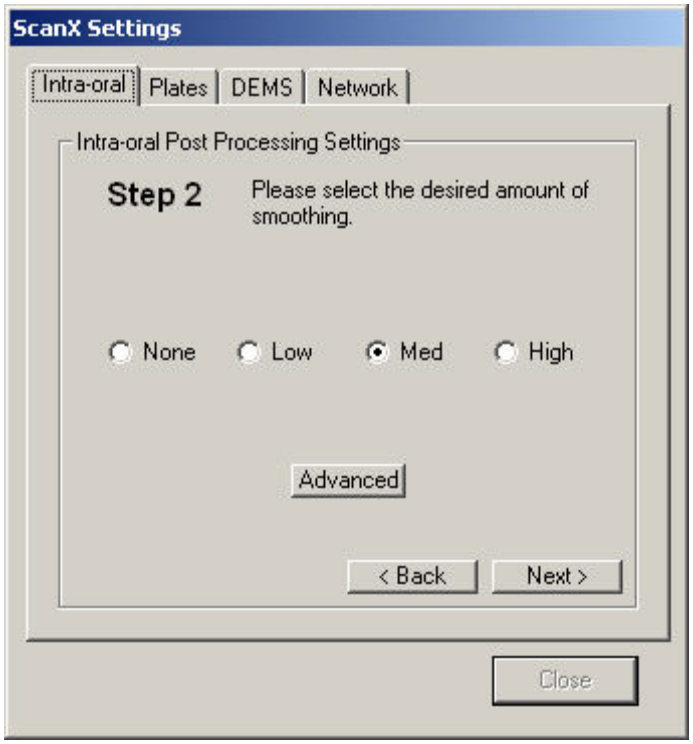
Step 2



Step 2 determines the amount of smoothing that should be applied to future images. Smoothing amounts range from None to High. Smoothing will attempt to remove any extra “noise” or graininess from the image caused by the edge sharpening applied.

As different levels of smoothing are selected, the image displayed in the Waterfall window will change to show what the application of that level of smoothing will look like.

The settings on the Advanced button should only be changed by trained service personnel. Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to return to Step 1. Click the Next button to move to Step 3.

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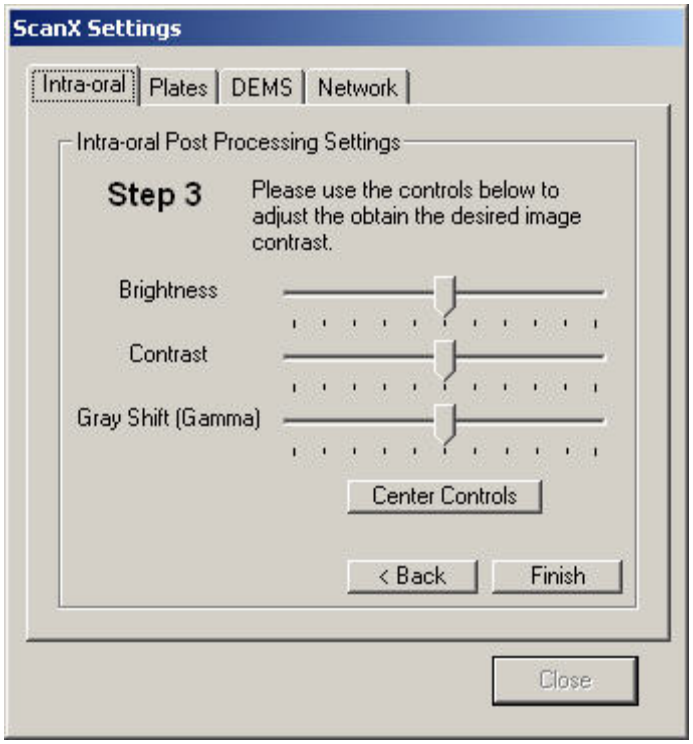
Step 3



Step 3 determines the amount of brightness, contrast, and gray shift (or gamma) that will be applied to future intra-oral images.

The default value for each slider is shown in the above window and can be set by clicking the Center Controls button Center Controls.

As the levels of brightness, contrast and gray shift are adjusted, the image displayed in the Waterfall window will change to reflect the adjustment.

Click the Back button to return to Step 2. Click the Finish button to move to complete the 1,2,3… Setup steps. The new settings will display on the Intra-oral window under the Current Settings heading.

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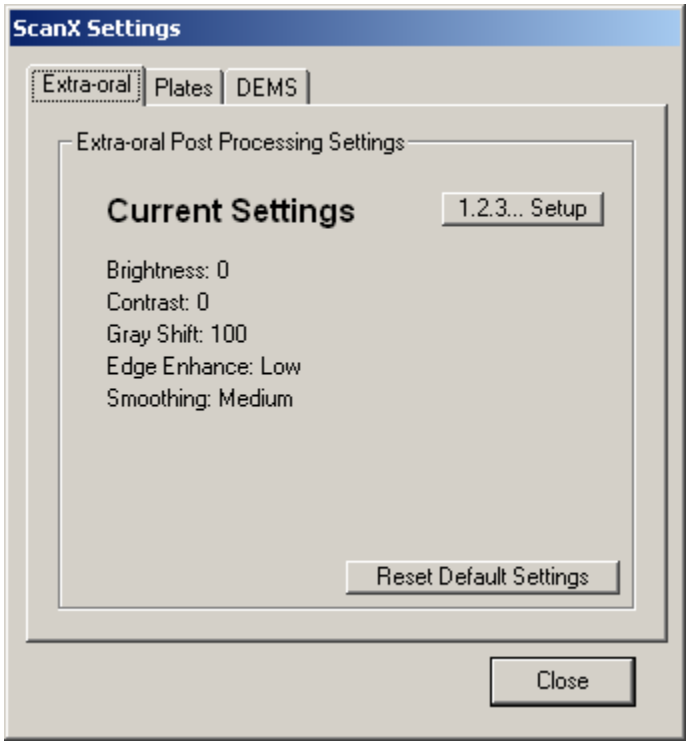
Settings Button – Extra-oral Window – ScanX scanner



Extra-oral Window 1, 2, 3… Setup

The Extra-oral settings window will display if the last image scanned was an extra-oral image. The Extra-oral settings are the same as the Intra-oral settings except that they refer to extra-oral images instead of intra-oral images. For an explanation of each setting please refer to the Intra-oral settings explanations listed before this section.

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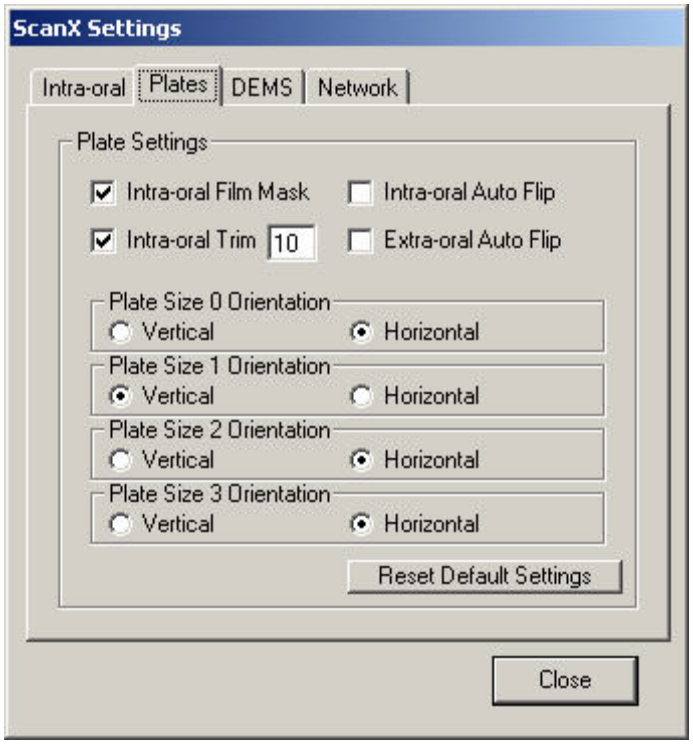
Settings Button – Plates Window – ScanX scanner



Intra-oral Film Mask

A Film Mask is a black border around an image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

Intra-oral Auto Flip

When an image is Auto Flipped the view is as though sitting on the tongue looking out at the x-ray head.

Intra-oral Trim

By default this option will be set to 10 which is the highest trim value. Instances where intra-oral trim would be used include cone-cut images and images that have “scatter” (extraneous black dots) around their edges. These types of images have

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white borders that the Intra-oral trim will delete, creating a cleaner image.

Extra-oral Auto Flip

When an extra-oral image is Auto Flipped, it's flipped left right.

Plate Orientation

The Plates window lists each size of intra-oral phosphor plates and whether it is to be displayed in Visix in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Reset Default Settings

Clicking the Reset Default Settings button will restore the original settings for this window.

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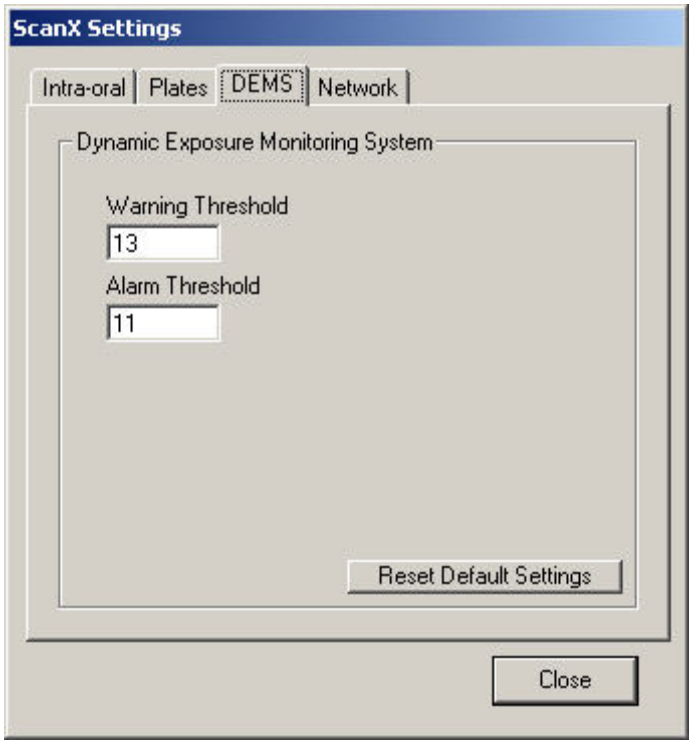
Settings Button – DEMS Window – ScanX scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset Default Settings button will restore the original settings.

The Dynamic Exposure Monitoring System lets the user know if the image being captured was shot with a less than optimum x-ray exposure setting.

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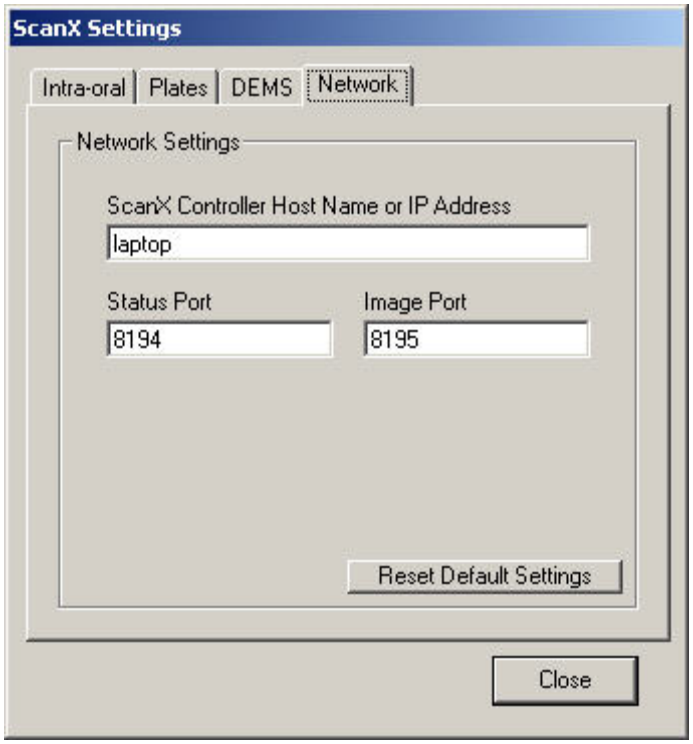
Settings Button – Network Window – ScanX scanner



ScanX Controller Host Name or IP Address

Enter the name or IP address of the computer the ScanX is physically connected to.

Status Port

Enter the number of the Status Port that will be used to send ScanX status information to this Visix workstation. Enter the same port that was entered in the ScanX Controller Configure window. The two entries must match.

Image Port

Enter the number of the Image Port that will be used to send images from the ScanX to this Visix workstation. Enter the same port that was entered in the ScanX Controller Configure window. The two entries must match.

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Scan Parameters

The Scan Parameters for the ScanX phosphor plate scanner specify the type of image being x-rayed and the resolution for the resulting digital image.

The Scan Parameter setting is selected from the list that displays by left clicking once on the ScanX icon in the System Tray.

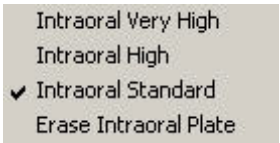

Image Type

Image types include:

- Intra-oral, where a phosphor plate is placed inside the patient's mouth and an x-ray is taken of a small group of teeth.
- Pan, where a panoramic x-ray machine takes a picture of the patient's entire jaw.
- Ceph, where a cephalometric x-ray machine takes an x-ray of the side of the patient's head.

Resolution

Selecting a high or very high resolution will result in an image with a greater amount of detail along with a larger file size that requires more hard drive space. For most x-rays, a Standard resolution scan setting is appropriate.

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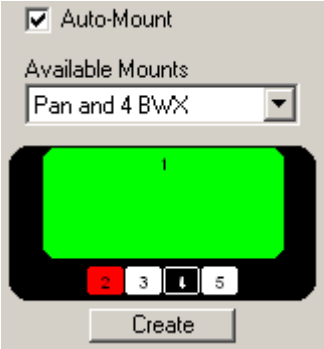
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

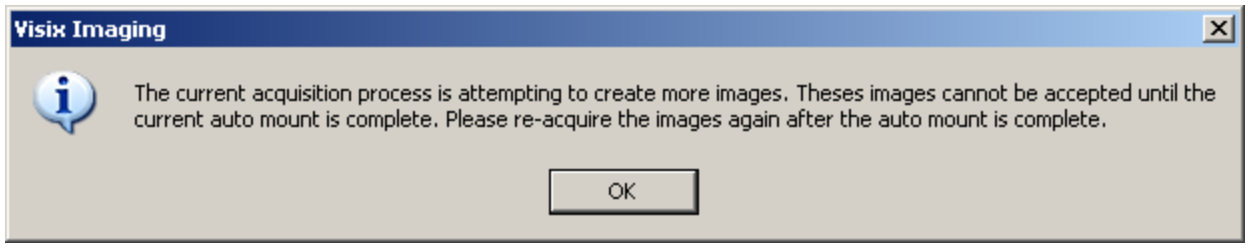
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

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Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

At the ScanX Scanner

Load the phosphor plate or plates according to the manufacturer's directions into a ScanX track that displays a green light.

During the Scanning Process

Visix will automatically capture the image from the ScanX scanner. As the phosphor plate or plates advance through the ScanX scanner they will drop down the Visix Current Image box on the ScanX Acquisition window in a waterfall effect. As the plate is being scanned, the Status light on the ScanX and the corresponding light in Visix will turn red. A red light indicates that an image is being processed in that track. When a light turns green another phosphor plate can be inserted into that track to begin another scan. If the Cancel Button is clicked during the scanning process, the scan will be aborted.

Please note that the Current Image box on the Acquisition Window is not a diagnostic quality image. The Current Image box is only used to show the image's progression through the scanner.

After the Scanning Process

Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the ScanX window. A DEMS light on each image will be green if Visix is satisfied with the x-ray machine settings used to acquire this image, yellow if Visix thinks the x-ray settings could be slightly better, and red if Visix thinks the x-ray settings are poor and the image should be checked.

To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the

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Close Window box ☒ in the upper right corner of the window. If the image quality is not acceptable, close the View window and consider either rescanning the plate, if it hasn't been erased, or retaking the x-ray.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

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Save an Image

To save images, click the Close and Save button at the bottom of the ScanX Acquisition window. Close and Save The images will save, no matter what color their DEMS lights are, to the currently selected patient.

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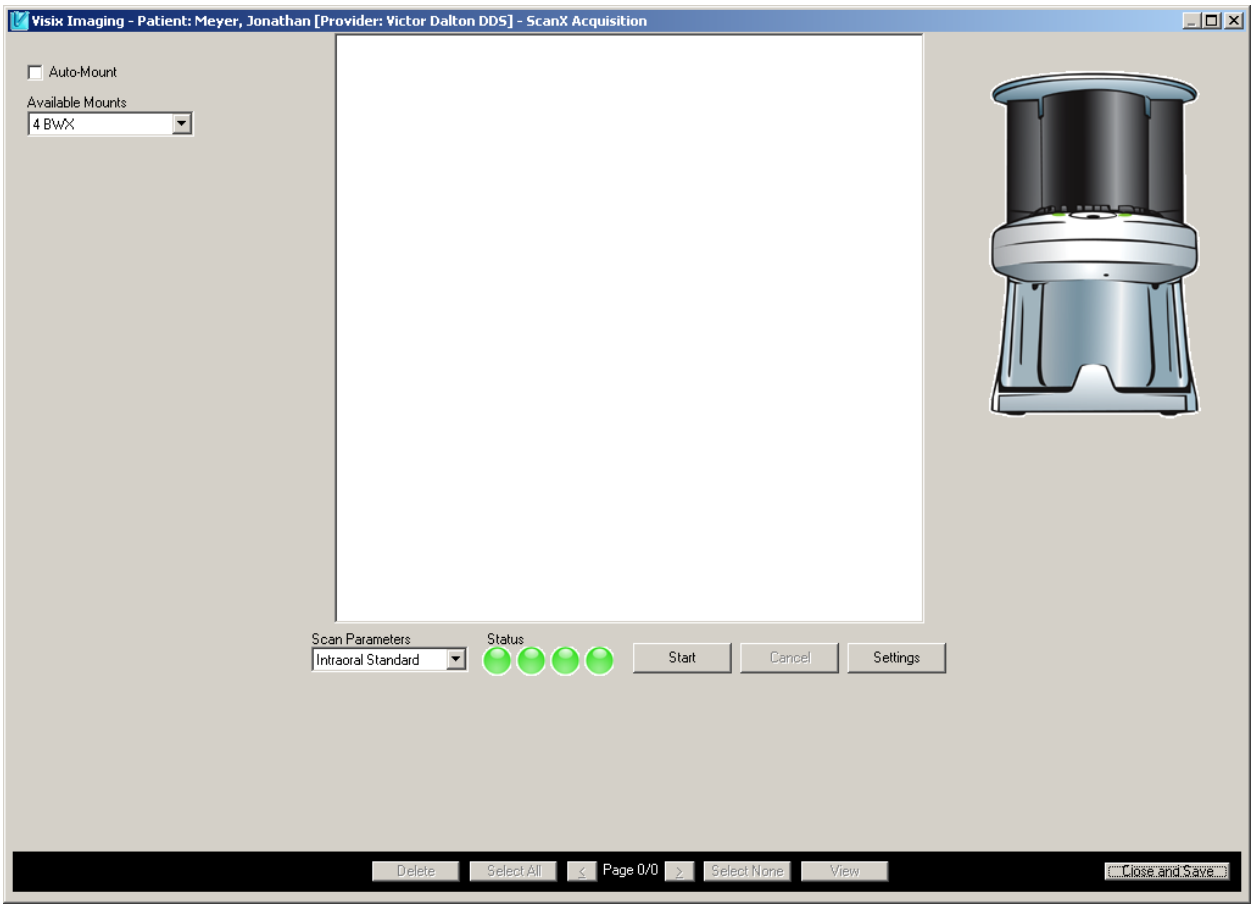
Intelligent Track Control – Setup Option 3

Although the ScanX is physically connected to this workstation, one or two other workstations will acquire images from it.

When the ScanX is physically connected to this workstation but controlled by other workstations, the ScanX Acquisition window looks the same as when Visix is setup in Direct Connect Mode. For instructions on how to use this window, please refer to the Direct Connect Mode section of this manual.

ScanX Acquisition window when Setup Option 3 of ITC Mode is selected:
The ScanX is connected to this workstation but one or two other workstations will acquire images from the ScanX



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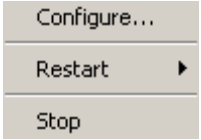
ScanX Controller

If the ScanX is configured for Client/Server mode the ScanX Controller will appear in the System Tray (the lower right corner on the computer screen). The background color of the ScanX Controller will be green if the ScanX is available for scanning, white if the ScanX and the ScanX Controller are not communicating with each other, and red if the ScanX is currently scanning plates.

ScanX Icon Right Click Menu

Right clicking once on the ScanX icon in the System Tray will display the following menu:



Configure

Information on the Configure windows should only be changed when:

- Visix is installed on this computer
- The Visix port numbers have changed
- The computer the ScanX scanner is connected to has had its name or IP address changed
- The Scan Mode needs to be changed.

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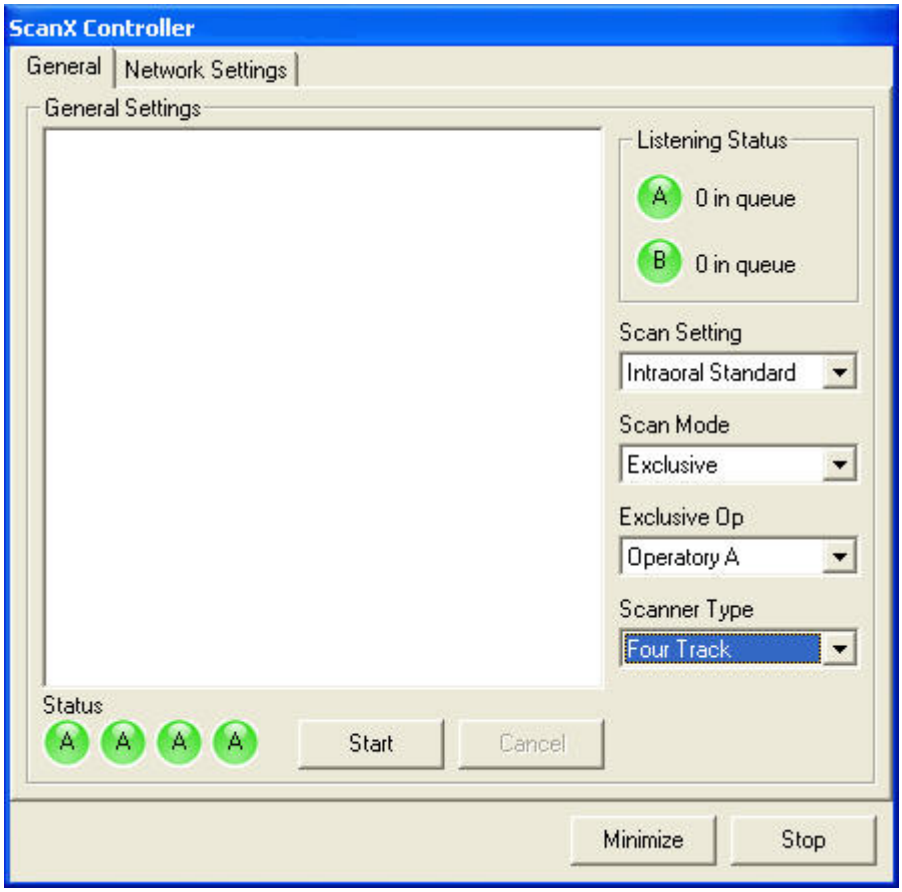
ScanX Controller - General Window



Queue

If plates were scanned by the ScanX Controller instead of from the Visix Op A workstation or Op B workstation, the images will sit in a queue until the client opens, at which time they will appear as thumbnails on the ScanX window and can be selected and saved.

Scan Setting

Select the ScanX Scan Parameter Setting that should be used when scanning images directly from the ScanX Controller instead of from the Visix Op A workstation or Op B workstation.

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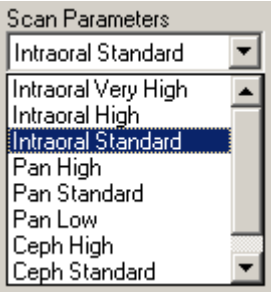

Scan Mode

Select Exclusive to allow just one workstation, either Op A or Op B, to acquire images from the ScanX. In Exclusive Mode, the workstation that is selected will be able to use all of the ScanX tracks.

Select Shared Mode to allow both workstations to acquire images from the ScanX. In Shared Mode each workstation is allowed to use only half of the ScanX tracks. In Shared Mode, Op A uses tracks 1 and 2, and Op B uses tracks 3 and 4. When using a ScanX Duo, Op A uses track 1 and Op B uses track 2.

Exclusive Op

If the Scan Mode is Exclusive, select the op that will acquire the images from the ScanX.

Scanner Type

Select Two Tracks if a ScanX Duo will be used to scan plates. Select Four Tracks if a ScanX will be used to scan plates.

Minimize and Stop Buttons

The Stop button at the bottom of both Configure windows will end the communication between Visix and the ScanX.

The Minimize button will close the Configure window.

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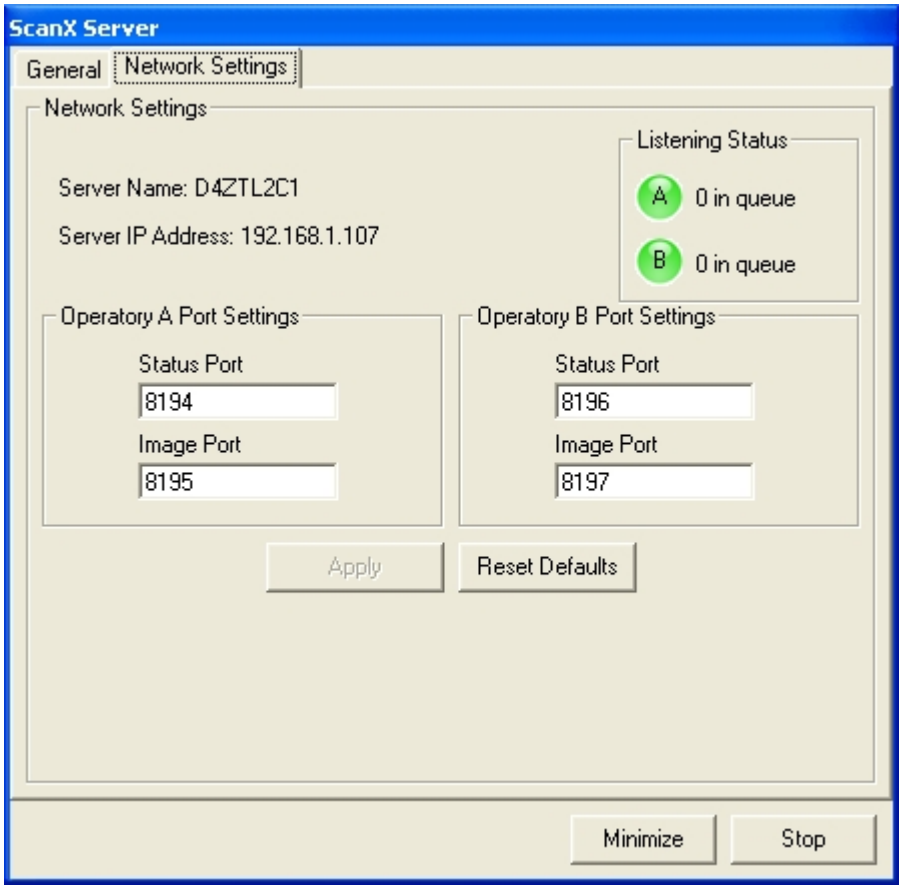
ScanX Controller - Network Window



Operatory A Port Settings

Enter two unused ports that the computer the ScanX is connected to will use to send ScanX status information and images to the workstation set up as the Visix Op A workstation. The Op A ports listed on the computer the ScanX is connected to must match the Op A ports listed on the Op A computer.

Operatory B Port Settings

Enter two unused ports that the computer the ScanX is connected to will use to send ScanX status information and images to the workstation set up as the Visix Op B workstation. The Op B ports listed on the computer the ScanX is connected to must match the Op B ports listed on the Op B computer.

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Minimize and Stop Buttons

The Stop button at the bottom of both Configure windows will end the communication between Visix and the ScanX.

The Minimize button will close the Configure window.

Restart

Selecting Restart will display the following menu:

Rebooting this computer will have the same effect as selecting the ScanX and Communication options. Select ScanX to restart the ScanX controller on this computer. Select Communication to open the communication link between this computer and the ScanX scanner.

Stop

Select Stop to close the ScanX Controller.

ScanX Icon Left Click Menu

Left click on the ScanX icon in the System Tray to display the list of ScanX Parameter Settings along with the option to automatically erase the plate after it has been scanned.

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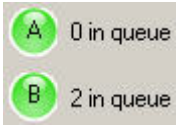
Scanning Images Without Visix Open

The ScanX Controller can be used to scan phosphor plates if the Visix Op A and Op B workstations are not available for use. To use the ScanX Controller in this manner, perform the following steps:

- Determine which Visix workstation, Op A or Op B, would normally have been used to acquire the images.
- Right click one time on the ScanX controller in the System Tray of the workstation the ScanX is directly connected to, and select Configure.
- On the General tab, select the Scan Setting that should be used to scan the phosphor plates.
- On the General tab, click on the Start button.
- Feed the plates into the ScanX tracks that are used by the Visix Op A or Op B workstation that would normally have been used to acquire the images.
- The images will be placed in the queue belonging to the Visix Op A or Op B workstation that would normally have been used to acquire the images.



- When the ScanX Acquisition window is opened on the Visix Op A workstation, the ScanX images acquired by the ScanX Controller using Op A tracks will appear at the bottom of the window as thumbnails.
- When the ScanX Acquisition window is opened on the Visix Op B workstation, the ScanX images acquired by the ScanX Controller using Op B tracks will appear at the bottom of that window as thumbnails.
- To save the images, click on the Select All button at the bottom of the ScanX Acquisition window, then on the Close and Save button. The images will save to the currently selected patient.

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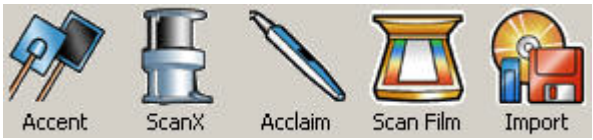
Acquisition Windows

Acclaim Camera

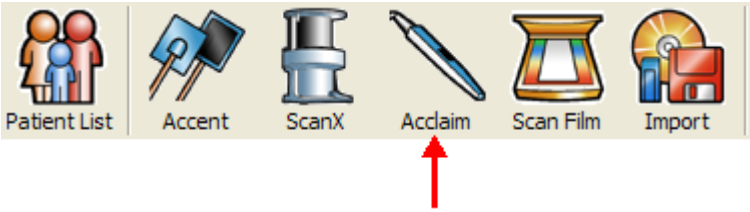
Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

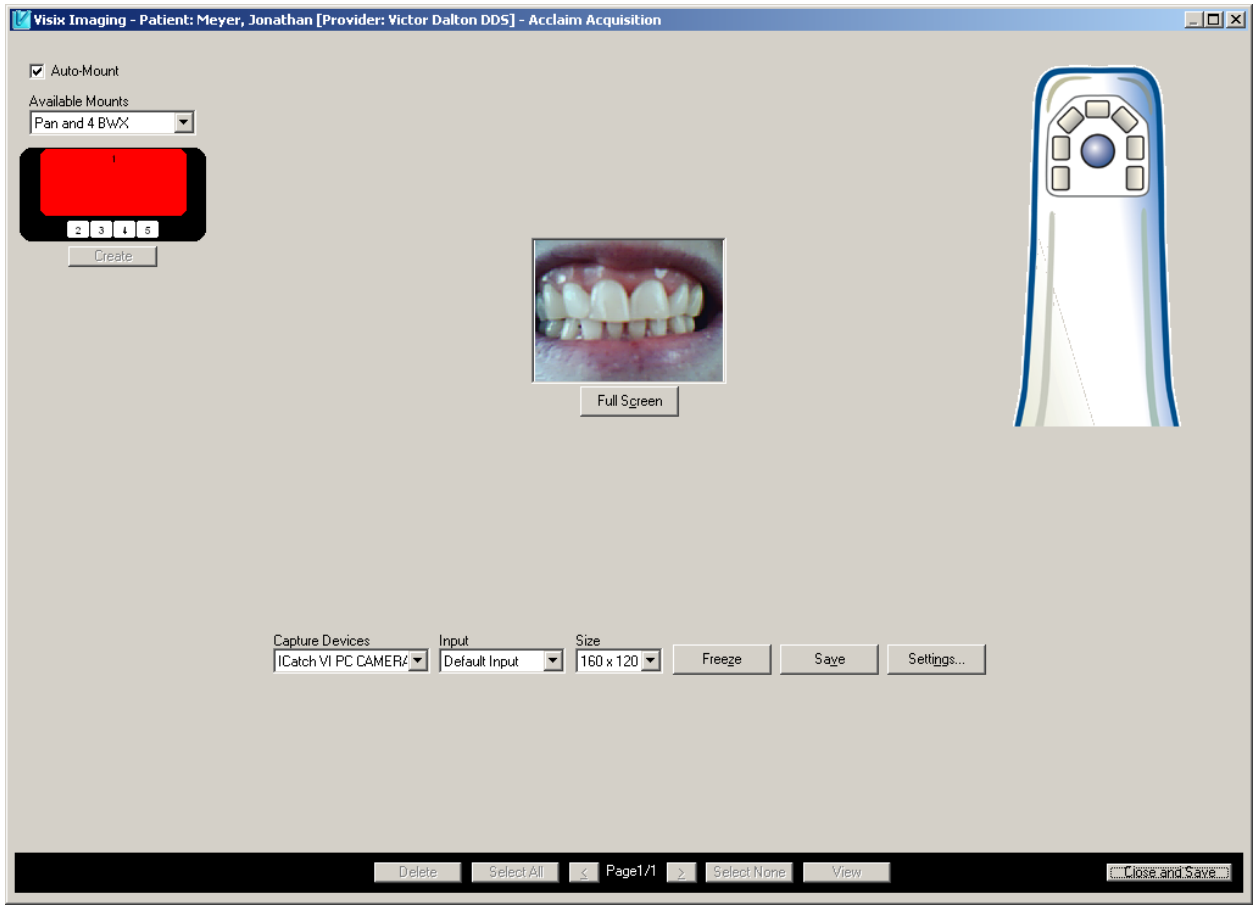


By default, Visix can only capture video images from the Acclaim USB camera and the SLC USB camera. For other intra-oral camera support, the Universal Video module must be used.

Acclaim Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Acclaim Acquisition window.





Capture Devices

Click on the down arrow of the Capture Devices drop down box to display the devices Visix can retrieve still images from. Select an intra-oral camera.

Input

Click on the down arrow of the Input drop down box to display different types of input such as S-Video or Composite. Select the correct type for the intra-oral camera that is connected to this workstation.

Size

Click on the down arrow of the Size drop down box to view the different sizes that the window used to display the camera's live picture can be adjusted to. A few of the available dpi settings are pictured below.

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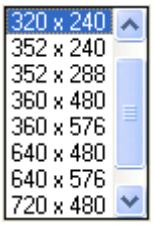

Select a size. The recommended size for the Acclaim is 640 by 480.

Freeze / Live

Click on the Freeze button to cause the current image from the camera to freeze in the Current Image box. After Freeze is clicked on, either click on Save to put the image in the thumbnail row at the bottom of the window, or click on the Live button to restore the live feed from the camera to the Current Image box. The picture still needs to be saved to bring it into Visix.

Save

Click the Save button to capture an image. A thumbnail version of the image will appear at the bottom of the screen. The Current Image box will return to live feed. The image still needs to be saved to bring it into Visix.

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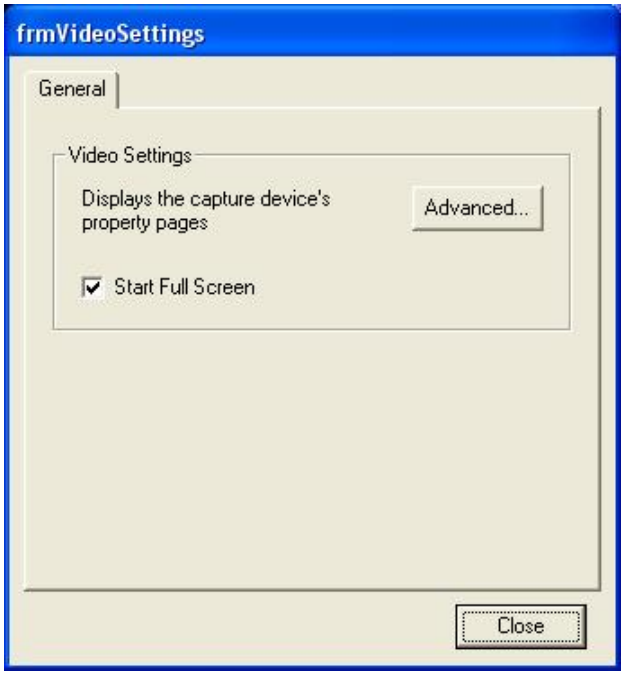
Settings Button

Settings Button – Acclaim Camera



Start Full Screen

Checking this box will automatically start the camera in full screen mode.

Advanced…

Clicking on the Advanced button will open the settings windows for the camera. Please refer to the camera manufacturer's instructions for an explanation of each setting. Please be aware that any changes made here will affect every future image taken by this camera.

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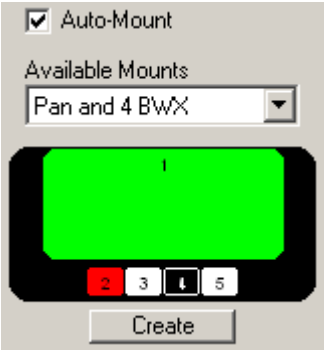
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

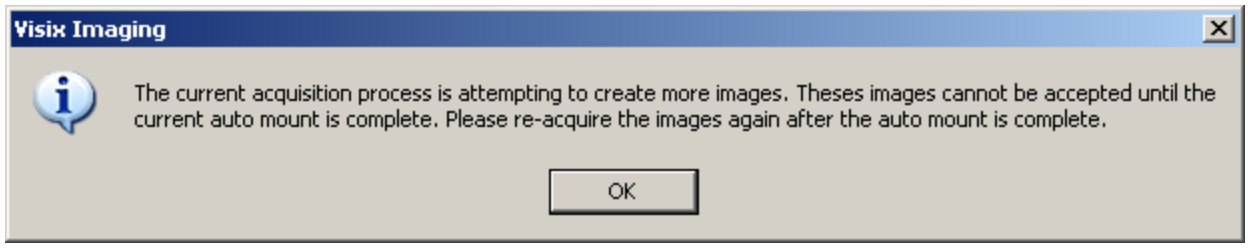
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

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Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window. Select None

View an Image

To open an image into the View window, first select the image or images to be viewed and then click the View button at the bottom of the window. View

Save an Image

To save an image or images, click the Close and Save button at the bottom of the window. Close and Save All of

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the images on the bottom of the window will be saved to the currently selected patient.

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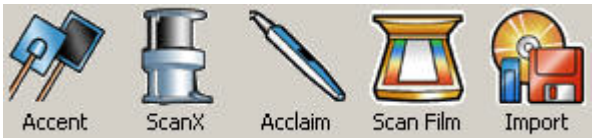
Acquisition Windows

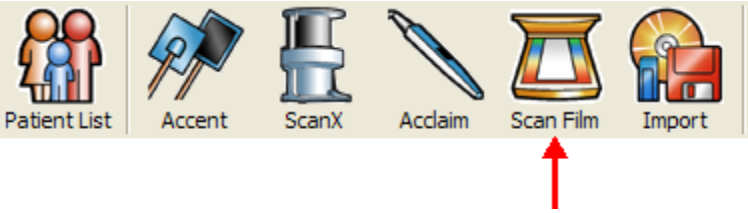
Flatbed Scanner

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.



Film Scanning Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Film Scanning Acquisition window.



Setting up Film on the Flatbed Scanner Bed

When scanning film, make sure the scanner's transparency cover – if it has one – is off. It will need to be replaced for scanning documents and photographs.

If the scanner's transparency area does not include the entire scanner bed, line up the negatives under the area of the scanner bed that the transparency area does cover. For example, the Epson Perfection 1600 transparency area includes just an oblong section of the center of the scanner bed. In this case, negatives would be placed in a straight row within the oblong area.

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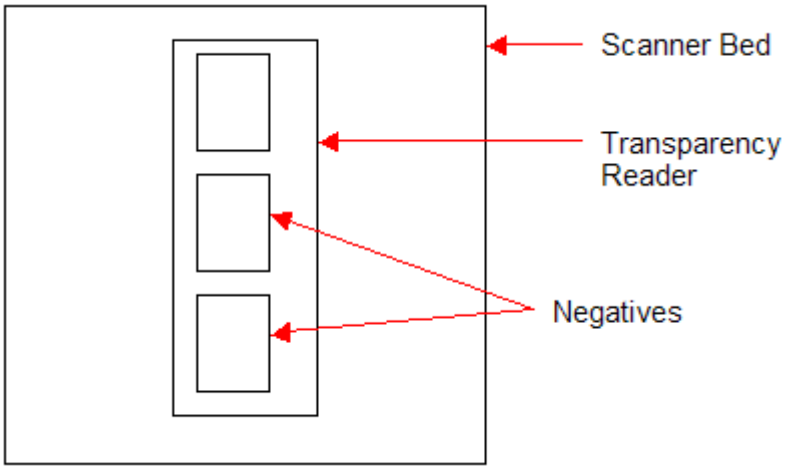
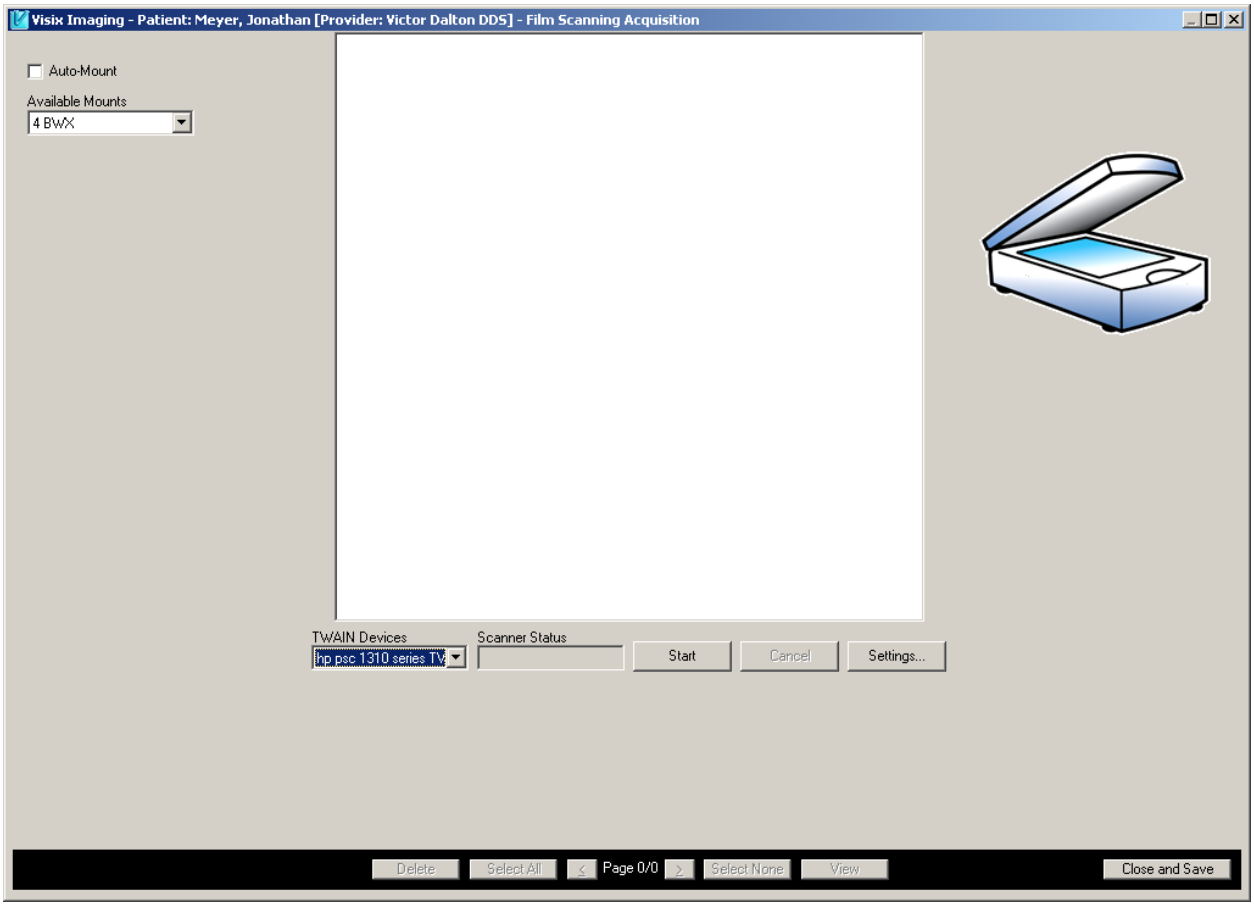


Film Scanning Acquisition Window



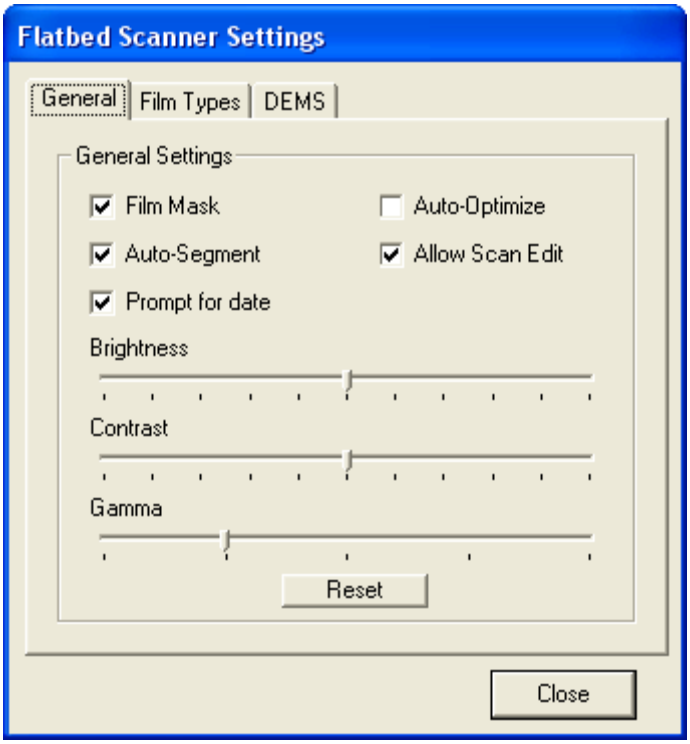
TWAIN Devices

Click on the down arrow of the TWAIN Devices drop down box to display the devices Visix can retrieve scanned images from. Select the appropriate flatbed scanner.

Settings Button for a Flatbed Scanner

The Settings button will display windows that hold optional scanning settings for the scanner that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this scanner. The Reset button on each window will change the settings for that window back to the original settings Visix came with.

Settings Button - Flatbed Scanner



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General Window

Film Mask

A Film Mask is a black border that is placed around an image in the same way a colored mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future flatbed scanned images.

Auto Optimize

Auto Optimize will turn Visix processing routines on in an attempt to enhance the quality of the scanned image. When the film being scanned is over exposed turn Auto Optimize off. A check mark indicates that Auto Optimize is on.

Auto-Segment

Auto-Segment is the ability to automatically recognize separate items on the scanner face as separate images. If four standard size negatives are placed on the scanner face and Auto-Segment is on (the Auto-Segment box has a check mark in it), Visix should place a green selection box around each negative indicating that it recognizes four separate pieces of film to scan.

If Auto-Segment is off (the box is not checked), the user must draw a selection box around each image manually by clicking and dragging a box around the image. Allow Scan Edit must be on (checked) to manually draw selection boxes. Auto-Segment and Allow Scan Edit should never both be off.

Any image that does not have a selection box around it will not be scanned into Visix.

Allow Scan Edit

Allow Scan Edit will allow the user to be able to manually draw selection boxes around each image, or edit the selection boxes Visix automatically drew around the images using Auto-Segment.

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Any image that does not have a selection box around it will not be scanned into Visix.

For instructions on how to add, edit and remove boxes please refer to the Add a Box Around an Item, Edit a Box Around an Item, and Remove a Box paragraphs coming up in this section of the manual.

Prompt for Date

If Prompt for Date is on (checked) Visix will prompt the user to enter the date the film was originally taken on. If Prompt for Date is off (unchecked), Visix will save each scan using the current date.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. Changing the Gamma setting can make the image very dark.

Reset

Reset restores the default settings that came with Visix.

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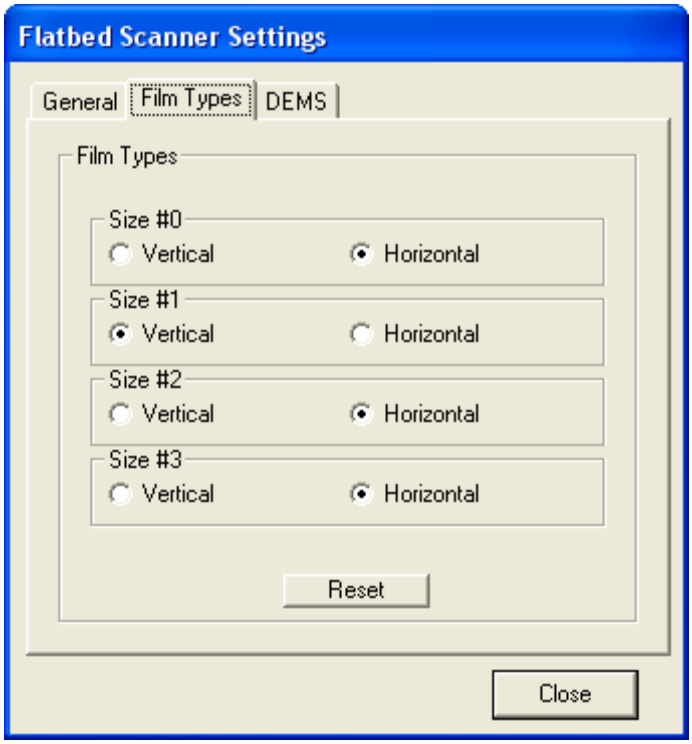
Settings Button – Flatbed Scanner



Film Types Window

The Film Types window lists four sizes of film and whether each is to be scanned into Visix in either a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical.

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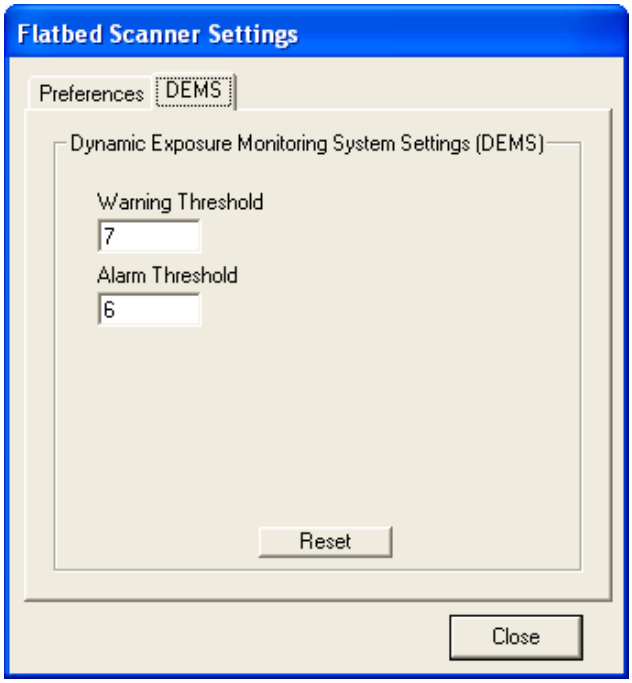
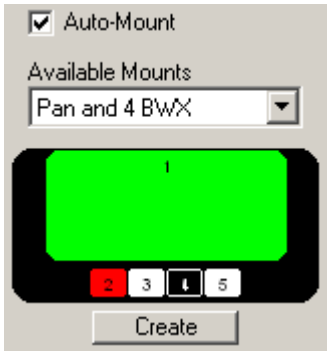
Settings Button - Flatbed Scanner



DEMS Window

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is

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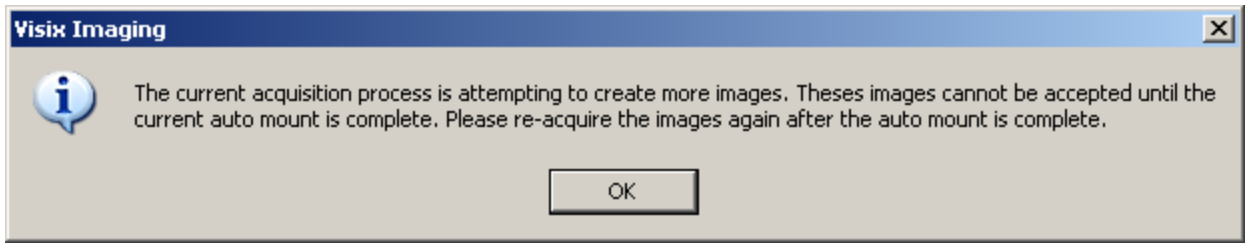
scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

At the Flatbed Scanner

Load the film onto the flatbed scanner.

Start Button

Click on the Start button on the Film Scanning window to tell Visix a scan is ready to begin.

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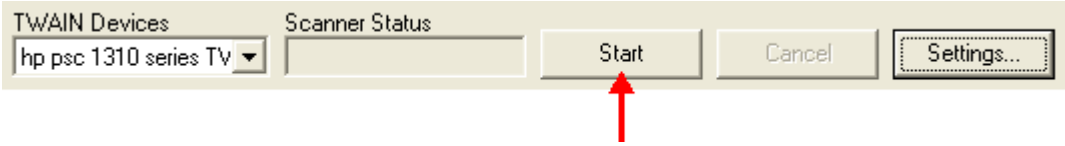
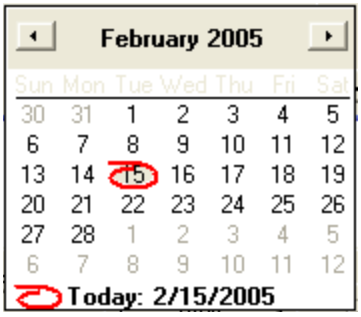


Enter Film Date

Enter the date that this film was taken then click on the OK button. If you are not sure of the date, click on the down arrow of the Enter Film Date drop down box to display a calendar.



Click on the left and right arrows that are on either side of the month and year to step backwards or forwards through the months. Click on a day to automatically insert that date into the Enter Film Date box and close the calendar.

After the scan date has been entered, the scanner software will open.

Scanner Settings

For most flatbed scanners, the settings for the scanner driver window should resemble the following:

- Mode Professional
- Document Type Film
- Film Type Positive Film
- Image Type 8-bit Grayscale
- Resolution 200dpi

Once the settings have been adjusted, click on the Scan button to begin the scan. Note that some scanners perform better if a Preview scan is performed before the actual scan.

During the Scanning Process

Visix will automatically capture the image from the flatbed scanner. If the Cancel button

is clicked on during the scanning process, the scan will be aborted.

After the Initial Scanning Process if Allow Scan Edit is on

Once an image has been scanned, if Allow Scan Edit is on (the Allow Scan Edit box is checked on the Settings Button – General tab), Visix will pause to allow the user to add or edit selection boxes around each image. At this point, the scanner software will have closed, Visix will be open with the scan visible in the Current Image Box, and the Finish button will be present. An image must have a selection box around it for Visix to acquire it.

Add a Selection Box Around an Item

Adding a selection box around an item will cause Visix to scan that item. To add a selection box, left click on a corner of the item, hold the left mouse button down and drag the mouse to the opposite corner of the item to scan. Each side of the box should touch its matching side on the image. If they don't, refer to the next paragraph.

Edit a Selection Box Around an Item

Editing a selection box involves using the resizing or rotating arrows on the box to change its size or orientation. The rotating arrows are curved arrows that are located at the corners of the box. The resizing arrows are straight arrows and are located in the middle of each side. Click and drag the appropriate arrow until each side of the box touches its matching side on the image.

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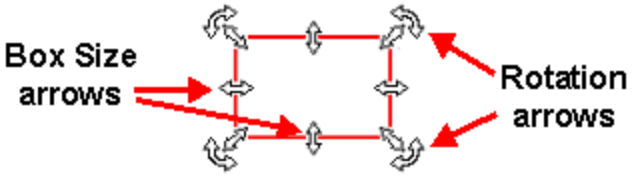

Remove a Selection Box

Removing a green or blue selection box from around an item prevents that item from being scanned. To remove a selection box, right click on the box and select Delete Outline.

After the Boxes have been Adjusted

Once the user is done adjusting boxes the Finish button should be clicked to allow the final scanning processes to start. Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the Film Scanning window. The image still needs to be selected and saved into the Visix database.

After the Final Scanning Process

To check an image, double click on the image to open it into the Visix View window. When finished, close the View window by clicking on the Close Window box ☒ in the upper right corner of the window.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are <u>not</u> recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window.
Close and Save All of the images that appear as thumbnails at the bottom of the Acquisition window will save to the currently open patient.

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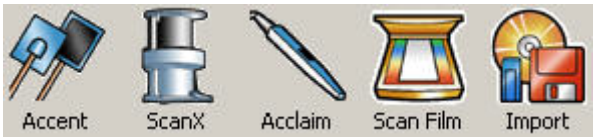
Acquisition Windows

Import

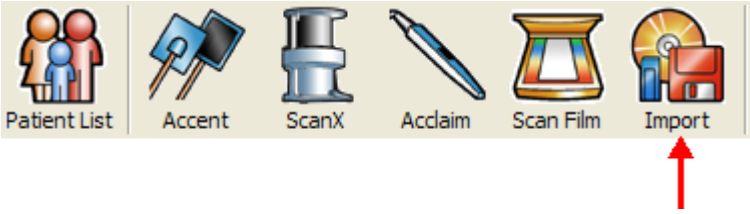
Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

Importing is the process by which a digital image, photo or document can be copied into Visix from a location that is outside of Visix.



Import Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Import Acquisition window.



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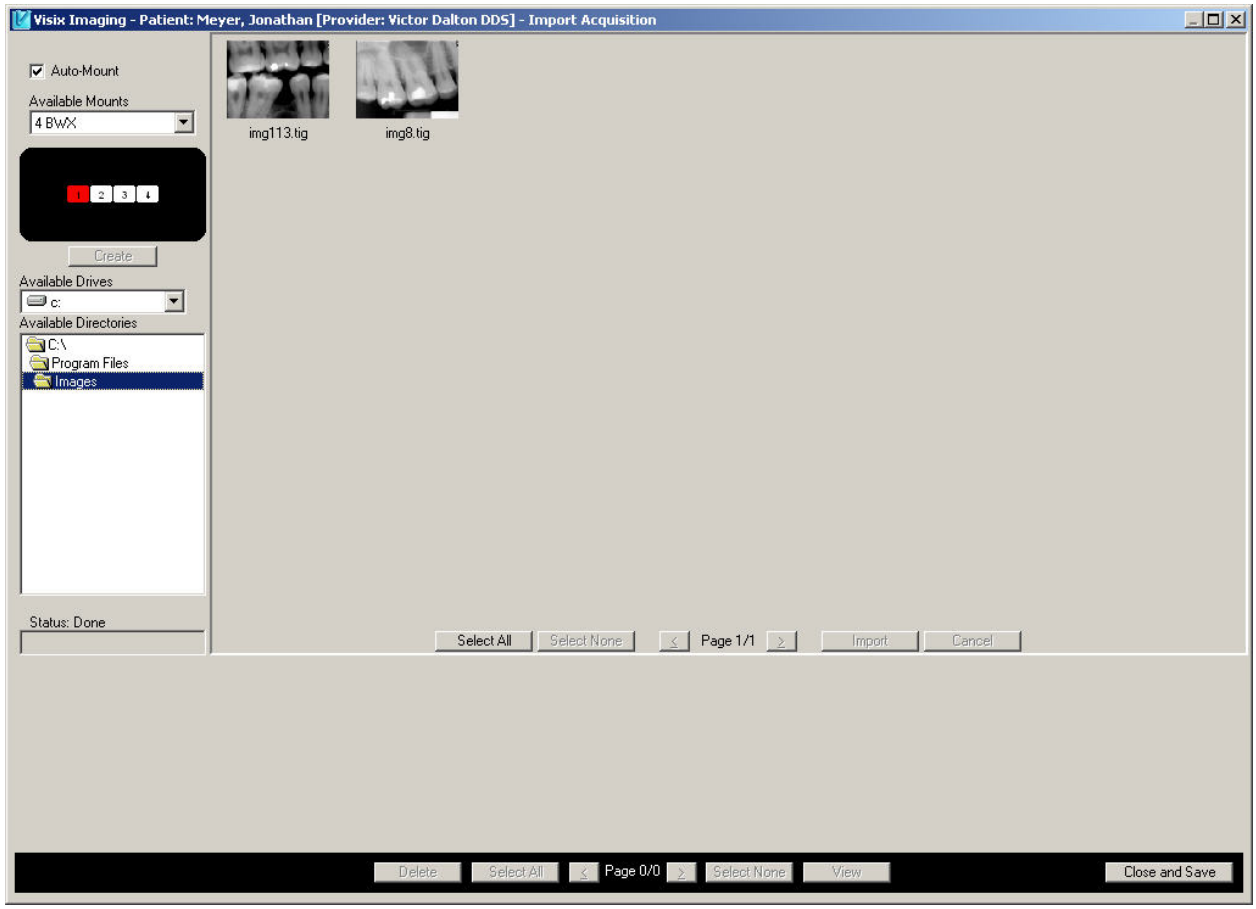
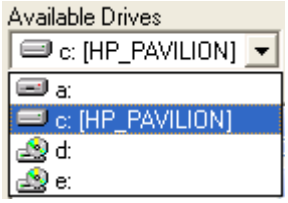


Available Drives

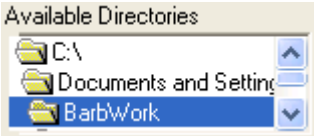
Click on the drop down box arrow to display the list of drives this computer can access. If this computer is on a network and has network drives mapped, the network drives will also display.



Select the drive where the imported images can be found. Note that the computer views many digital cameras as removable hard drives.

Available Directories

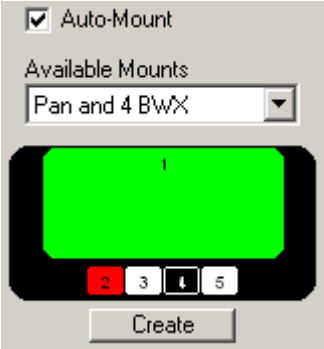
After the drive is selected, a list of the folders (also called Directories) on that drive will display.



Select the folder where the imported images can be found. Any images in the selected folder (directory) on the selected drive will display in the Current Image box on the Acquire window.

To import an image, select the image by left clicking on it once then click on the Import button. The image will appear at the bottom of the window, and, if Auto-Mounting is turned on, in the selected mount. Select the image at the bottom of the window and click on the Save button to save the image to the currently selected patient.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

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Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is

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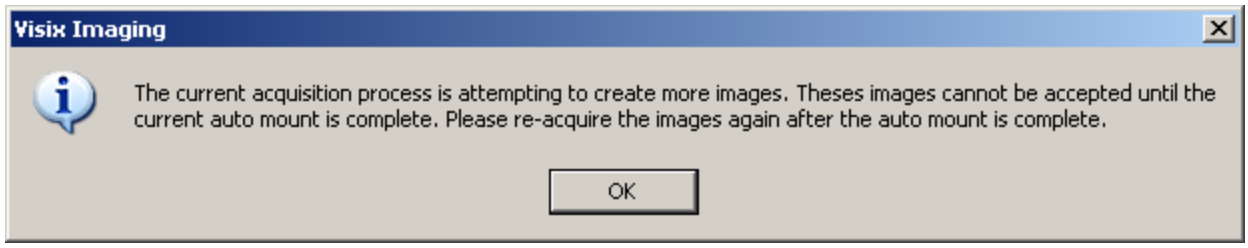
still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Image Buttons Within the Current Image Box

Select an Image

To select an image to import, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of the Current Image box.

A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it a second time. To deselect all of the images click on the Select None button at the bottom of the Current Image box. Select None

Import an Image

To import an image, first select the image or images that require importing then click on the Import button at the bottom of the Current Image box. Import The image or images still need to be saved into the Visix database.

Stop the Import

If, during the import operation, the image is no longer desired, click on the Cancel button at the bottom of the Current Image box. Cancel The Cancel button will abort the import operation.

After the Import

Once an image has been selected and imported it will move to the area under the Available Directories box as a thumbnail image. The image still needs to be selected and saved into Visix.

To check an image, double click on the image to open it into the Visix View window.

Image Buttons below the Current Image Box

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the Acquisition window. Delete Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the Acquisition window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the Acquisition window. Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window. View

Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window. Close and Save All of the images that appear as thumbnails at the bottom of the Acquisition window will save to the currently open patient.

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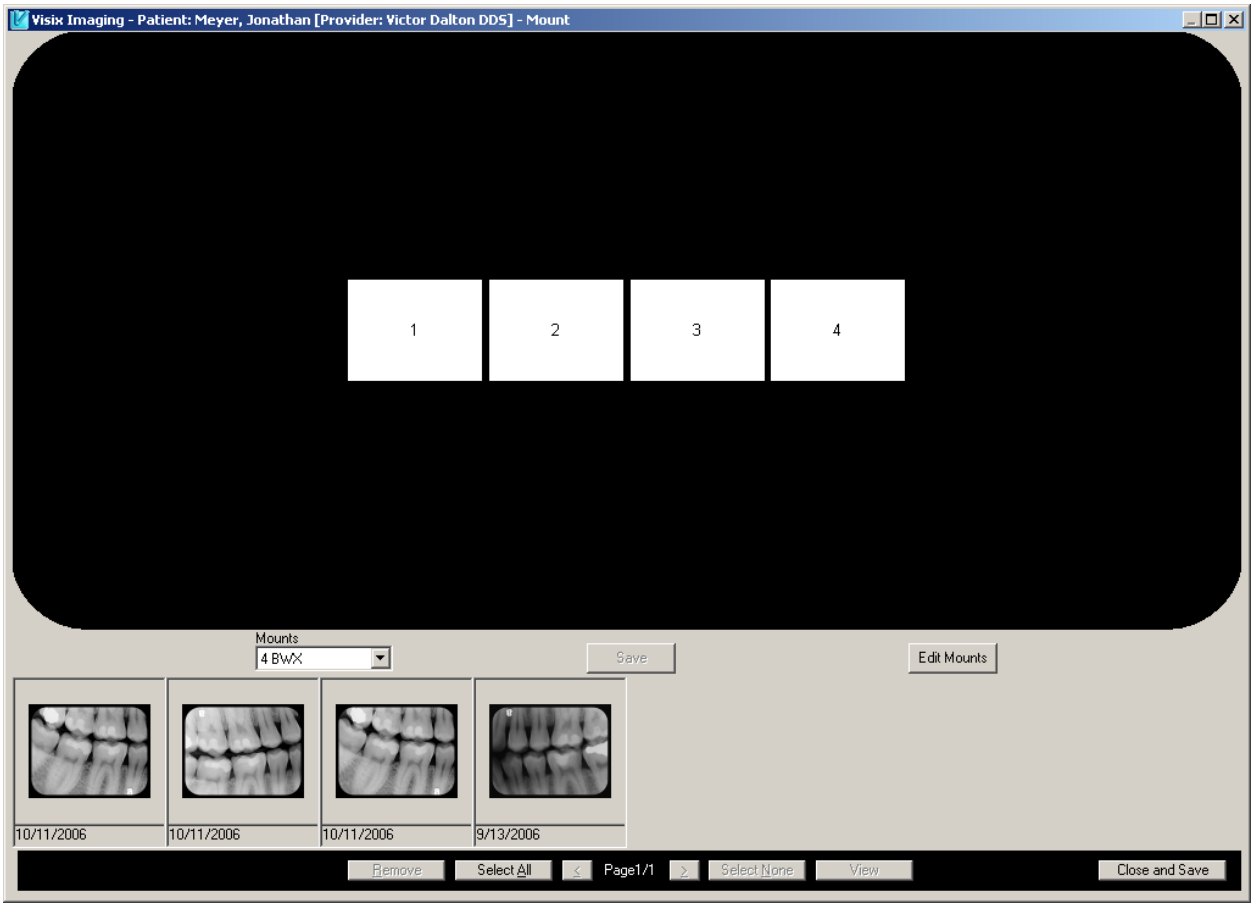
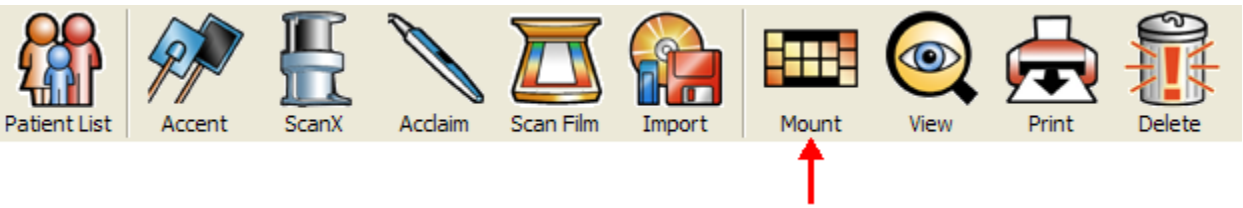
Mount Window



Any saved image can be brought to the Mount window to be viewed, and/or mounted.

Bring Images to the Mount Window

To bring images to the Mount window, select the images from the Images window, and then click on the Mount button at the top of the main Visix window. The images will appear on the Mount window below the black Digital Light Box.



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Using the Mount window to view existing mounts

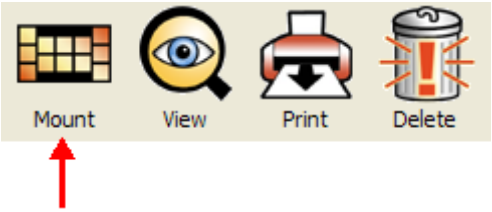
To use the Mount window to view an existing mount that has images in it, bring the mount to the Mount window then drag the mount onto a dark part of the Mount box. Double left click on each image in the mount to view that image in the View window.

Using the Mount Window to Mount Images

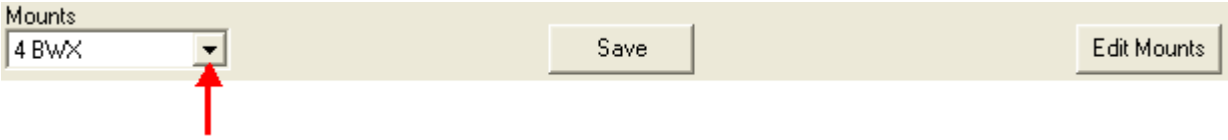
Mounting images is similar to placing photographs inside a mat that has multiple openings. The mounted photographs are now grouped together and can be viewed as one large picture. In the same way, images can be placed into the same mount then viewed, printed and exported as a single image.

Mount Images Using Existing Mount Templates

Move the images that need to be mounted to the Mount window by clicking on them and then clicking on the Mount button.



Click on the down arrow of the Mounts drop down box and select a mount.



The white boxes that appear in the black Digital Light Box are meant to hold the images. Drag the images, one at a time, onto a white Image Holder box. The order that the images are dragged onto the white boxes does not matter.

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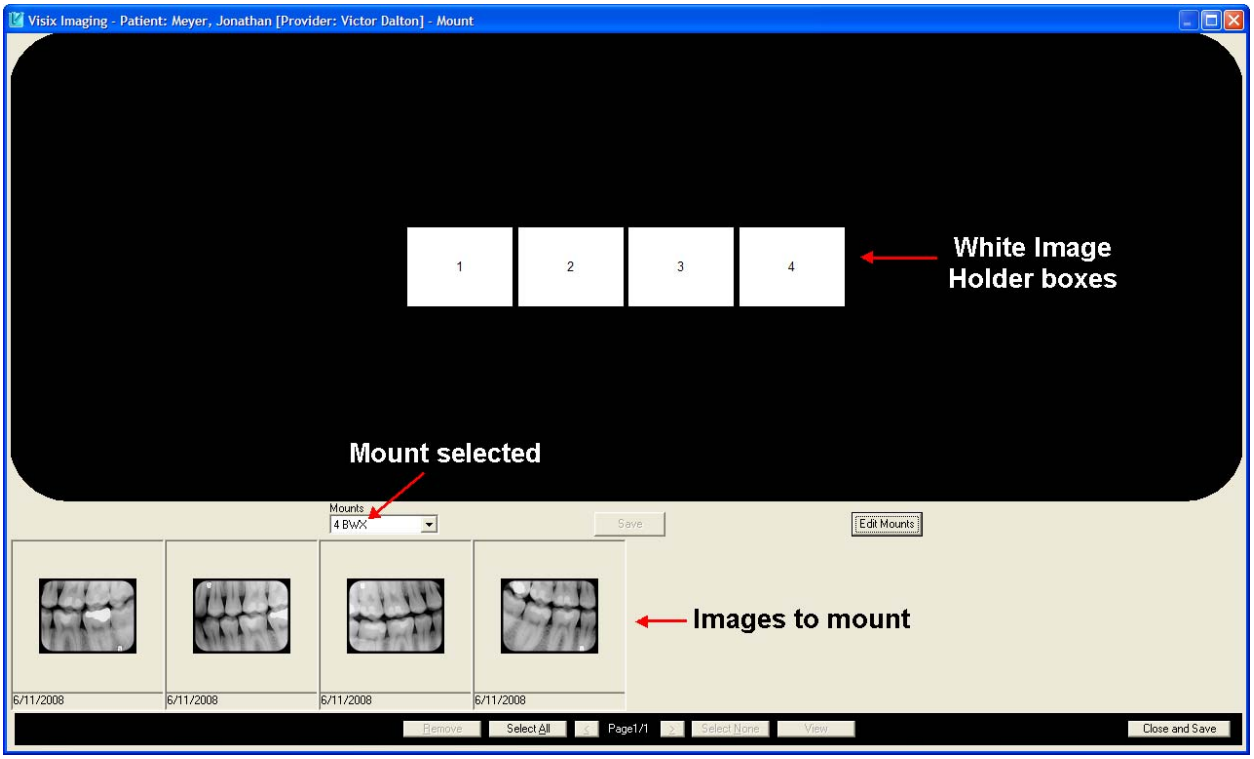


- To move an image within the mount, drag the image from its current location in the mount to a different Image Holder Box.

- To remove an image from the mount, right click on the image in the mount and select Remove from the Right Click Menu that appears.

- To change the orientation of an image in the mount from vertical to horizontal or from horizontal to vertical, the orientation of the Image Holder Box must be changed. For instructions on how to change the orientation of an Image Holder Box on an existing mount please refer to the Edit An Existing Mount section below.

When the images have been correctly placed in the mount, click on the Save button Save to save them as a single mounted image

Making Changes after Images have been mounted and the Mount has been saved

Select a mount, plus any additional images that need to be placed in that mount, by clicking on them, and then click on the Mount button.

In the Mount window, drag the mount onto a black area of the Digital Light Box instead of onto a white Image Holder Box. The mount will open for editing. Images can be moved, removed, or added to the mount.

Move an Image in an Existing Mount

Once an existing mount has been opened for editing, an image can be moved by dragging it to a different Image Holder Box.

Remove an Image from an Existing Mount

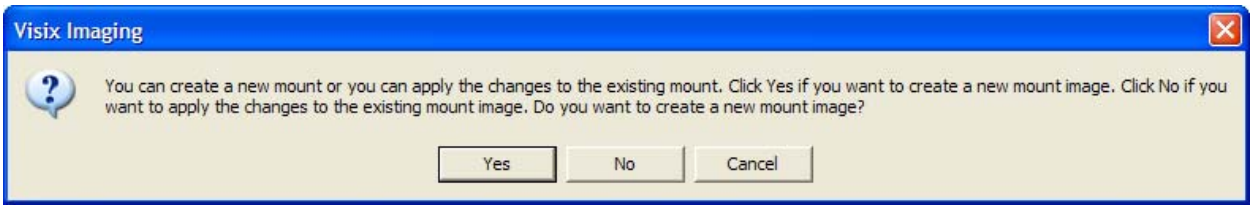
Once an existing mount has been opened for editing, an image can be removed from it by right clicking on the image and selecting Remove from the Image Holder Right Click Menu that appears.

Add an Image to an Existing Mount

The mount plus the images to add to it must be moved to the Mount window at the same time. Once an existing mount has been opened for editing, images can be added by dragging them to Image Holder Boxes.

Save the Updated Mount

Click on the Save button to save the updated mount. The following window will open:



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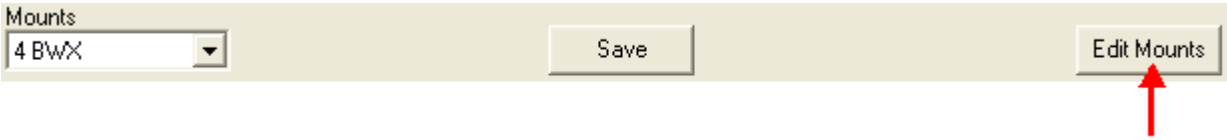
- Click on Yes to keep the original mount and save the updated mount as a separate image.
- Click on No to save the updated mount and delete the original mount image.
- Click on Cancel if the mount needs additional adjusting.

Create a New Mount Template

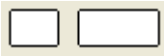
To create a new mount, in the Mount window click on the Edit Mounts button.



The area of the window underneath the Digital Light Box will change.

Click on the Add button to create a new mount.

The area of the window underneath the Digital Light Box will change again.

To create a new mount, drag one of the two boxes  onto the Mount box to create an Image Holder. The boxes that are dragged onto the Mount box cannot touch each other. The larger oblong box, when dragged onto the Mount box, will hold a pan or ceph image. Notice that the Image Holder boxes are numbered. The numbers are important only if the mount is going to be used with the Visix Auto-Mount feature.

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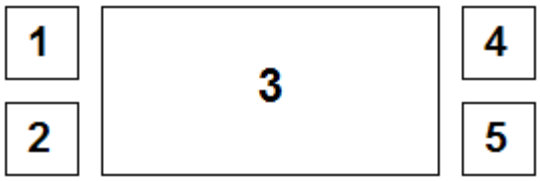
Creating a Mount that will be used with for Auto-Mounting

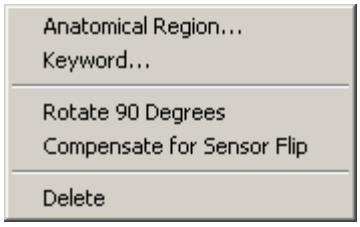
If the Auto-Mount feature is going to be used with this mount, the Image Holders must be placed on the mount in the same order that the images coming into Visix will be loaded into the mount. For example:



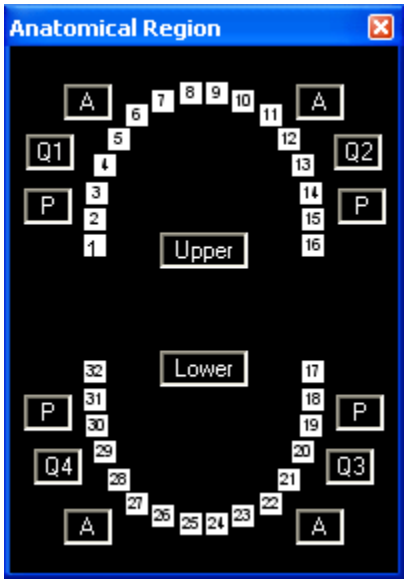
In the mount above, two bitewings are located on each side of a pan. Using a phosphor plate scanner for this example, the first plate that is scanned will be placed into the Image Holder with the number 1 on it, the second plate that is scanned will be placed into the Image Holder with the number 2 on it, the third plate that is scanned will be placed into the Image Holder with the number 3 on it (the pan), etc. If the plates are fed into the scanner in the wrong order the pan may end up in a bitewing sized Image Holder.

Image Holder Right Click Menu

To change one of the image holder boxes on the Digital Light box, right click on it. The Image Holder Right Click Menu will appear.



Anatomical Region



If the same type of image will always be placed in this image holder, the anatomical region represented can be preset. Select the teeth in the diagram that correspond with the teeth in the image by clicking on them. Clicking on “A”, “P”, “Q1”, “Q2”, “Q3”, “Q4”, “Upper” or “Lower” will highlight sets of teeth in green. Left clicking on a specific tooth number will highlight an individual tooth. Clicking highlighted teeth will un-highlight them. Changes to this window are saved when the window’s close button ✕ is clicked.

Saving the anatomical region allows this image to appear (or not appear) in response to a search by anatomical region. The search is performed on the Patient Window.

Keyword

If the same keyword will be assigned to every image placed in this image holder, the keyword associated with it can be preset. Assign Keywords by selecting them from the pull down menu. For instructions on how to use the Keywords window please refer to the Right Click On An Image section of this manual.

Rotate 90

Select Rotate 90 to rotate the Image Holder 90 degrees.

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Compensate for Sensor Flip

Select Compensate for Sensor Flip to automatically flip an image being placed in this image holder by a sensor. A check will appear next to this option on the Image Holder Right Click Menu to indicate that this function has been activated.

Delete

Select Delete to remove the Image Holder from the mount.

Complete the New Mount

When the Image Holders are adjusted correctly in the mount, click in the Description box and enter a descriptive title for this mount, then click on the Save button to save the new mount.

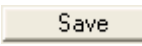
Edit an Existing Mount Template

To change an existing mount, in the Mount window click on the Edit Mounts button.

The area of the window underneath the Digital Light Box will change.

Click on the down arrow of the Mounts drop down box to select the mount to edit, then click on the Edit button to edit the selected mount.

The area of the window underneath the Digital Light Box will again change.

Anything on the mount, including its description, can be changed. If the mount is being used with the Auto-Mount feature be cautious about adding and deleting Image Holders. You may affect the order that the digital images should come into Visix (see Creating A Mount That Will Be Used For Auto-Mounting above). When all of the changes have been made, click on the Save button 

to save the mount. Click on the Close Editor button to end this edit session.

Delete an Existing Mount Template

To delete an existing mount, in the Mount window click on the Edit Mounts button.

The area of the window underneath the Digital Light Box will change.

Click on the down arrow of the Mounts drop down box to select the mount to delete, then click on the Delete button. Click on the Close Editor button to end this edit session.

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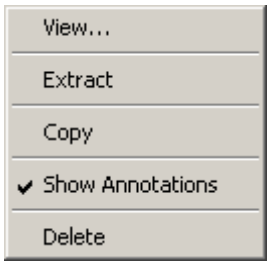
Right Click Menu for Images in the Mount Window

Placing the cursor on an image that has been dragged onto an Image Holder in the Mount box, then clicking the right mouse button once opens the Right Click Image Menu displayed below.



View

To view an image in the View window, right click on the image in the Mount and select View from the menu that appears. In the View window the image can be magnified, rotated, flipped, colorized, embossed, annotated, measured, inverted, etc.

Extract

To copy an image from the Digital Light Box to the area underneath the Digital Light Box, right click on the image in the Digital Light Box and select Extract from the menu that appears.

Copy

To copy an image to the clipboard from the Digital Light Box, right click on the image in the Digital Light Box and select Copy from the menu that appears. The image will be copied to the clipboard and can then be pasted into any software product that can utilize the clipboard.

Show Annotations

Show Annotations will cause the annotations to display on the thumbnail version of the image. Selecting Show Annotations when the annotations already display will cause the annotations to be hidden.

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Delete

To remove an image from a mount but leave it on the Mount window under the Digital Light Box where it can be used again, right click on the image in the Mount and select Delete from the menu that appears.

How to Drag and Drop an Image

To drag an image

Place the cursor (the arrow that moves on the screen when the mouse is rolled on a flat surface) on top of the desired image. Press down and hold the left mouse button. While holding the left mouse button move the cursor, by sliding the mouse on a flat surface.

To drop an image

To drop an image, release the left mouse button.

Image Buttons

Remove an Image from the Mount Window

To remove an image from the Mount window, click on the image under the Digital Light Box then click on the Remove button at the bottom of the Mount window.

Select an Image

To select images, left click on them. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. A selected image will have a green box around it.

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Deselect an Image

To deselect an image, left click on the image again. To deselect all of the selected images, click on the Select None button at the bottom of the window.

If an image was mistakenly removed from the Mount window right click on the image in the mount and select Extract. A copy of the image will be placed under the Digital Light Box.

View an Image

To open an image in the View window, first select the image or images to be viewed, and then click on the View button at the bottom of the Images window. Another way of opening images in the View window is to first select the image or images to be viewed, then right click on one of the images and select View from the right click menu. For instructions on how to use the View window, please refer to the View Window section of this manual.

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View Window

The View window is used to examine and manipulate an image, through measurements of angles and lines, flipping, rotating, colorizing, zooming, changes in brightness and contrast, magnifying, annotations, etc.

Open an Image into the View window from the Images Window

To open a single image into the View window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Menu.

To open multiple images into the View window do one of the following:

- Left click on the All button at the bottom of the Images window then right click on one of the selected images and select View from the Right Click Menu.
- Left click once on each image that needs to be viewed to select it, then left click once on the View icon at the top of the Visix window.
- Left click once on each image that needs to be viewed to select it, then right click on one of the selected images and select View from the Right Click Menu.

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Sections of the View Window

The box where the image appears is the Current Image box. To the left of the Current Image box are the tools available to examine and manipulate the image. At the top of the Current Image box are any settings and requirements needed for the currently selected tool. To the right of the Current Image box are the tools that adjust the brightness and contrast.

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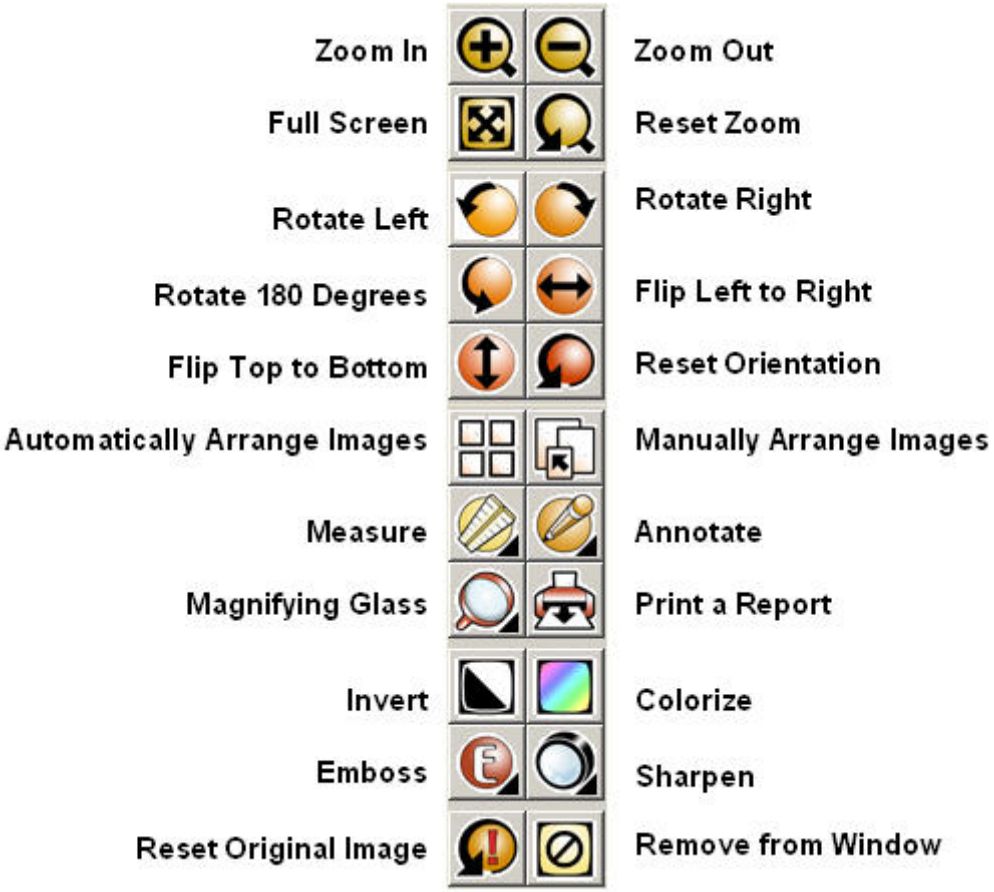
View Window Toolbar



View Window Tools

The tools will affect either the single image in the View Window, or, if there are multiple images in the window, the selected image. Left click once on an image to select it. The selected image on the View window will have a green box around it.

Pan Tool

When viewing an image that has been zoomed in on, the Pan Tool can be used to move the area being displayed.

Click and drag the red Pan Box to change the section of the zoomed in image that is currently displayed in the View window.

Zoom In

Each click on the Zoom In tool will make the image a little larger.

Zoom Out

Each click on the Zoom Out tool will make the image a little smaller until it's restored to its original size.

Full Screen

If more than one image is open in the View window, clicking on the Full Screen tool will make the selected image (the image with the green box around it) fill the View window. Click on Full Screen again to make the selected image fill the entire window. Click on Full Screen a third time to return the image to its original size.

Reset Zoom

Click on the Reset Zoom tool to return the image to its original size.

Rotate 90 Degrees Counter Clockwise

Click on this tool to turn the image 90 degrees to the left.

Rotate the Image 90 Degrees Clockwise

Click on this tool to turn the image 90 degrees to the right.

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Rotate the Image 180 Degrees

Click on this tool to turn the image 180 degrees so that what had been at the top of the image is now at the bottom of the image.

Flip the Image from Left to Right

Click on this tool to flip the image over from left to right.

Flip the Image from Top to Bottom

Click on this tool to flip the image over from top to bottom.

Reset the Image to its Original Orientation

Click on the Reset tool to return the image to the orientation it had when it was originally acquired.

Automatically Arrange Images

Click on the Auto Arrange Images tool to move the images in the View window to the position they were in when the View window was opened.

Manually Arrange Images

Click on the Manually Arrange Images tool to allow the images to be resized and moved anywhere on the View window. To move an image, click on the image and drag it to a new location. To resize an image, move the cursor on top of a corner box. When the cursor becomes a two headed arrow click and drag the corner box until the image becomes the desired size.

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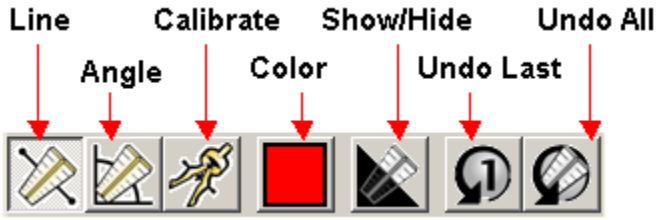
Measure

Click on the Measure tool to open the Measure Options window. The Measure tool might need to be calibrated before it can be used. After calibrating, if the color the lines will be drawn in needs to be changed, click on the Line Color button and select a new color. At this point, measurements may be taken.

Note: For accurate measurements, not only does the calibration need to be precise, but also the patient positioning and the acquisition device positioning needs to be precise to avoid images that are taken on an angle. Images taken on an angle will have measurements that are slightly different from reality.

To close the Measure options window, click on the Measure tool again.



Line

Click on the Line option to measure a line. Left click on one end of the line then left click on the other end of the line. Right click to stop measuring lines.

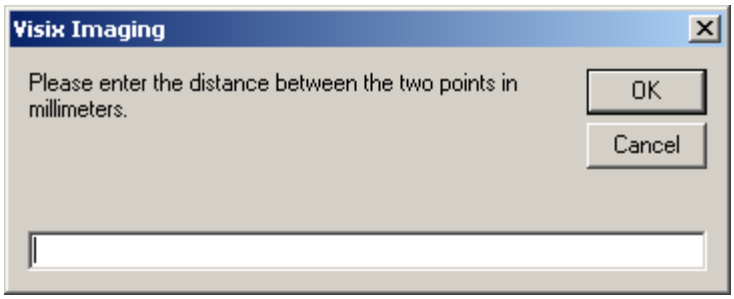
Angle

Click on the Angle option to measure an angle. Click on the end of one leg, then at the point of the angle, and finally on the end of the second leg. Right click to stop measuring angles.

Calibrate

To calibrate, something that has a known measurement in millimeters must be on the image. Click the Calibrate button, click on one end of the object to measure, then click on the opposite end of the object to measure. Do not click and drag.

The Calibrate window will appear.



Enter the length of the object in millimeters. For example, if the object is 20 millimeters long enter 20 then click on the OK button. Do not enter “mm” for millimeters. Once the system is calibrated, angles and lines can be measured.

Note: Be as precise as possible when drawing the calibration line. Try to start and end the calibration line exactly on the edges of the object that is being used for calibration. In addition, try to keep the calibration line as straight as possible, avoiding the tiny jogs in the line that the computer adds to create a line that angles across the screen.

Line Color

Select the color of the line from the pallet window that opens. The color must be selected before the line is drawn.

Show/Hide

The when the Measure tool is opened the default for Show/Hide is to Show the lines. Click on the Show/Hide option to allow the measurement lines to remain on the image but not display. Click on the Show/Hide option again to display the lines.

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Undo Last

Delete the last measurement made on the currently selected image.

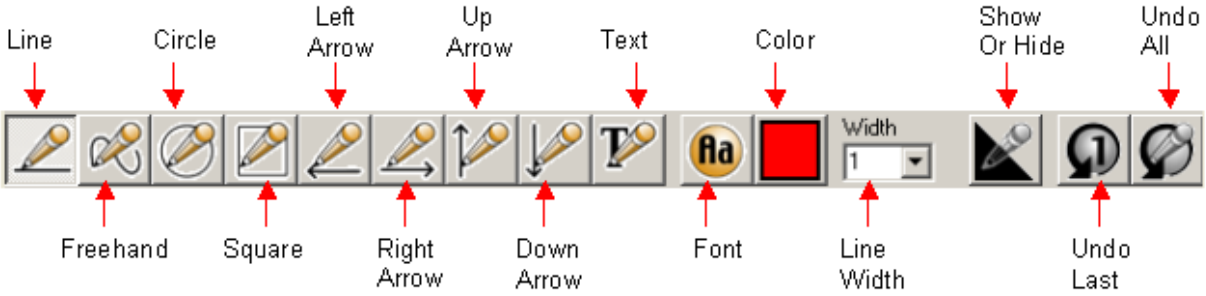
Undo All

Delete all of the measurements from the currently selected image.

Annotate

When the Annotate tool is clicked, the Annotation options window appears above the Current Image box. Note that annotations on an image cannot be moved or changed in any way. To move or change an annotation, the annotation must be deleted and then reentered.

To close the Annotation options window click on the Annotate tool again.



Line

Select the line width and color first, then left click on the image on one end of the line, left click on the other end of the line, and right click to stop the line drawing. A series of connected lines (for example, to draw a triangle) can be drawn by left clicking at each corner and right clicking only when all of the lines have been drawn.

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Freehand

Select the line width and color first, then hold down the left mouse button and draw.

Circle

Select the line width and color, then click and drag a circle on the image.

Square

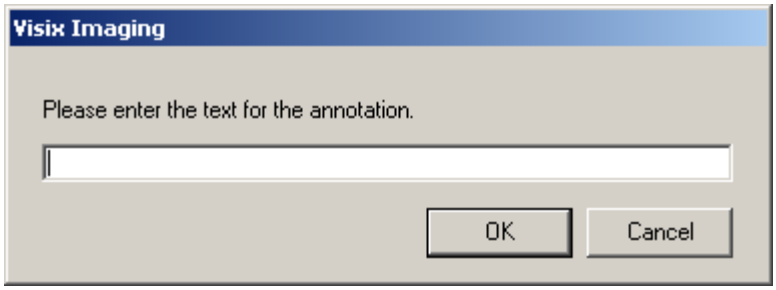
Select the line width and color first, then click and drag the square on the image.

Arrows

Select the left, right, up or down arrow option then left click where the tip of the arrowhead should be. Arrows and text are not affected by line width.

Text

Select the text color and font first then click on the point at which the first letter of the text should be placed. The Text Entry window will display allowing the text to be entered. Arrows and text are not affected by line width.



Font

Select the font, font style and font size for the text before entering the text.

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Color

Select the color the annotation will display in before creating the annotation.

Width

Select the width of the line for a line, freehand, circle or square before it is drawn.

Show/Hide

The when the Annotation tool is opened the default for Show/Hide is to Show the annotations. Click on the Show/Hide option to allow the annotations to remain on the image but not display. Click on the Show/Hide option again to display the annotations.

Undo Last

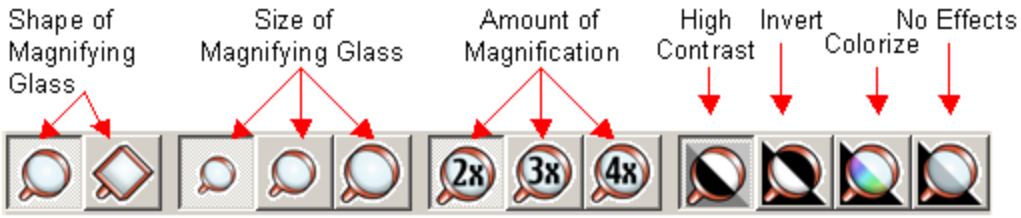
Delete the last annotation placed on the currently selected image.

Undo All

Delete all of the annotations from the currently selected image.

Magnifying Glass

Click on the Magnifying Glass tool to open the Magnifying Glass Options window.



Click on the desired shape, size, magnification amount and special effect then hold the left mouse button down as the

mouse is moved over the image. The area under the mouse will be affected.

Click on the Magnifying Glass tool again to close the Magnifying Glass Options window.

Print Selected Image

When the Print tool is clicked, the Microsoft Print window is opened to select the device to print to, the number of copies to print, etc. The selected image will print along with the patient's name, ID, date of birth, and gender, plus the provider's name and phone number, and the date the image was taken. The practice's name, address and phone number will display above the image.

Negate Image

When the Negate Image tool is clicked, the image areas that were black become white, and the image areas that were white become black. Click the Negate Image tool again to return the image to its previous appearance.

Colorize Image

When the Colorize Tool is clicked, a different color will be substituted for each grayscale value in an image. To return an image to its original grayscale appearance, click on the Colorize Image tool again.

Pseudo 3D

When the Pseudo 3D tool is clicked, the image will appear to be more three-dimensional, helping to emphasize the edges of the teeth. To return the image to its original 2D view, click on the Pseudo 3D tool again.

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Sharpen Image Edges

Sharpness looks for the boundaries between the light and dark areas of an image. When a boundary is found, sharpening it will make the first few pixels on the dark side darker and the first few pixels on the white side whiter. This causes more contrast at the edges. Making an image too sharp can cause the image to appear grainy.

Click on the Sharpen Image Edges tool again to return the image to normal.

Reset Original Image

When clicked, the Reset Original Image button will return the image to its original appearance at the time the image was acquired. Measurements and annotations that were previously saved on the image will still be there.

Remove From Viewer

Removing an image from the View window does not delete the image from Visix; it simply takes the image off the View window. Left click once on the image that needs to be removed to select the image. A green box displays around a selected image. Click on the Remove From Viewer button to take the image off the View window.

Brightness/Contrast Control

Left click and drag the small red circle on the Bright/Cont Tool. Moving the circle causes changes in the brightness (overall lightness) and contrast (the whites become whiter and the blacks become blacker) of the image.

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Gray Shift (Gamma)

Gamma will not change the whitest and blackest grayscale values in the image. It will, however, change the in-between colors – the different shades of gray. When the Gamma Slide Bar is slid down, the grays are lightened. When the Gamma Slide Bar is slid up, the grays are darkened.

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A Few Recommendations from the maker of Visix . . .

Equipment

Make sure that the equipment used to run Visix at the very least meets the minimum requirements for Visix as well as for each acquisition device used. Remember that better computer equipment (including the monitor and the printer) and acquisition devices result in better images. Image printouts should be made on high quality color ink jet printers such as those made by HP and Epson.

Backups

Make a backup of your database and image files daily. We also strongly recommend that you use multiple backup media. For example, if you are backing up your files to disks, use a different disk for each day of the week plus a set of disks for each month end. By using multiple media in this way you reduce the risk of copying a damaged file over your only good backup.

Training

There is no substitute for investing in good hands-on training. As staff is added, make a practice of having the employee with the strongest knowledge of Visix completely train the new employee. In addition, make sure the Visix manual is easily accessible by all employees, and strongly consider purchasing a yearly support contract, which provides you with Visix support over the telephone.

Internet Access

Image files are large. If you intend to transfer them using the Internet (using, for example, email with the images sent as attachments) high speed Internet access is preferred.

Office Phones

Please have at least one cordless phone or cell phone available for use by the office staff for making support calls to Visix. Solving problems frequently involves multiple computers so mobility is important.

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What Folders to Backup – Short Guide

The maker of Visix recommends that the Visix database and images be stored on the network server and backed up nightly. There are many different backup schemes and software. Which is employed is up to the user.

To locate the folder(s) to backup:

- Close Visix
- Open Visix Administration
- Login to the Administration program
- Click on Program Configuration and then click the Next button
- Click in the top box labeled “Database Connect String” and use the right arrow on the computer keyboard to move to the right, down the string. The location of the database is listed immediately after “Data Source = “. Tvdata.mdb is the database.
- The middle box displays the location of the images folder, where the images are kept.
- By default, the Images folder is located in the same folder that holds the database.

If you have questions, call Visix Technical Support at 1-866-908-4749.

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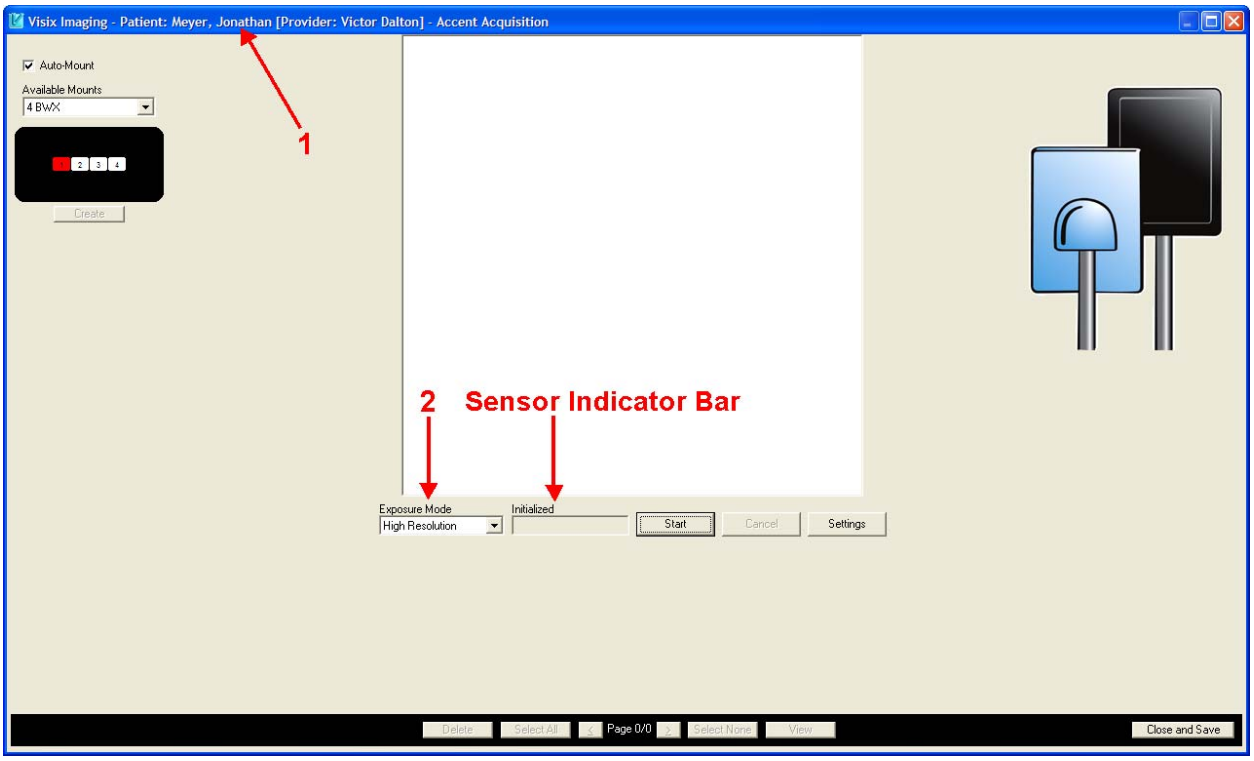
Accent Sensor Short Guide

Visix



Check 2 things:

1. Is this the correct patient?
2. Is this the correct Exposure Mode?

Sensor Indicator Bar:
During the time that the Accent Sensor is initializing, the Sensor Indicator Bar to the left of the Start button will display the word “Initializing”. Once the Accent Sensor is ready to be used, the bar will display the word “Initialized”, and then will flash green and the text “Waiting for Exposure” will display. After the x-ray button has been pressed to take the x-ray, the bar will flash red, the text “Processing Image” will display, then the thumbnail image will appear at the bottom.

If the Accent sensor has been set to automatically re-arm, the Sensor Indicator Bar will return to the “Waiting for Exposure” message. If the Accent sensor has not been set to automatically re-arm, click on the Start button to activate the sensor for the next shot

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, and then click on the Close and Save button at the bottom of the screen.

For more information, refer to page 42 in the Visix manual

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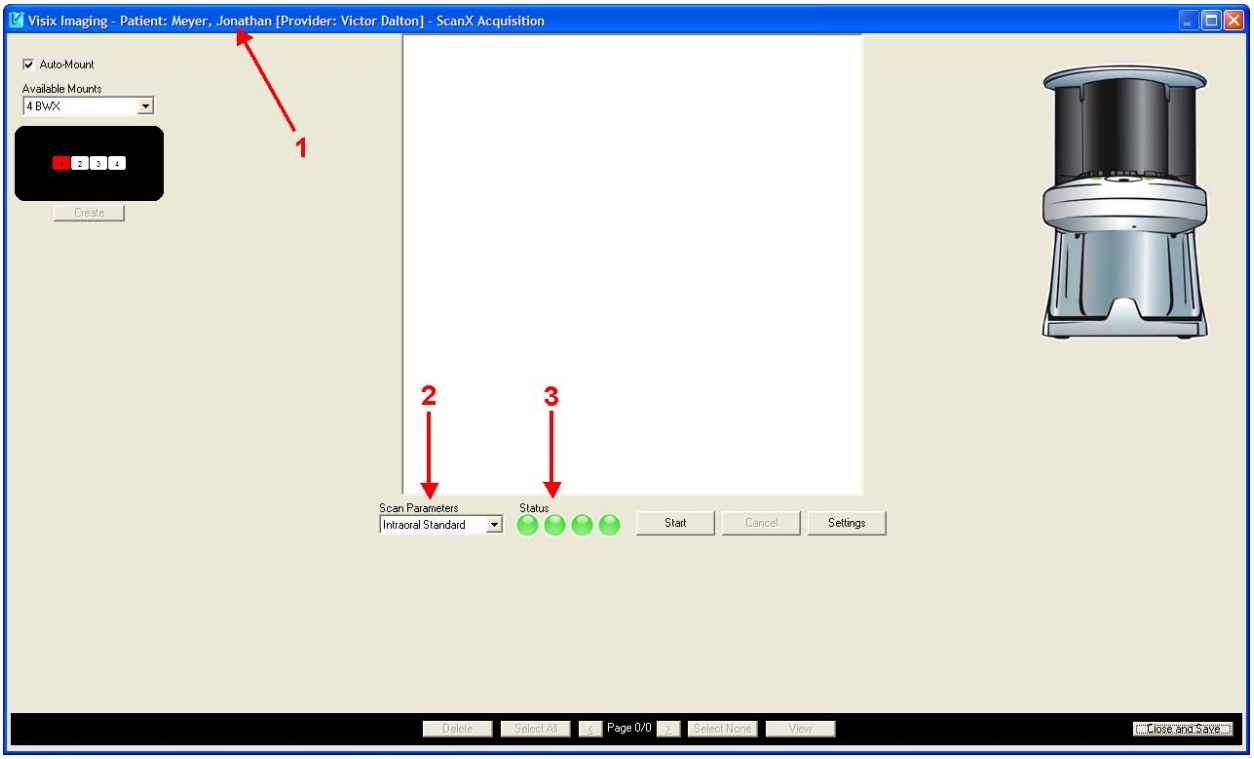
ScanX Scanner Direct Connect Short Guide

Visix



Check 3 things:

1. Is this the correct patient?
2. Is the Scan Parameters setting correct?
3. Are the Slot Status lights green?

If the three things listed above are all correct, the plate can be scanned.

Feed the plate into a slot with a green light. The white side of the plate should be against the ScanX. Press the plate down until you feel the ScanX rollers grab it.

A crude version of the image will float down the waterfall window, showing the progress through the ScanX. The actual image will appear in thumbnail size on the lower part of the window.

Check the DEMS light on each image. Images with a red DEMS light should be opened into the Viewer and checked there.

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.

For more detailed information, refer to page 55 in the Visix manual

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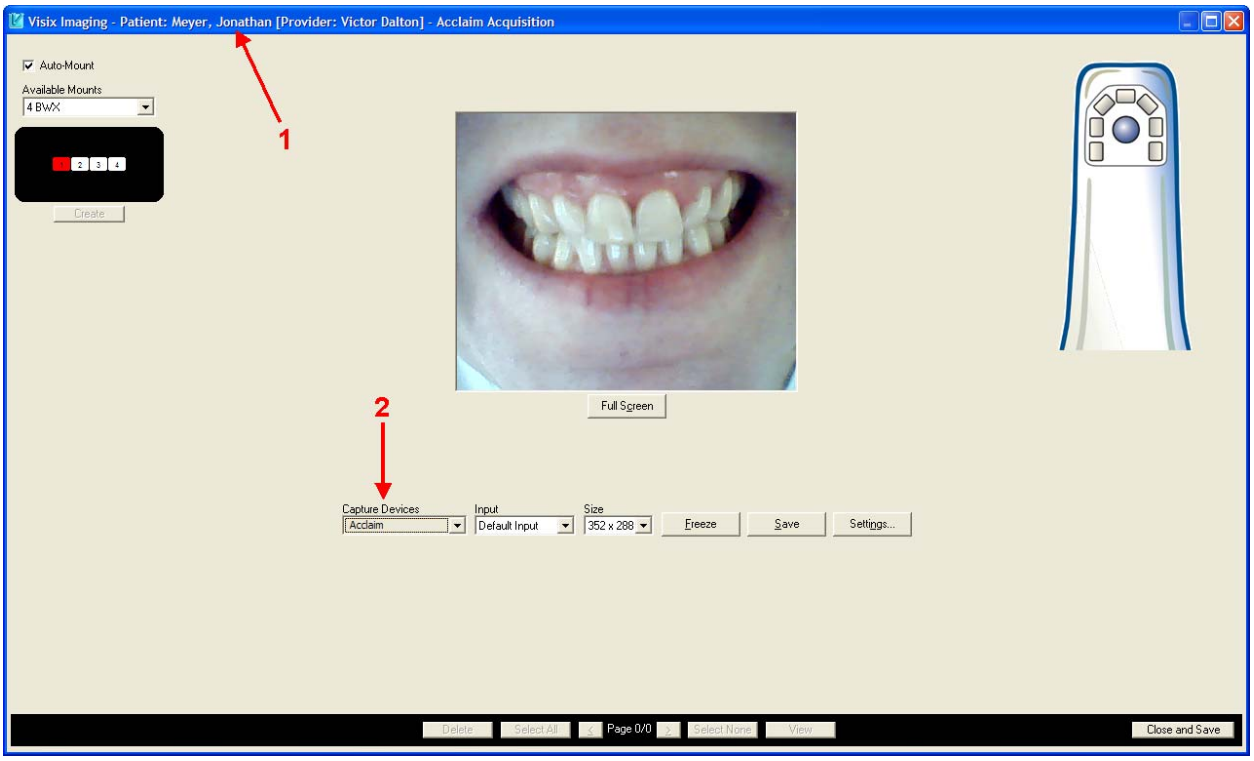
Acclaim Camera Short Guide

Visix



Check 2 things:

1. Is this the correct patient?
2. Is this the correct camera?

Prepare the Acclaim camera by placing a sheath over it and then removing the extra section from the lens side of the camera. Pull the sheath down snuggly over the lens so the picture is clear.

Point the camera at the area to take a picture of. When the correct teeth display on the screen, either click on the Freeze button on the screen or press the forward button on the camera to freeze the picture. If the picture is good enough to save, either click on the Save button on the screen or press the rear button on the camera. An image called a "thumbnail" will appear at the bottom of the window.

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.

For more information, refer to page 96 in the Visix manual

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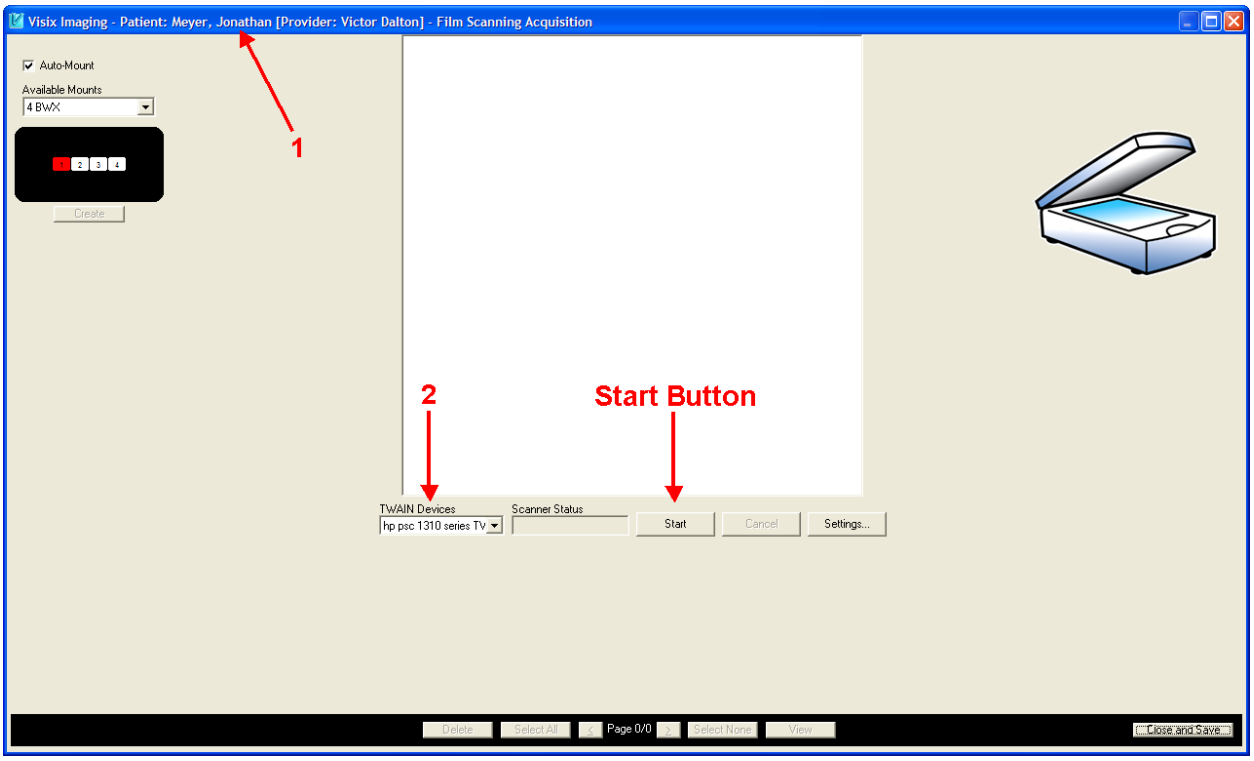
Flatbed Scanner Short Guide

Visix



Check 2 things:

1. Is this the correct patient?
2. Is this the correct Flatbed Scanner?

Place the film to scan on the scanner bed, close the lid and click on the Start button.

If the scanner was setup to ask for a date, a window will open that asks for the date the x-rays were taken. Click on the down arrow and then click on the date.

The software that runs the scanner will open.

For most flatbed scanners, the settings for the scanner driver window should resemble the following:

- Mode — Professional
- Document Type — Film. Film refers to something that light can shine through, such as film or transparencies.
- Film Type — Positive Film
- Image Type — 8-bit Grayscale
- Resolution — 200dpi

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Once the settings have been adjusted, click on the Scan button to begin the scan. When the scanner is finished scanning the image will appear in the Visix window.

If the scanner was setup with Allow Scan Edit on, the program will stop to allow you to add, delete or adjust image boxes. Whatever is inside an image box is what Visix will capture as an image. Once the boxes are adjusted, click on the Finish button.

If the scanner was not setup with Allow Scan Edit on, thumbnail images will appear in Visix according to what the scanner thinks is a separate image to scan. With Allow Scan Edit off, you are not allowed to adjust what is being acquired.

To Save:
Click on the individual thumbnail images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.

For more detailed information, refer to page 104 in the Visix manual

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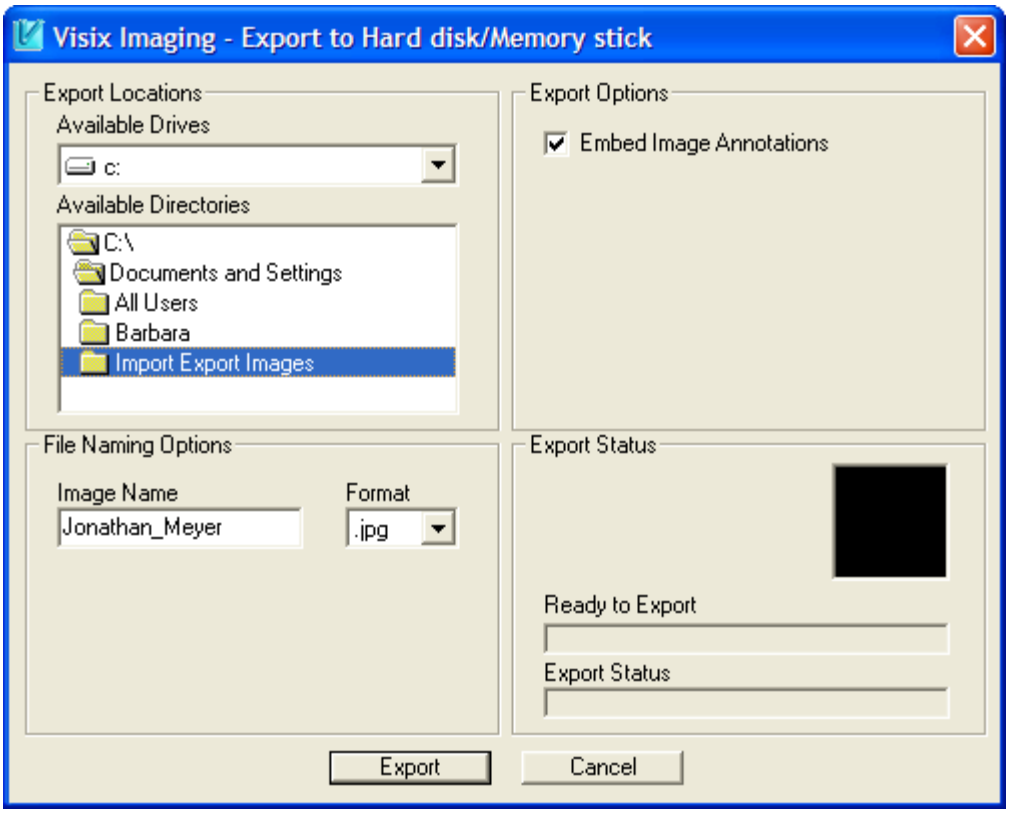
Export Images Short Guide

Visix



1. Left click one time on each image that needs to be exported.

2. Right click once on any of the images that were just left clicked on

3. Select Export

4. The Export window will open

5. The makers of Visix recommend creating a folder called “Import Export” directly under the Documents and Settings folder on Local Disk C: and using it to Export to and Import from.

6. Left click on the folder to export to. Locate it using Available Drives and Available Directories.

7. Click on the Format down arrow to select the type of export file to create. JPG is the safest file type to send because most programs will read it.

8. If you want all of the annotations that are on the images to go with the images, click on the Embed image annotations checkbox to put a check in it.

9. Click on the Export button

For more information, refer to page 32 in the Visix manual

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For questions about Visix that are not answered in this manual, please call the Visix support line at 1-866-90-VISIX from 8:15 AM EST to 5:00 PM PST.

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

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Perfecting Your Practice…

Visix Imaging Administration Manual

Dental Imaging Software

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Indications for Use

Visix is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data and measurements.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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

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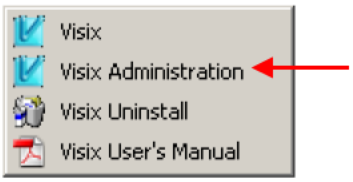
To Open Visix Administration

On your desktop, click on the Start button

Go to All Programs

Go to Visix Imaging

Then click on Visix Administration.



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

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Select a Provider

The first Visix window that opens is the Login Provider Window.

A provider is a doctor. If the name that displays is the correct provider click on the OK button. Otherwise, click on the Provider name down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, select a different one and use the Administration program to enter the missing provider.

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

Visix Imaging Administration Main Menu

To update administration information click on the radio button next to the information that requires updating then click on the Next button at the bottom of the window.

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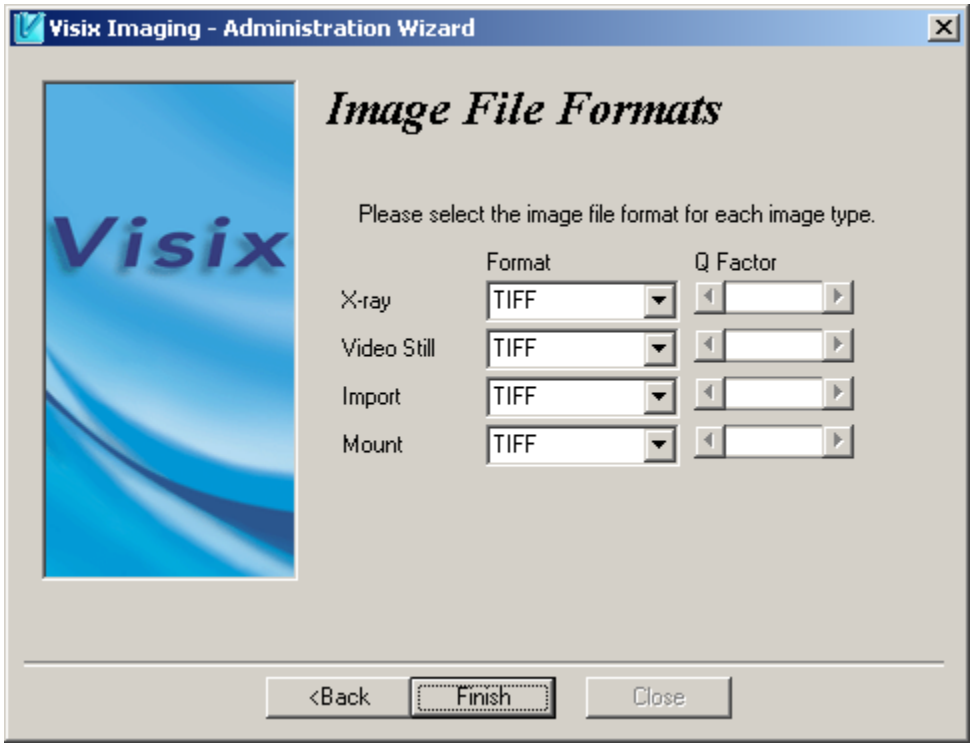
Image File Formats



To access the Image File Formats window click on the radio button next to Image File Formats on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Format

Select the type of image file for each type of image Visix saves. Image file formats include TIFF, JPEG (lossy) and JPEG (lossless). If JPEG (lossy) is selected the Q Factor slider will become accessible.

Q Factor

Q Factor stands for “Quality Factor” and is available only for JPEG (lossy) files. The Q Factor determines the amount of compression that will be applied when the image file is saved. Some images can be compressed more than others. Images with a lot of detail cannot be compressed as much as images without a lot of detail and still maintain the same image quality. The lower the Q factor the higher the degree of image quality and the

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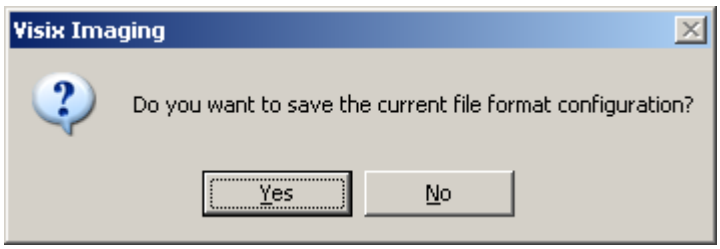
smaller the amount of compression applied. Entries from 2 through 50 are allowed.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the image format information that was entered. Click on No if any changes that were made should be edited.

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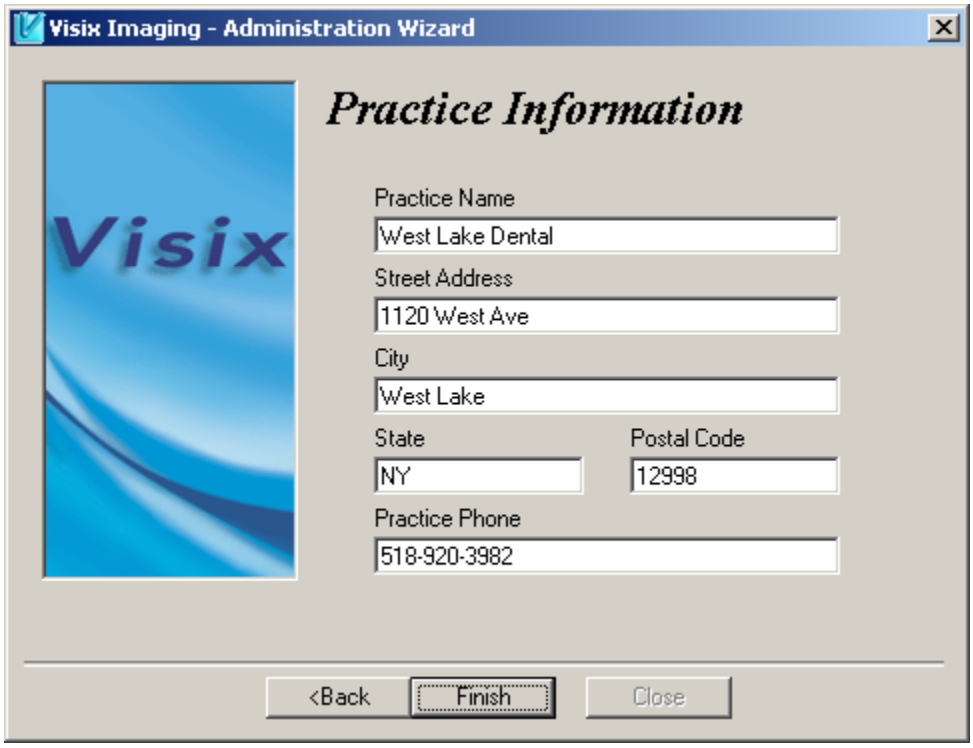
Practice Information



To access the Practice Information window click on the radio button next to Practice Information on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Practice Name

Enter the business name of the practice.

Street Address

Enter the street address of the practice.

City

Enter the name of the city that the practice is located in.

State

Enter the state that the practice is located in.

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Postal Code

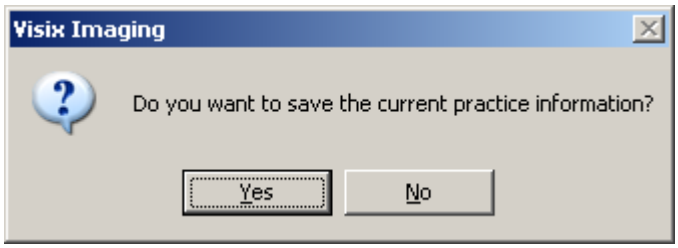
Enter the postal or zip code that the practice is located in.

Practice Phone

Enter the main phone number for the practice. A dash (minus sign), period, or parenthesis can be used as a separator character between sections of the phone number for ease of viewing.

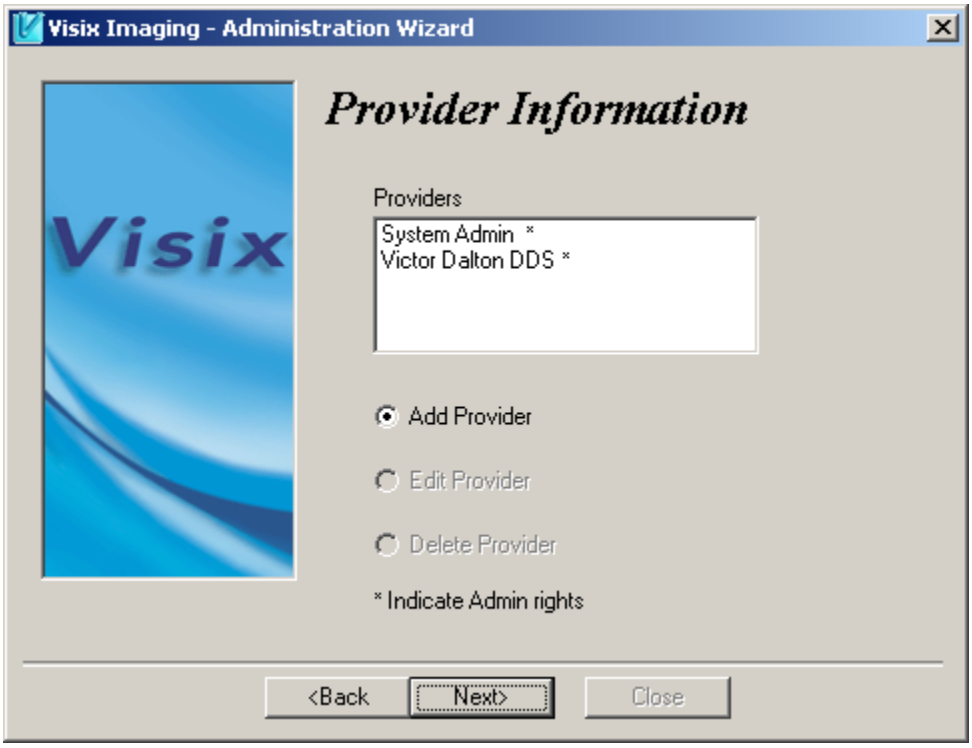
Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the practice information that was entered. Click on No if any changes that were made should be edited.

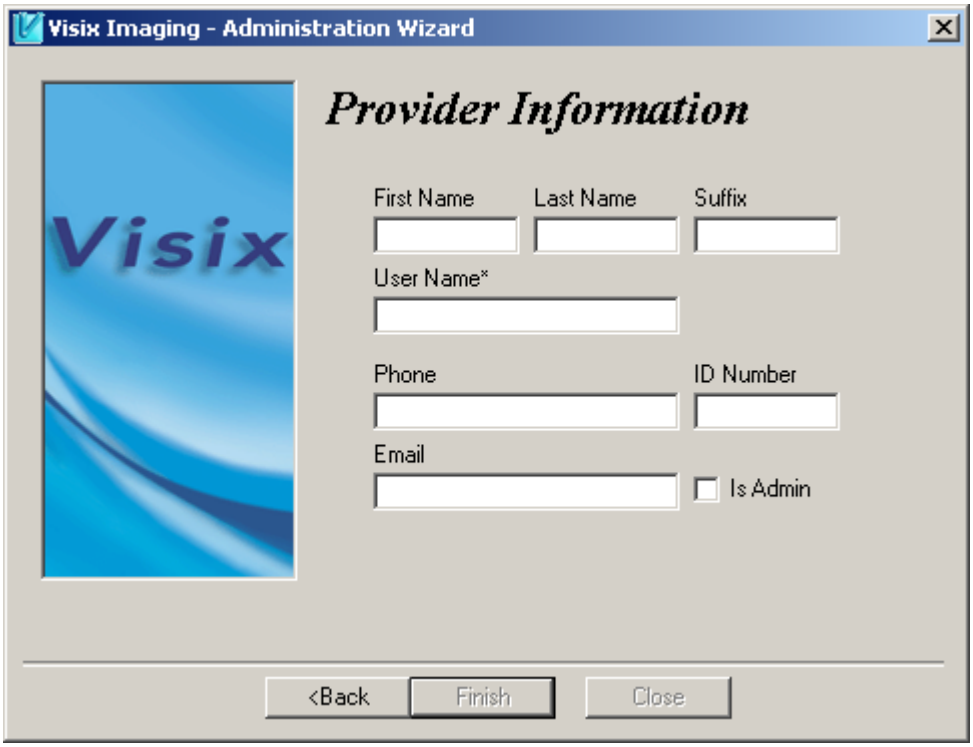
Provider Information



To access the Provider Information window click on the radio button next to Provider Information on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Add a Provider

To add a provider (a doctor) click on the radio button next to Add Provider then click on the Next button at the bottom of the Provider Information window. An empty Provider Information window will display.



First Name

Enter the first name of the doctor. This information is required before the doctor's record can be saved.

Last Name

Enter the last name of the doctor. This information is required before the doctor's record can be saved.

Suffix

Enter any initials that should be placed at the end of the doctor's name. A maximum of 10 characters may be entered. The characters that can be used in the Suffix include letters, a period, and a dash (minus sign).

User Name

Enter a name of at least five characters that will represent this provider. The characters that can be used in the User Name include letters and numbers. This information is required before the doctor's record can be saved.

Phone

Enter the provider's office phone number. The characters that can be used as a separator character in the phone number include a period, parenthesis, or dash (minus sign).

ID Number

Enter the ID number assigned to this provider for use inside Visix. The characters that can be used in the ID Number include a period, letters and numbers.

Email

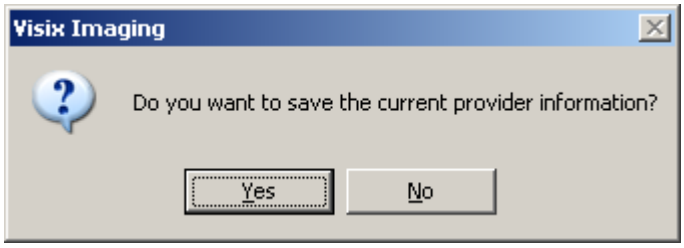
Enter the email address for this provider.

Is Admin

Put a check mark in the box by clicking on the box if this provider should have administrator rights in Visix. To remove a check, click on it.

Back and Finish Buttons

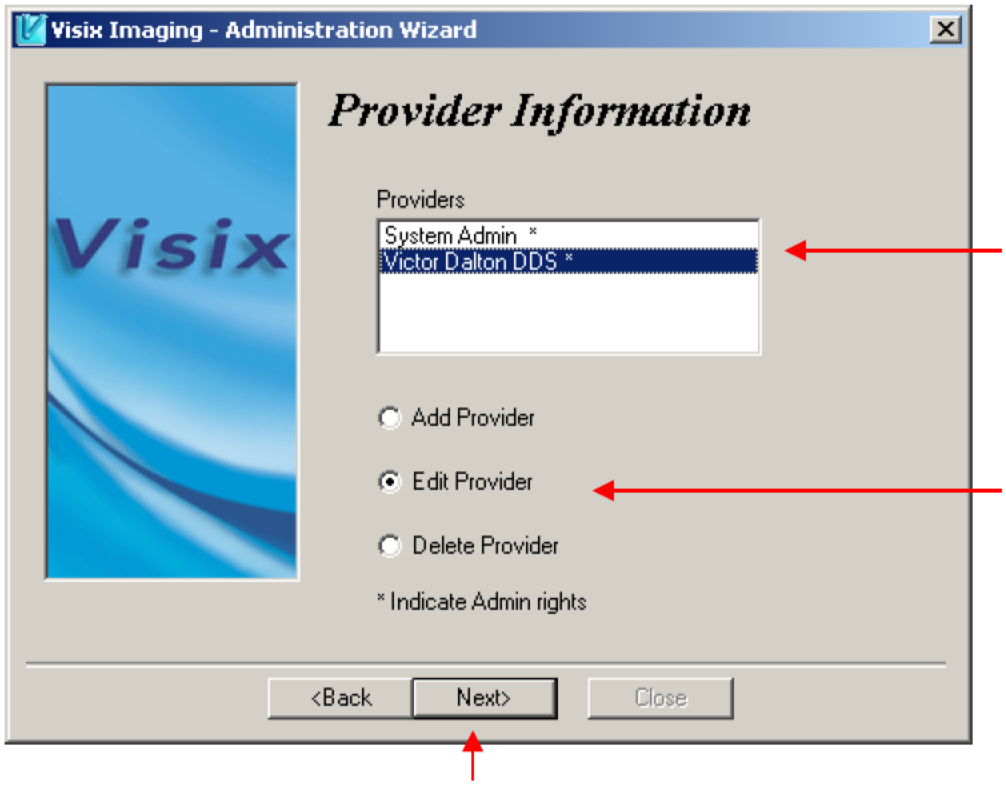
Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the practice information that was entered. Click on No if any changes that were made should be edited.

Edit Provider

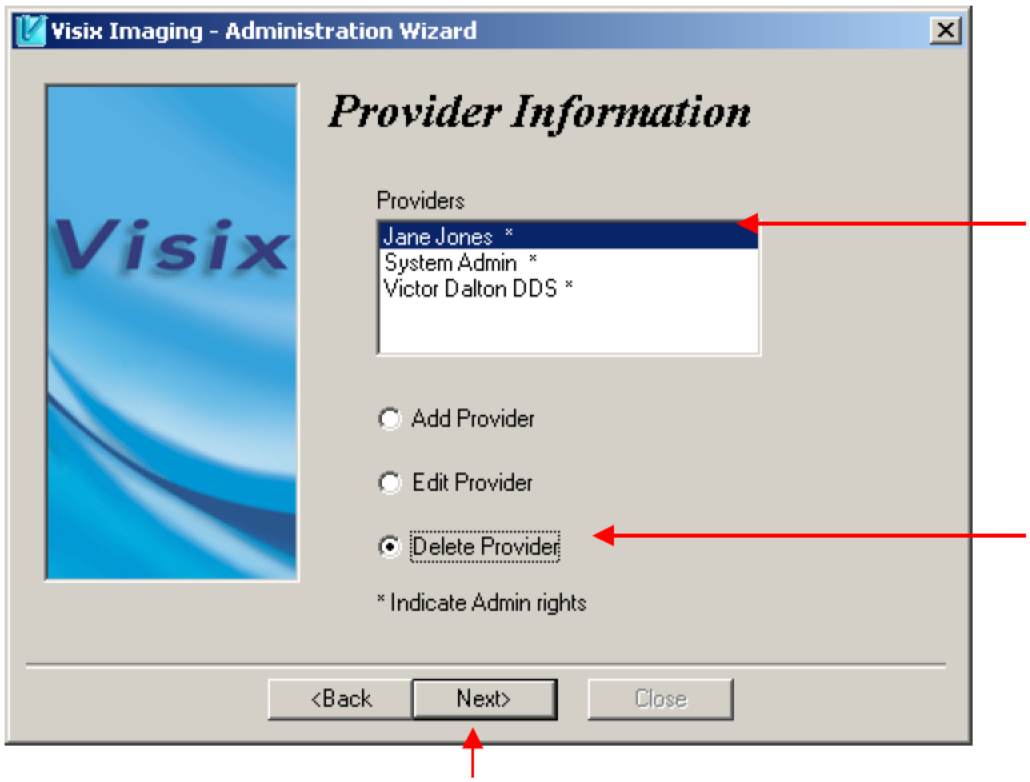
To edit provider information click on the provider's name in the first Provider Information window then click on the radio button next to Edit Provider and finally click on the Next button at the bottom of the window.



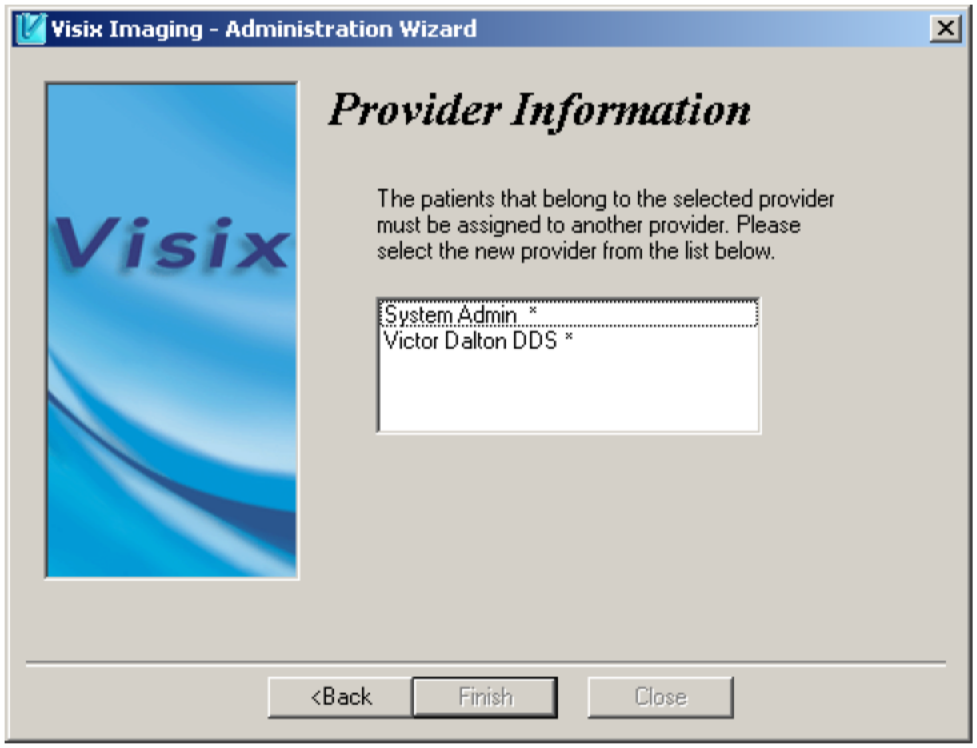
The same Provider Information window will display that displayed for Add Provider. Edit information as needed then click on the Finish button at the bottom of the window.

Delete Provider

To delete a provider click on the provider's name in the first Provider Information window then click on the radio button next to Delete Provider and finally click on the Next button at the bottom of the window.

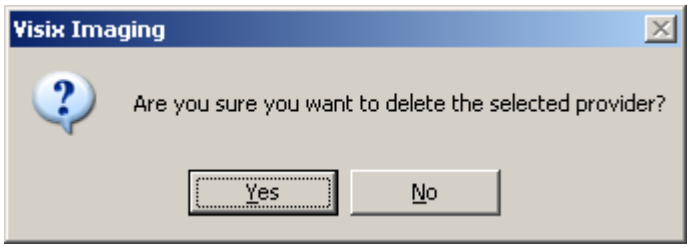


If the provider being deleted has patients, a window will open that asks which single provider to transfer the patients to.



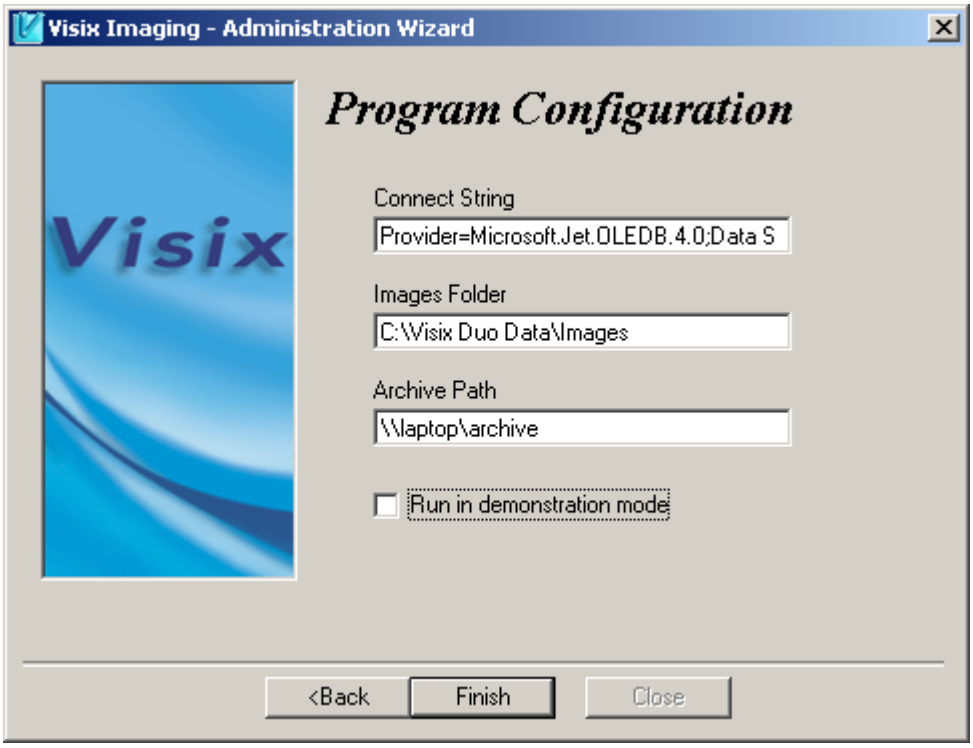
Click on the provider who will receive the patients then click on the Finish button.

Once the patients have been transferred the following screen will display:



Click on the Yes button to delete the provider.

Program Configuration



To access the Program Configuration window click on the radio button next to Program Configuration on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Database connect string

The Database Connect String specifies which version of the Microsoft Jet engine is used and the name and location of the Visix data file. Do not change this.

Images Folder

The Images Folder specifies the name and location of the folder where Visix stores the image files. Do not change this.

Archive Folder

The Archive Folder specifies the name and location of the folder where Visix will store its archived images. The

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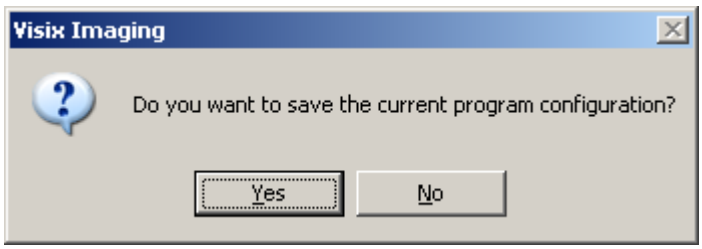
folder must be shared and entered with its UNC path (\\computername\shared folder name).

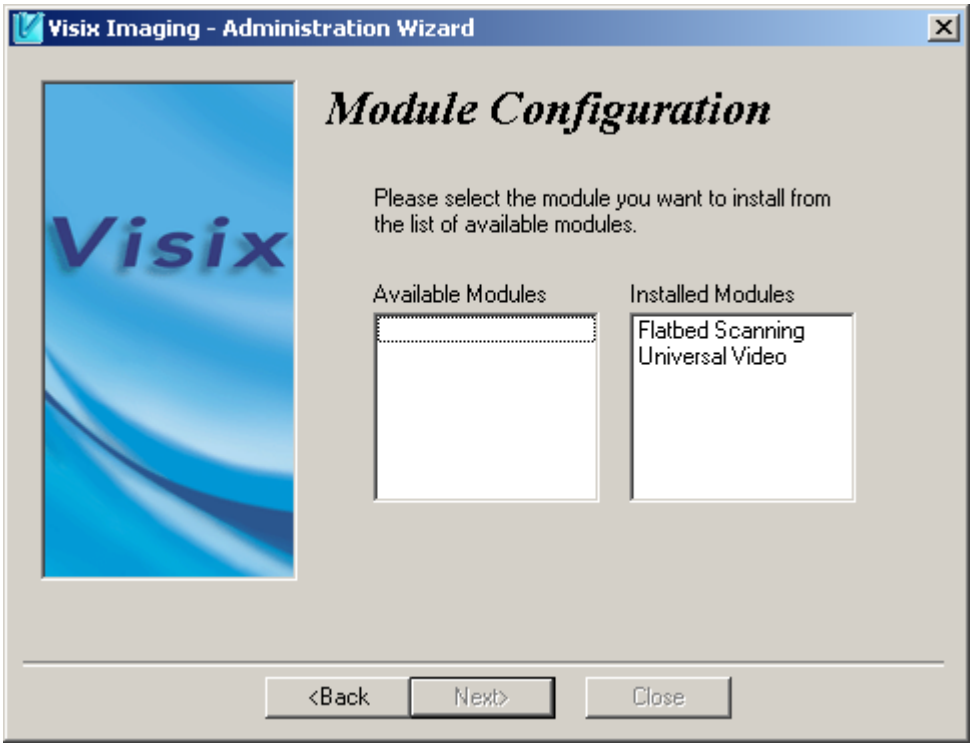
Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the program configuration information that was entered. Click on No if any changes that were made should be edited.

Module Configuration



To access the Module Configuration window click on the radio button next to Module Configuration on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Available Modules

All of the modules available for use with Visix are listed in the Available Modules window. A module must be purchased, by either calling Visix and providing credit card information or by sending Visix a written order with a check attached, before it can be installed.

To install a module after it has been purchased click on the module in the Available Modules window then click on the Next button. A small window will open that asks for an activation code. Call the Visix 800 number and ask a support technician for an activation code. The support technician will ask you to tell him the code that is displayed on your computer screen and will then give you a code to type in. This code will allow Visix to install the requested module.

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Installed Modules

All of the modules that have had their activation codes entered into Visix are listed in this window.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window.

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ScanX Configuration

The ScanX can be setup in either Direct Connect Mode or Client/Server Mode.

If the ScanX is setup in Direct Connect Mode, it will be directly connected to this computer and only the copy of Visix that runs on this computer will acquire images from it.

If the ScanX is setup in Client/Server Mode, also known as Intelligent Track Control Mode, it has the option of operating in three different ways:

- The ScanX will be directly connected to this computer and the copy of Visix that runs on this computer will acquire images from it. This is similar to the Direct Connect Mode except that a second workstation can also be setup to acquire images from the ScanX.
- The ScanX will be directly connected to this computer but Visix on two different workstations will acquire images from it.
- The ScanX will be directly connected to a different computer but Visix on this workstation will acquire images from it.

Note that in Client/Server Mode, all of the Visix workstations on the network will be able to access ScanX images after they have been acquired and saved, but no more than two of those Visix workstations may actually acquire the images from the ScanX.

Direct Connect Mode

Click on the Direct Connect Mode radio button then click the Next button to display the Save window.

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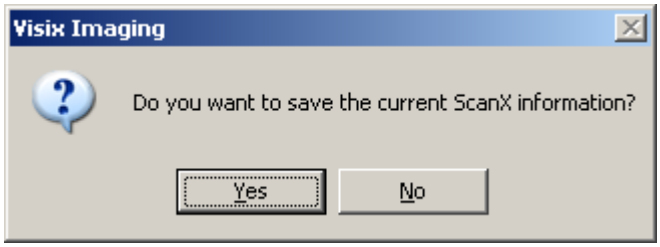
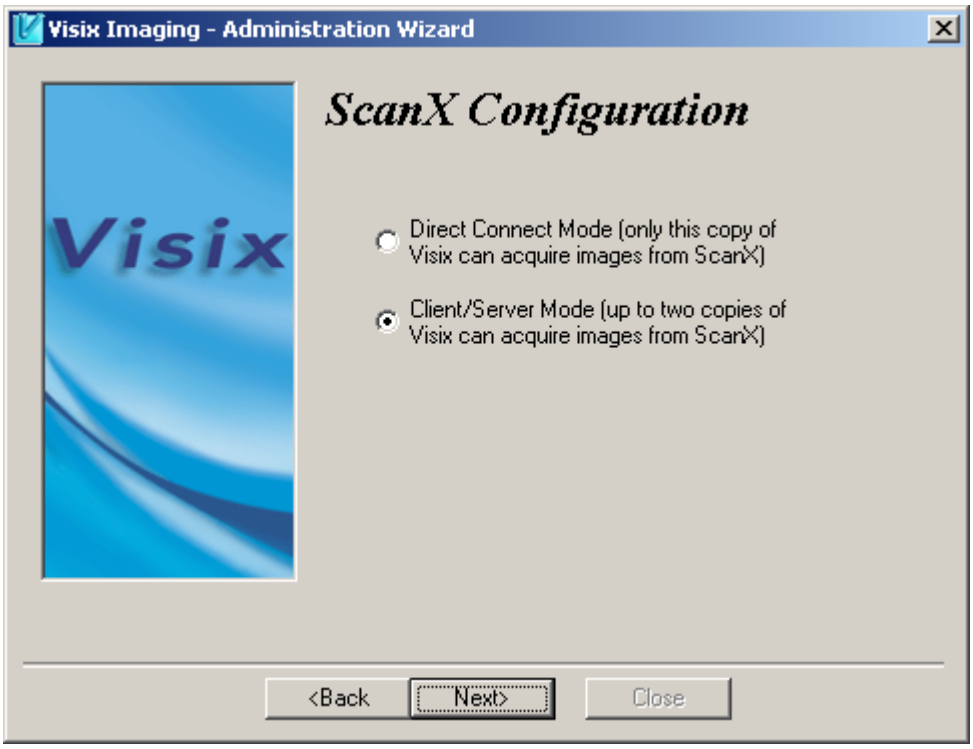


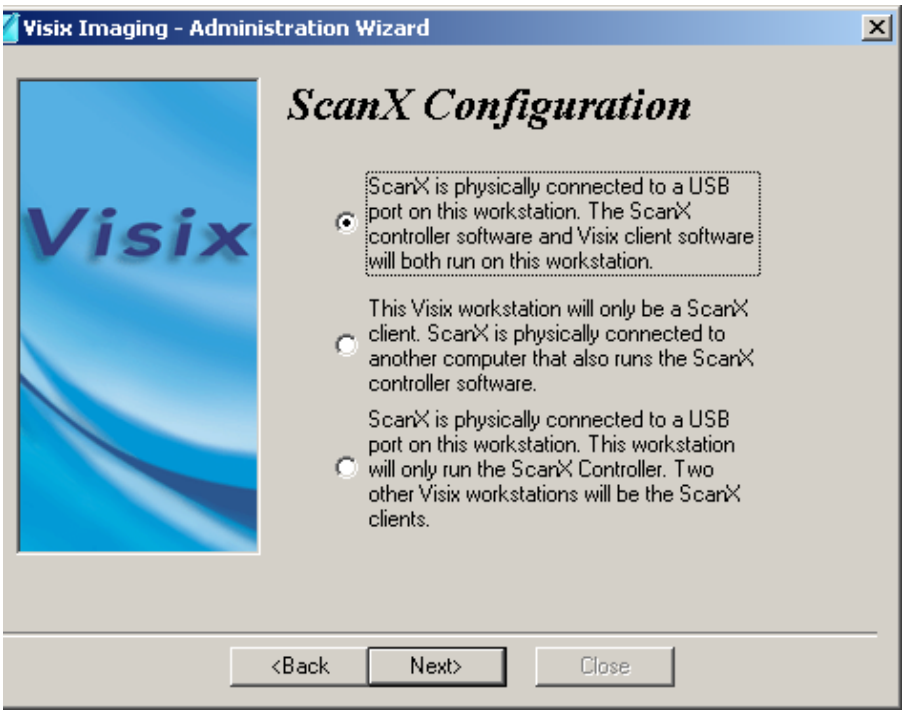
Click on the Yes button to save the ScanX setup information.

Client/Server Mode

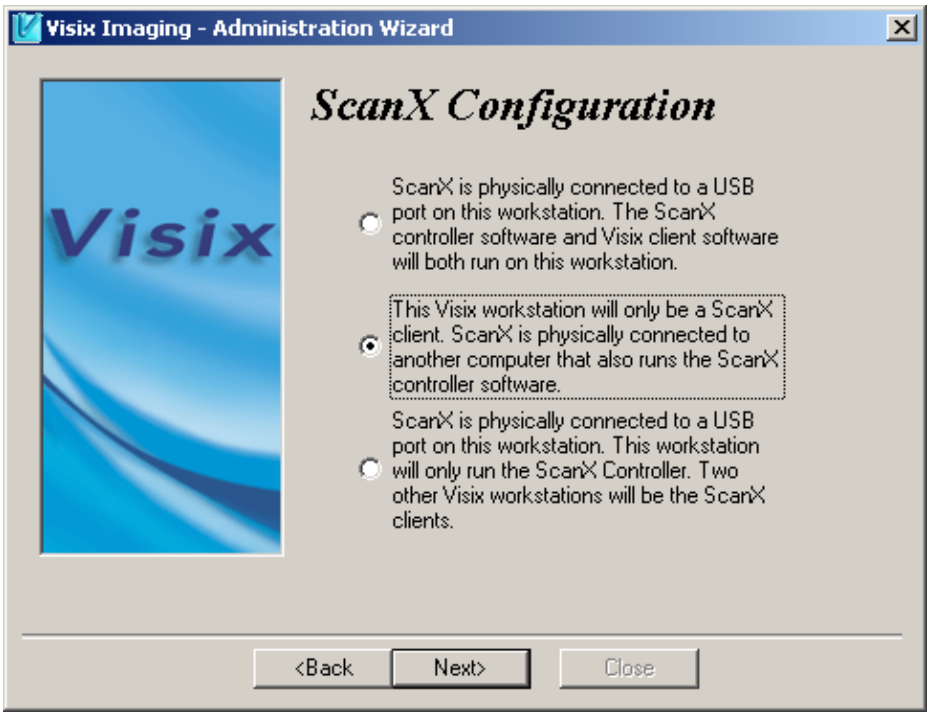


Click on the Client/Server Mode radio button then click the Next button to display the second ScanX Configuration window.

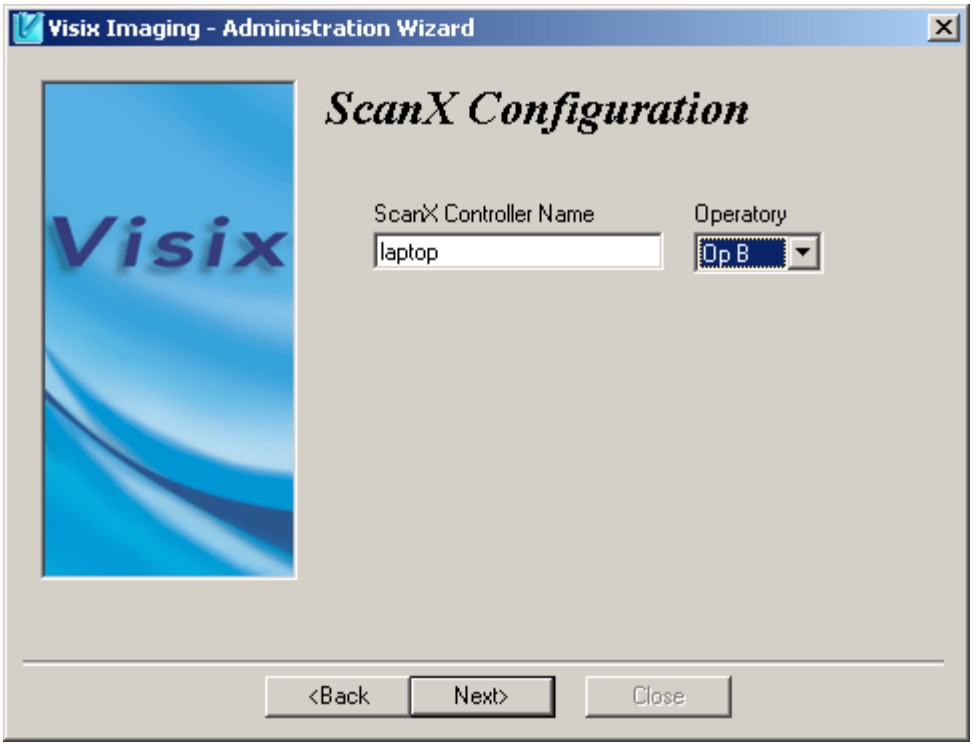
The ScanX is directly connected to this workstation with a cable and the copy of Visix on this workstation will be used to acquire images from it



The ScanX is not connected to this workstation with a cable but the copy of Visix on this workstation will still be used to acquire images from it



If the ScanX will be directly connected to this computer and the copy of Visix that runs on this computer will acquire images from it, OR if the ScanX will be directly connected to a different computer but the Visix on this workstation will still acquire images from it (the top two options in the ScanX Configuration screen above), clicking the Next button will display the following window:



ScanX Controller Name

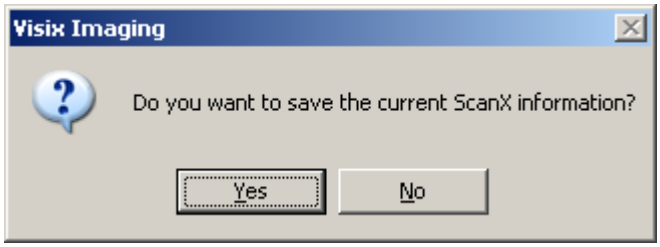
Enter the name of the computer that has the ScanX directly connected to it with a cable.

Operatory

Click on the Operatory down arrow and select either Op A or Op B. If two copies of Visix will be acquiring images from the ScanX make sure that one is set to Op A and the other is set to Op B.

Next and Back Buttons

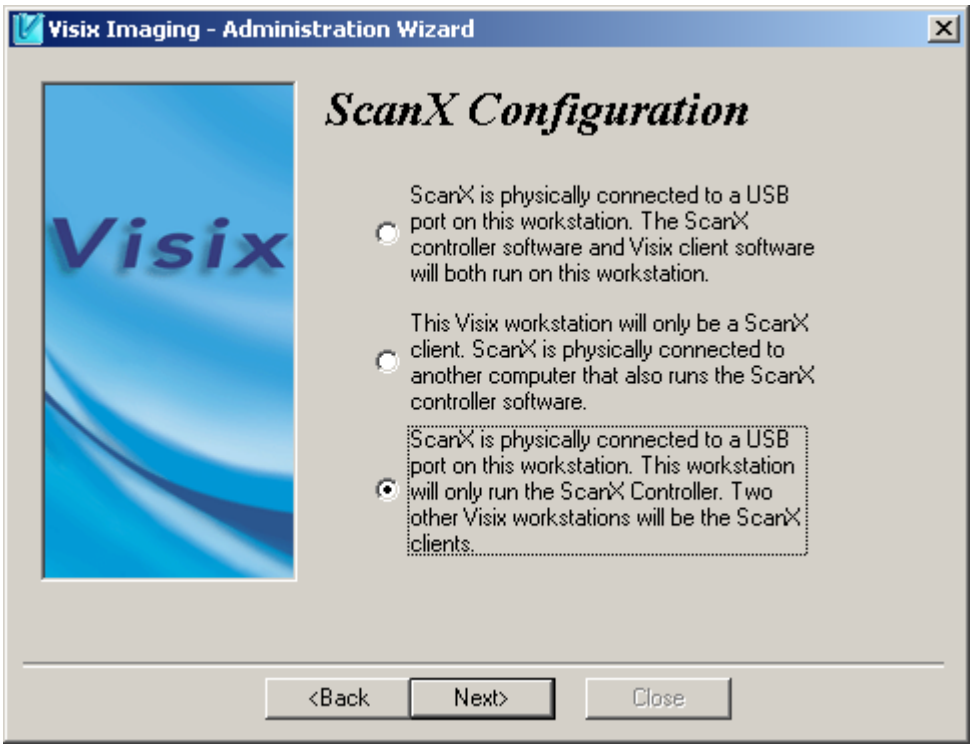
Click on the Back button to return to the previous window. Click on the Next button to display the Save window.



Click on the Yes button to save the ScanX setup information.

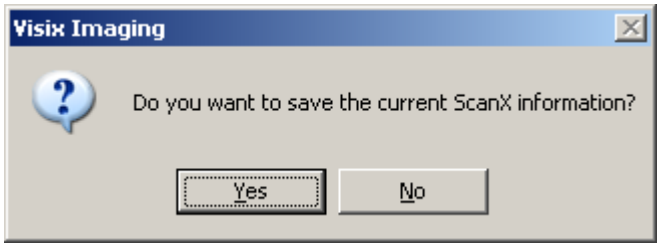
Third ScanX Configuration Option:

The ScanX is connected to this workstation with a cable but the copies of Visix that will be used to acquire images from it are on two different workstations.



Next and Back Buttons

Click on the Back button to return to the previous window.
Click on the Next button to display the Save window.



Click on the Yes button to save the ScanX setup information.

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For questions about Visix Imaging
that are not answered in this manual, please call
the Visix support line at 1-866-908-4749 from
8:00AM EST to 5:00PM PST.

82508

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

CONFIDENTIAL

PRODUCT LABELING

CD Label for Visix Imaging disk

Web Site Main Page:

VISIX Imaging Software

...the superb software complement for Accent, ScanX and Acclaim.

Air Techniques is pleased to introduce Visix, our new comprehensive digital imaging software program. Visix seamlessly integrates with our digital imaging suite; the Accent CCD Intraoral Sensor, ScanX PSP System and Acclaim Intraoral Camera.

Key Features

- Easy to learn
- Simple to use
- Acquire, mount, view and store images with just a few mouse clicks
- Customize images to your personal preference with our simple Set-Up 1-2-3 tool
- Exposure: Our Stop Light Exposure System is a unique indicator to ensure optimum data capture. It helps you acquire great images by monitoring X-ray exposure.
- Viewing. Visix provides automatic image mounting that is completely customizable.
- Visix includes a built-in bridging solution to over 35 Practice Mangement Software titles.

Product Specifications

PN 74500 Visix Dental Imaging Software (includes 5 licenses)

Computer Requirements

Minimum Computer Requirements

CPU Speed: 2 GHz Pentium IV Class.
Operating System: Windows 2000 Professional with Service Pack 4 or later, or Windows XP Professional Service Pack 1a or later.
RAM: 256 MB.
CD ROM Drive: 48X speed
Hard Drive: 60GB (2GB free for image acquisition, the rest for program files and image storage.)
Monitor (1024 x 786 resolution or higher): SVGA 17", contrast ratio 450:1, .22 dot pitch capability.
Video Display Adaptor: 128 MB RAM.
Keyboard/Mouse: Standard keyboard and mouse.
USB Port: USB 1.1.

Web Site Main Page (con't):

Preferred Configuration

CPU Speed: 2.8 GHz Pentium IV or higher.
Operating System: Windows 2000 Professional with Service Pack 4 or later, or Windows XP Professional with Service Pack 2.
RAM: 2 GB.
CD ROM Drive: 48X speed.
Hard Drive: 120 GB (2GB free for image acquisition, the rest for program files and image storage).
Monitor (1024 x 786 resolution or higher): SVGA 17" or larger, contrast ratio 1000:1, .22 dot pitch capability.
Video Display Adapter: 256 MB RAM.
Keyboard/Mouse: Standard keyboard and mouse.
USB Port: USB 2.0.
Backup Device: Recommended.

Warranty Information

Visix support is available to every new owner for a 30 day period. Please call 1-866-90-Visix/84749.
Yearly support agreements and on-site training are available. Please download ordering information below for more details.

For software registration, please visit www.visixsoftware.com

Suggested Products

You may also want to look at:
ACCENT™ CCD Direct Digital Sensor
Acclaim® Intraoral Camera
ScanX®

DOWNLOADS

Visix Ordering Information
Visix Quick Start Guide
List of compatible Practice Mangement Systems
Visix Supported Cameras
Visix Supported Scanners

Visix Web Site Downloads section (bottom of page 2 above):

Visix Ordering Information

VISIX™ Imaging Software

Visix is the superb software complement to Air Techniques' Accent, ScanX and Acclaim. You will appreciate the simplicity of Set-Up 1-2-3. This utility enables a quick start using a one-time routine that allows you to customize images to your personal radiography preferences.

The Visix Stop Light Exposure System® is a unique indicator that ensures optimum data capture. Incorrect exposure reduces image quality. The Stop Light system helps you acquire great images by monitoring X-Ray exposure.

Visix accommodates a limitless range of image mounting and display preferences by providing automatic image mounting that is completely customizable. Create mounts to match the sequence in which you take images; for example left to right or top to bottom. Perhaps you want to see different image formats mounted and presented together, like panoramic and bitewings. Fully customizable mounting will make your edition of Visix feel like it was created just for you.

What's more, Visix includes a built-in bridging solution to over 35 practice management software titles. The bridge, Visix Link®, allows you to access a patient's images with a single click from the patient record in the management software.

Ordering Information

PN 74500	Visix Dental Imaging Software (includes 5 licenses)	$1,995.00
PN 74505	Visix Dental Imaging Software License Pack (5 licenses/pack)	$ 995.00
PN 74510	Visix Dental Imaging In-Office Training (on-site, 3 hours)	$ 995.00
PN 74509	Visix License Add-on	$ 250.00
PN 74525	Visix Software 1 year support contract	$ 795.00
PN 74540	Visix Film Scanning/Intraoral Camera Module	$1,495.00

Visix Imaging Software integrates seamlessly with all of Air Techniques' digital imaging products.

AIR TECHNIQUES INC.
1295 Walt Whitman Road, Melville, NY 11747-3062
516-433-7676 • Fax 516-433-3831 • www.airtechniques.com

Visix Web Site Downloads section (bottom of page 2 above):

Visix Quick Start Guide

VISIX Imaging Software

Version 2

Quick Start Guide

August 29, 2008

FOREWORD

Air Techniques and its ALLPRO Imaging division have prepared this guide to provide brief instructions to install, configure, setup and use the VISIX Imaging Software provided with the digital imaging system (Scan*X*, Accent or Acclaim). References in this manual to Air Techniques include its division ALLPRO Imaging. This document is arranged as follows:

- Computer Requirements - Provides the minimum computer system requirements necessary to operate the digital imaging system (Scan*X*, Accent or Acclaim) with the VISIX Imaging Software.
- VISIX Installation - Provides the necessary instructions for the proper installation of the VISIX Imaging Software.
- Configuring VISIX Admin - Provides instructions to configure the VISIX administration settings. This allows the user to personalize their VISIX application and specify operating preferences as desired.
- Scan*X*Configuration Options - Provides instructions to configure the a Scan*X*I/O or Scan*X*Duo with VISIX. This allows the user to have two computer workstations acquire images from a single Scan*X*.
- VISIX Operation - Provides brief instructions to get the user started using the VISIX Imaging Software with either Scan*X*, Accent or Acclaim digital imaging system.
- 1. 2. 3 Setup - Provides instructions on using the 1. 2. 3 Setup tool of the VISIX Imaging Software. This tool adjusts the amount of edge enhancement filters, smoothing and amount of brightness, contrast and gray shift (or gamma) for the best image quality possible.

Since this guide provides basic information meant to quickly get the user started using VISIX, it is recommended that the user refer to the VISIX documentation included on the supplied CD for detailed information.

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COMPUTER REQUIREMENTS

Computer System Requirements.
The Computer System (laptop or computer, monitor, etc.) and any related peripheral or equipment must comply with the requirements for accessory Equipment as specified in the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard. The minimum computer system requirements necessary to operate the digital imaging system (Scan*X*, Accent or Acclaim) with the VISIX Imaging Software are listed below:

Important: The Bluetooth Accent Camera requires Windows® XP Professional with Service Pack 2.

Operating System:

Windows® 2000 Professional for an Intel 32-bit processor with Service Pack 4 and the KB 820759 update, or later; or
Windows® XP Professional for an Intel 32-bit processor with Service Pack 1 and the KB 822603 update, or later.

USB Port:

Must be USB 1.1 or later

RAM Memory:

1 GB minimum

Processor Speed:

Pentium 4, 2 GHz or faster

Hard Drive:

120 GB

Peripherals:

CD-RW Drive

SIS Driver Note.
There are known issues with the device drivers provided by SIS. If you have a SIS USB controller and experience problems operating the digital imaging system (Scan*X*, Accent or Acclaim) , it is recommended that you disable the SIS device drivers and use drivers provided by Microsoft. Microsoft and SIS are working to resolve these problems.

Display Setting Setup.
The color quality of the computer display must be set to True Color (32 bit) for proper operation using VISIX Imaging Software. Change the display settings in Windows® by performing the following:

1. Open the Control Panel window by pressing the ***Start*** button and selecting ***Settings*** and ***Control Panel***.
2. From the Control Panel window, open the Display Properties window by double-clicking the display Icon.
3. Click the ***Settings*** tab the Display Properties window and select True Color (32

bit) from the Color drop down list.

4. Set the Screen Area for 1024 by 768 pixels or higher.
5. Click ***Apply*** and ***OK*** and return to the Desktop.

VISIX INSTALLATION

The installation of the VISIX Imaging Software is a multi-step process. To simplify the process, an installation script is provided on the VISIX CD that should start automatically when inserted into the the CD-ROM drive. If not, go to **My Computer,** open the CD-ROM drive letter (typically located at drive ***D:***) containing the VISIX CD and Run the ***setup.exe*** program.

Important: If in a network situation, install the **Database** on the designated server computer. Make sure that all network connections or mapped drives to the server are set with **full** read and write access to the Data folder and its contents.

Database Installation.
This starts the installation script that provides the steps necessary to install VISIX. When given the option on whether to install the **Database** or **Workstation**, choose to install the **Database** first.

Important: The VISIX **Workstation** portion must be installed separately on each workstation computer on a network.

Workstation Installation. After finishing the **Database** installation, run the CD again and choose to install the **Workstation** this time. If installing VISIX across a network, take the VISIX CD to each workstation computer and install **only** the workstation portion.

Important: It is strongly recommended that the VISIX data folder be backed-up daily.

Database Connection. During the **Workstation** install, the installation script will ask to connect to the database. So prior to installing the workstation component, make sure that all network connections or mapped drives to the server are set with full read and write access to the Data folder and its contents.

VISIX Activation. Once the **Workstation** installation is completed on all computers, a one-time activation code must be obtained for the VISIX software. There is a 10-day grace period to activate the VISIX software. If this code is not obtain within 10 days, the user will be locked out of the VISIX Application.

Activation is done in a two-step procedure. First a reference code is given when double-clicking the VISIX icon on your desktop. This reference code is needed by the VISIX staff to generate an activation code.

Second, obtain your activation code by calling the VISIX Technical Support at 1-866-90-VISIX or by visiting www.visixsoftware.com. Mention you are activating VISIX and have the following available to complete activation:

1. Doctor's name
2. VISIX reference code(s)
3. VISIX part number
4. VISIX serial number

CONFIGURING VISIX ADMIN

Configuration of VISIX administration settings allows the user to personalize their VISIX copy and specify operating preferences. Configure VISIX as follows:

1. Go to the **Start** button and select ***Programs***.
2. Select the ***VISIX Imaging*** program option and click on **VISIX Administration**.
3. Observe that the The ***VISIX Imaging - Login Provider*** window opens as shown below.

The ***VISIX Imaging - Login Provider*** window starts allowing the selection of a provider. Make sure that ***System Admin*** is selected in the **Provider** field and click the **OK** button to open the ***VISIX Administration Main*** window.

VISIX Administration Main Window

This window allows the editing of VISIX configuration categories:

1. Image File Formats
2. Practice Information
3. Provider Information
4. Program Configuration
5. Module Configuration
6. Scan*X* Configuration

Select a radio button to edit the configuration category desired.

Image File Formats Window

This selection opens a window to allow the setup of the **save** file format for each type of image that can be acquired in VISIX.

The default settings are shown in the screen to the right. If using JPEG (lossy) setting, the compression factor applied to the image can also be specified.

Practice Information Window
This selection opens a window to allow the input of your professional practice information including the practice name, address and phone number if applicable and/or desired.

CONFIGURING VISIX ADMIN

Provider Information Window
This selection opens a window to allow the addition and editing of provider information for the practice as necessary. A Provider is any individual you wish to have access to VISIX.
Each new provider must select a user name. There is also the option to allow each provider Administrative rights by checking the ***Is Admin*** box.

Program Configuration Window
This selection opens a window where you will find the location of your database (Connect String) and images (Images folder) folder in Program Configuration.

You also have the opportunity to specify an Archive directory. This must be entered as a UNC path (i.e. //server name/share name)

The ***Run in demonstration mode*** check box, when checked, will run both Scan*X*and Accent in demo mode with sample images. Un-checking this box returns VISIX to powering the hardware in Live mode.

Module Configuration Window

If purchased, you can activate support for another Direct show compatible video device here. Obtain a one time activation code by calling 1-866-90-VISIX and providing the module serial number.

If you are interested in purchasing this module, please contact your dealer.

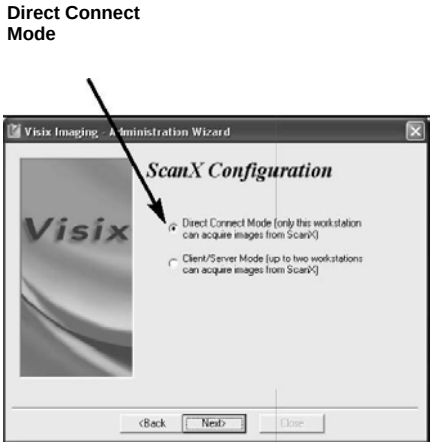
CONFIGURING VISIX ADMIN

Important: The Scan*X*Configuration window is only necessary for use with either a Scan*X*I/O or Scan*X*Duo image scanner manufactured by Air Techniques, Inc.

Scan*X* Configuration Window
This selection opens a window that allows setting up a Scan*X*I/O or Scan*X*Duo with VISIX. There are 2 modes available:

1. Direct Connect Mode
2. Client/Server Mode

Refer to the configuration options below to determine which mode is best for your office setup



SCANX CONFIGURATION OPTIONS

Direct Connect Mode
The Direct Connect Mode is the default setup for VISIX as shown above with the Direct Connect Mode Radio Button selected. The Direct Connect Mode option allows only the Scan*X* connected directly to a single computer to acquire images.

. Direct Connect requires only one computer.
. The computer is normally located in a centralized location such as a hallway and not located in an operatory.
. The Scan*X* must be physically connected to the computer via USB.
. This computer only needs the VISIX workstation software running.
. All Scan*X* tracks are operated via the installed computer.

If you plan to position your Scan*X* in a hallway or room connected to a dedicated computer that all x-ray technicians will access via a computer network, then Direct Connect Mode is the best option for that office setup.

The Direct Connect mode enables VISIX to receive images from all Scan*X* tracks at the dedicated computer connected to Scan*X* via USB. Once the images are saved at this computer they will be accessible from all network computers running the VISIX software. Change to the Direct Connect Mode from the Client/Server Mode by selecting the Direct Connect Mode Radio Button and pressing the Next button. Save the new configuration. This ends the configuration setup and the computer must be rebooted in order for the changes to take effect.

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

SCANX CONFIGURATION OPTIONS

Client/Server Mode

The Client/Server Mode uses Intelligent Track Control to enable up to two computer workstations to acquire images from one Scan*X*. Intelligent Track Control allows for half of the available tracks to be assigned to one operatory and the other half to a second operatory. This enables a single Scan*X* I/O or Scan*X* Duo to be shared between two operatories.

. ITC requires at least two computers connected together by a network. One of the computers must run a piece of VISIX software known as the Scan*X* Controller (Server). The ScanX device must be physically connected to this computer

. Both computers must run VISIX workstation (Client) software.

Note: For most installations operating in Client/Server mode, the Scan*X* Controller must be installed on the computer directly connected via USB to the Scan*X*.
The second computer with access to the Scan*X* will only have the Client software installed on it.

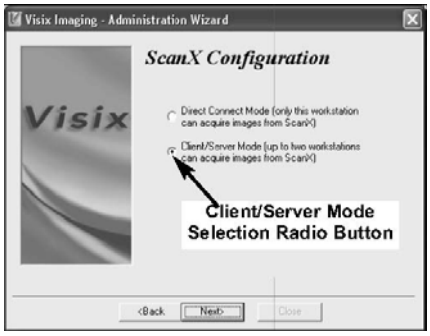
If you plan to position your Scan*X* in a pass-through between operatories or in location that can be easily accessed by technicians from two different operatories, then the Client/Server mode is an option for you.
There are two main approaches when operating in Client/Server mode:

1. There are total of two computers.
2. One computer is the “Server” running Scan*X* Controller software, and both computers run the “Client” software.
   a. The “Server” must be the computer that is directly connected via USB to the Scan*X* machine. The Scan*X* Controller will be installed on this computer.
   b. The “Client” is one of two computers that can receive the images from the Scan*X* Controller.

Client/Server Mode Selection

The Client/Server Mode is selected from the Scan*X* Configuration Window shown to the right. This is accomplished by selecting the Client/Server Mode Radio Button and pressing the Next button. A new window as shown on the top of page 9.

Scan*X* Configuration must be done on at least 2 computers when operating in Client/Server Mode.



SCANX CONFIGURATION OPTIONS

Important: Separate Scan*X* Configurations must be run on each computer used to receive images from Scan*X*. Reboot all computers in order for the configuration changes to take effect.

Client/Server Mode Window

The Client/Server Mode Window (shown to the right) provides 3 separate configuration options.

Read all three descriptions first and use the one that applies to the office setup.

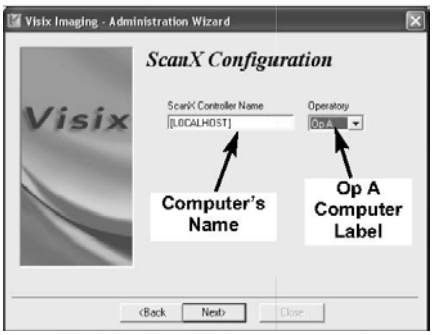
Controller and Client Software

This option activates both the Scan*X* Controller and the Scan*X* Client software on the subject computer that is physically connected via USB to the Scan*X*.

Choose the first option (top radio button) and press the Next button to run this Scan*X* Configuration on the subject computer.

As shown to the right, a new window opens showing that VISIX has input your computer's name as the Scan*X* Controller Name. By default this computer will be labeled Op A and will communicate via ports 8194 and 8195.

Press the Next button and save the changes to Scan*X* Configuration. Reboot the computer once completed.



Note: Editing of the Scan*X* Controller name or port numbers can be done in the Scan*X* Controller configuration and/or the Network tab in the VISIX Client.

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

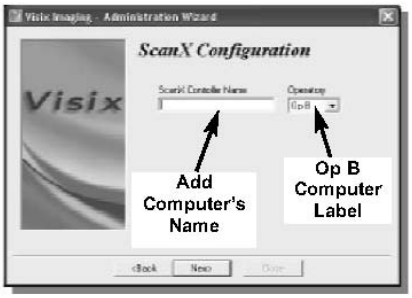
SCANX CONFIGURATION OPTIONS

Client Software Only
This option activates **only** the Scan*X* Client software on the subject computer that is **not** physically connected to the Scan*X* but will receive images. Choose the second option (middle radio button) from Client/Server Mode Window and press the Next button to run this ScanX Configuration on the subject computer

Note: Editing of the Scan*X* Controller name or port numbers can be done in the Scan*X* Controller configuration and/or the Network tab in the VISIX Client.

Observe that a new window opens (shown right) with a blank field seeking the computer name. Enter the computer name from the first option configuration of the computer that is directly connected via USB to the Scan*X* as the Scan*X* Controller Name.

By default this computer will be labeled Op B and communicate via ports 8196 and 8197. Press the Next button and save the changes to Scan*X* Configuration. Reboot the computer once completed.



Important: Choosing the third option requires you to run Scan*X* Configurations on **3 total** computers. This configuration is for a 3-computer network and is rarely used.

Controller Software Only
Choose the third option if your office setup uses a 3-computer network where the computer that is directly connected to the Scan*X* acts as the network server and the two other computers will receive images from the Scan*X*.
This option activates **only** the Scan*X* Controller software on the subject computer that is physically connected via USB to the Scan*X* and acts as the network server.
Choose the third option (bottom radio button) from Client/Server Mode Window and press the Next button to run this Scan*X* Configuration on the subject computer. Save the changes to Scan*X* Configuration. Reboot the computer once completed.
The two other computers of the network must be configured to receive the images from Scan*X*, using the second option (Client Software Only) described above. The Scan*X* Controller name given during the option three configuration must be entered on both computers configured under the second option.

VISIX OPERATION

Open VISIX.

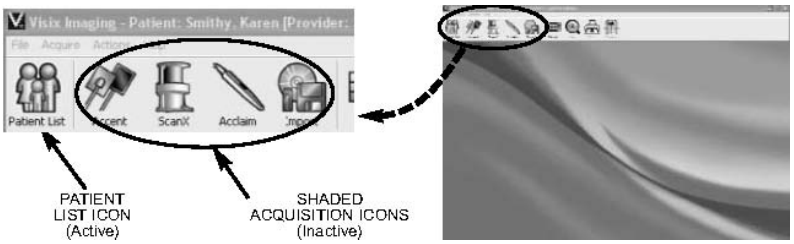
Launch VISIX simply by double clicking the VISIX icon on the desktop. or via the ***Start*** button as follows:

1. Click on the ***Start*** button and select ***All Programs.***
2. Select the ***VISIX Imaging*** program option.
3. Then select the VISIX icon.

Upon startup, the first VISIX window that opens is the Login Provider Window shown below. If the name that displays is the correct provider, click on the ***OK*** button to Login to VISIX. Otherwise, click on the Provider down arrow to display a drop down box of other active providers. Select the correct provider and click the ***OK*** button to Login.

Main VISIX Window.

The Main VISIX window opens upon the correct provider Login as shown below. Note that the Patient List Icon is brightly colored denoting that it is active while the next four acquisition icons are gray or inactive.



Patients Window.

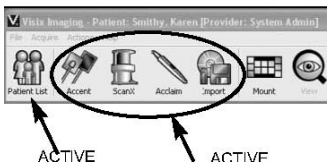
In order to acquire images, the **Patients Window**, shown below, must be opened to define or select a patient. VISIX initially opens **without** a patient selected. Notice that the Main VISIX window title bar displays the message ***Patient: No Current Patient, [Provider: System Admin]***.

The **Patients Window** is divided in two sections:

1. The left side is the patient's area where a patient is selected or information is added, deleted, edited.
2. The right side provides a Search Criteria area used to locate specific images previously acquired for the selected patient.

VISIX OPERATION

Adding a New Patient.
Add a patient by clicking the ***Add*** button on the top left side of the **Patients Window**. Observe that the **Add New Patient Window**, shown on the right, opens containing the patient information form.
Enter the patient's information in the form as desired and click the ***OK*** button to to save the patient record.
Once saved, the patient record will appear on the **Patients Window** in alphabetical order by last name.



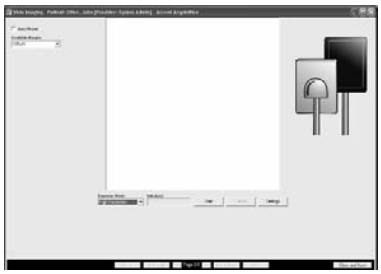
Acquiring Images.
Refer to page 7 above if needed and open VISIX and Login.

Select a patient by clicking the **Patient List** icon and double-clicking the patient's name from the list on left side of the **Patients Window**.
Observe that the Main VISIX window opens with active Acquisition Icons.

Important: Make sure that after a patient is selected the patient's name appears in the title bar of the Main VISIX window.

After selecting a patient, images can be acquired by VISIX through the Acquisition icons located on the Main VISIX window tool bar. The input methods consist of X-rays (Accent and Scan*X*), Video (Acclaim), and imported images from other media. Acquire an image by left clicking on the Acquisition Icon corresponding to the desired image input as follows.

Acquiring Images with the Accent Sensor

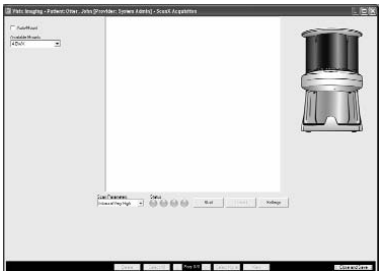


Selecting the Accent icon opens the Accent acquisition window. If the device is installed per manufacturer instructions, the initialized bar flashes and then turns solid green. This indicates that the sensor has been initialized and is ready to acquire images. Click the **Start** button to open the sub-acquisition window of the accent sensor. VISIX automatically captures X-ray images from the sensor. Select the **Settings** and **1. 2. 3 Setup** buttons to check and adjust the current settings as necessary. If the **Cancel** button is clicked during acquisition, the process is aborted.

VISIX OPERATION

Acquiring Images with the ScanX

Selecting the Scan*X*icon opens the Scan*X* acquisition window. If the device is installed per manufacturer instructions, the status bar is a solid green. This shows that the scanner has been initialized and is ready to acquire images.

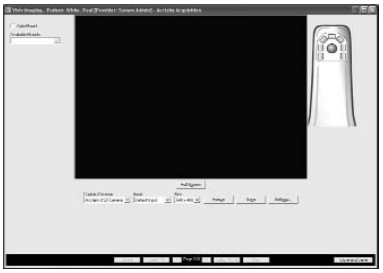


Select an appropriate scan setting from the Scan Setting list in the lower left hand corner. Intraoral Standard, Pan Standard, or Ceph Standard is suggested. Select the **Settings** and **1. 2. 3 Setup** buttons to check and adjust the current settings as needed.

Load the phosphor plate or plates into the Scan*X*in accordance with the manufacturer's directions. VISIX automatically captures the image from the Scan*X*. If the **Cancel** button is clicked during the process, the scan is aborted.

Acquiring Images with the Acclaim Camera

Selecting the Acclaim icon opens the Acclaim acquisition window if the device is installed per manufacturer instructions.



Observe that the live feed video input is displayed in the Preview Image box. If the video is not displayed check the following:

1. Make sure that the Acclaim USB Camera is selected on the **Capture Devices** drop down box.
2. Make sure that the **Input** drop down box should read ***Default Input*** indicating that the Acclaim drivers have been loaded successfully.
3. Set the image resolution by clicking the down arrow of the **Size** drop down box and selecting 640 by 480 dpi (recommended).

Freeze/Live Button

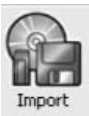
Click **Freeze** of the **Freeze/Live** button to freeze the video display to show a still frame image on the Preview Image box.Notice that clicking **Freeze**, changes the button's name to **Live**. Clicking the **Live** of the **Freeze/Live** button again brings the live feed back to the Preview Image box.

Saving an Image

After clicking **Freeze**, while a still frame image is in the Preview Image box, the **Save** button is enabled. Click the **Save** button to capture the existing still frame image. A thumbnail will appear at the bottom of the screen. The main image will return to live feed.

VISIX OPERATION

Imported Images from Other Media



Selecting the Import icon opens the Import acquisition window.

Click on the drop down box arrow to display the list of available disk drives the computer can access. If this computer is on a network and has network drives mapped, the network drives will also display.

Note: The computer views many digital cameras as removable hard drives.

Select the drive where the imported images can be found. After the drive is selected, a list of the folders (also called Directories) on that drive will display.

Select the folder where the imported images can be found. Any images in the selected folder (directory) on the selected drive will display in the **Current Image** box on the Acquire window.

To import an image, the image must be selected then imported, then selected and saved.

Note: A selected image will have a green box around it.

Selecting and Importing Images

1. Select an image or images as follows:.
   a. Select one image by left clicking on it.
   b. Select multiple images by left clicking on the rest of the desired images.
   c. Select all of the images by clicking on the **Select All** button at the bottom of the window.

2. Import the selected image or images by clicking on the **Import** button at the bottom of the Current Image box.

Saving Images

Once an image has been selected and imported it will move to the area under the **Available Directories** box as a thumbnail image. The image still needs to be selected and saved into VISIX by clicking the **Save and Close** button at the bottom of the window. All images will be automatically saved.

1.2.3 Setup

1. 2. 3 Setup is a tool that adjusts the amount of edge enhancement, smoothing, contrast and gray shift (or gamma) for the best image quality possible when using the Accent sensor or Scan*X*unit. The 1. 2. 3 Setup tool is accessed from the **Settings** button on the Accent or Scan*X*Acquisition window. One image must be processed before using the 1. 2. 3 Setup tool. Changes made in 1. 2. 3. Setup under the Intra-oral tab will only be applied to future Intra-oral images. Click the **1. 2. 3. Setup** button to start the process.

Step 1.
Step 1 allows the user to set the amount of edge enhancement filtering that is applied to all future images. Edge enhancement filters increase the sharpness of the edges and structure of the teeth. There are four setting selections; None, Low Med and High. While selecting different levels of edge enhancement, observe the result on the last processed image to better determine which setting gives the best image quality. The selected enhancements will affect all future images.
The ***Advanced*** button should only be accessed by trained service personnel! Changing its values may adversely affect image quality. Clicking the ***Back*** button will exit out of the 1. 2. 3. Setup tool without saving any of the changes made. Click the ***Next*** button to precede to Step 2. Observe that the Step 2 window opens.

Step 2.Step 2 allows the user to set the amount of smoothing that is applied to all future images, and ranges from None to High. Smoothing filters attempt to remove any extra "noise" or graininess from the image caused by the edge sharpening applied.
While selecting different levels of smoothing, observe the result on the last processed image to better determine which setting gives the best image quality.

The Advanced button should only be accessed by trained service personnel! Changing its values may adversely affect image quality. Clicking the ***Back*** button will return you to Step 1, Edge Enhancement and undo any selected smoothing setting. Click the ***Next*** button and observe that the Step 3 window opens.

Step 3.
Step 3 allows the user to set the amount of brightness, contrast and gray shift (or gamma) that is applied to all future images. The default values can be set by clicking the Center Controls button below the sliders. As the different levels of brightness, contrast or gray shift are adjusted, you will see live feedback on the last processed image to determine which setting gives the best image quality.

Clicking the ***Back*** button will return you to the Step 2 window, Smoothing. will undo any selected brightness, contrast or gray shift settings .

Click the ***Finish*** button to end the 1. 2. 3…Setup tool. You will see a summary of your new settings that will be applied to every image processed.

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

Air Techniques and ALLPRO Imaging are leading manufacturers of fine dental, medical and veterinary equipment from air and vacuum systems and X-ray film processors, to an impressive line of new products incorporating the most recent technological advances. These new products, vital components of the innovative professional practice, include intraoral cameras, digital imaging systems, which utilizes phosphor plate technology and, most recently, an intraoral digital X-ray system using sensor technology.

Air Techniques and ALLPRO Imaging have been manufacturing quality products for the dental, medical and veterinary professional since 1962.

Air Techniques and ALLPRO Imaging products are distributed only through authorized dealers. Refer to www.airtechniques.com or www.allproimaging.com to find a dealer in your area.

- ❑ Accent™ Intraoral Digital X-ray Image System
- ❑ Acclaim® Intraoral Digital Video Camera System
- ❑ Acclaim® USB Only Intraoral Digital Video Camera System
- ❑ AirStar®
- ❑ A/T 2000® XR
- ❑ Guardian™ Amalgam Collector
- ❑ Peri-Pro®
- ❑ Provecta 70™
- ❑ Rinsendo Root Canal Disinfection System
- ❑ ScanX®
- ❑ STS™
- ❑ VacStar™

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- ❑ ScanX® DVM
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- ❑ ScanX® NDT
- ❑ ScanX® 12 Portable
- ❑ ScanX® 14 Portable
- ❑ ScanX® NDT Portable
- ❑ ScanX® 14 In-Counter

ALLPRO IMAGING
1-800-AIR-TECH
(1-800-247-8324)
www.allproimaging.com

Visix Web Site Downloads section (bottom of page 2 above):

List of Compatible Practice Management Systems

Visix™

Compatible Practice Management Systems & Supported Hardware

Can I access the images from my practice management software? Yes, nearly all practice management software companies have "bridged" to Visix. The following companies have bridged to Visix:

Ablesoft
AbelDent
Ace Dental
Alphadent
BRS Computing
Ciraden
ComputerAge
The Complete Exam
Daisy
Datacon
Dental Exec
Dental Office Express (DOX)
Dental PRO
Dental Vision/Discus
Dental.com
Dentech
DentiMax
Dentisoft
Dentrix **
Desco
Direct Vision
DOM for Windows
Eaglesoft**
Easy Dental
Exact Dental
EZ Dent
First Pacific Corporation
FoxdentOffice
Genesis
Human Touch
Innova
Intellident
Kcomp
Medident
Mogo
NDC
Oasys
OCS
Open Dental
Oral Surgery Exec
Partner
PatientBase
Practice-Web
Practice works **
PBS Endo
PEB for Windows
PEB's XLDent **
Perio Apprentice
Perio Exec
Perio Vision
Primadent
Power Practice
Practice Outlook
Practice Web
QSI
Scandent
Softdent **
Softech
Suzy
Three Star
Time for Perio
Tri-Star
Vantage-Med
Windent

** In some cases these companies may charge a fee for their bridge. Under these circumstances Visix offers a free alternative called VisixLink, that allows Visix to access the patient name from the PMS and retrieve the image file corresponding to that specific patients' name.

Please call Visix for the most up-to-date list of compatible bridges. It is also prudent to contact your practice management software vendor to discuss the details of the bridge and or a proposed bridge.

Visix Imaging – 1-866-90-VISIX

Visix Web Site Downloads section (bottom of page 2 above):

Visix Supported Cameras

Compatible Cameras and Video Capture Cards

By default Visix Imaging supports only the Air Techniques' Acclaim intraoral video camera. With the addition of the Visix Imaging DirectShow Video Capture module, Visix Imaging supports virtually all intraoral video cameras.

Intraoral cameras fall into roughly two main categories, digital cameras and analog cameras. Digital cameras usually output video through a USB 2.0 or an IEEE 1394 interface (FireWire). Virtually all digital cameras include a CD that contains Microsoft DirectShow drivers that allow the camera to interface with Visix Imaging.

Analog cameras usually output video through S-Video or Composite Video connectors. Analog cameras require the addition of a Video Capture Device to convert the analog signal to a DirectShow compatible digital signal. There are many video capture devices available at your favorite computer/office supply store, many of them are priced less than $100. We have listed a small selection of devices that we have tested and know are compatible with Visix below. There are many other makes and models that our customers use with equal success.

Some intraoral cameras have buttons on the handpiece or footpedals for freezing live video and/or saving images. In order for Visix Imaging to respond to button or footpedal operations, the camera or footpedal must have DirectInput drivers. You can tell if your camera's buttons or footpedal will work with Visix Imaging by opening Control Panel and checking the Game Controllers Applet. If you see your device listed as a one button or two button game pad, it will work with Visix Imaging. Please contact your camera company to obtain these drivers if necessary.

Recommended Video Capture Cards

Make	Model	Price	Comments
ATI	All-in-Wonder Radeon 9000	~$180	Single card large capture size DirectShow Compatible
Dazzle	Digital Video Creator 90	~$79	USB 2.0 solution with full size video capture (640x480)
Hauppauge	WinTv-Go Video TV Tuner	~$50	Needs separate video card Video for Windows

Compatible Intraoral Cameras

Camera Manufacturer	Model	Special Instructions
A-Dec	A-Dec Intraoral Camera	
Acteon, Inc.	Sopro	Capture "button" not supported at this time
Air Techniques	Acclaim	
Dentrix Dental Systems	ImageCAM	
Digital Doc	Evolution Series	
Gendex	AcuCam	The firewire version requires connection by S-Video for proper function
Henry Schein	ViperCam	
Imagin Systems Corporation	HotRod Dental Imager	
Kavo Dental Corporation	ERGOcam	
Kodak Dental Systems	Kodak 1000	
Lightyear Direct	Lightyear Digital Camera	
Planmeca, Inc.	Intracam	
Progeny Dental	Progeny Micro	
RF Systems	Einstein	
Scican, Inc.	Intra Oral Ultimate	Requires configuration – call Visix support
Sota Precision Optics	Claris Series	Displays "mirrored" image only

Visix Support Office – 1611 Center Ave. – Janesville, WI 53545
1-866- 90- VISIX

Visix Web Site Downloads section (bottom of page 2 above):

Visix Supported Scanners

Visix™

Compatible Flatbed Scanners

Scanners Compatible for use with Visix is listed below in size order from smallest to largest.

In addition to these listed below, Visix will accommodate all Twain based flatbed scanners that have a transparency adapter. A transparency adapter is nothing more than a "light-lid" that fits on top of the scanner so light can pass through x-rays when they are being scanned. The adapter just adds the capability to scan x-rays and other transparent material such as 35mm slides. These scanners can scan in color as well as black and white.

All of the scanners listed below deliver excellent image quality, even the inexpensive ones. The major distinction between an inexpensive scanner and an expensive one is the size of the transparency adapter, time of the scan, and the durability of its components. The size of this adapter determines the maximum size of film that can be scanned. If you are interested in scanning pans and FMXs, you should consider the larger scanners listed below. If you will be scanning only individual x-rays or slides, then the smaller ones will be adequate.

Make	Model	Adapter Size	Price	Comments
Epson	Perfection 4870 Photo	6" X 9"	~$430	Scans 35mm slides, film strips
Microtek	i900	8" X 10"	~$600	Scans pans and some FMXs
Epson	Expression 1680 Pro	8.5" X 11.7"	~$1100	Scans pans and most FMXs.
Microtek	ScanMaker 9800XL	12"X 16"	~$1400	Scan pans and larger FMXs.

1-866- 90- VISIX

Visix Imaging Marketing Document:

Visix

IMAGING SOFTWARE SPECIFICATIONS

VISIX Imaging Network Computer Requirements/Recommendations

CPU Speed:	2 GHz Pentium Class, or higher.
Operating System:	Windows 2000 Service Pack 4, or later. Windows XP Professional Service Pack 1a, or later.
RAM:	512 MB, or higher.
CD ROM Drive:	48x speed, or higher.
Hard Drive:	100 MB of free disk space on each work station for program files. 80 GB, or higher, on server for image storage.
Monitor:	1024x768 resolution minimum. 1280 x 1024, or higher, recommended.
Keyboard/Mouse:	Standard keyboard and mouse required.
Backup Device:	Tape backup or external hard drive recommended. (Tape or drive capacity should be greater than the space designated for image storage on server.)
External Surge Protector:	Recommended.
Printer:	720 DPI of higher inkjet or photo printer. LaserJet's are NOT recommended.
USB Port:	USB 1.1 minimum. USB 2.0 is recommended.
Network:	100 mbps network speed, or higher. Client/Server network topology recommended. Microsoft 2000 or 2003 Server recommended for server OS.

AIR TECHNIQUES INC.
1295 Walt Whitman Road, Melville, NY 11747 / www.airtechniques.com
516-433-7676 / Fax 516-433-7684 / Toll free in the U.S. and Canada: 800-Air-Tech
Western Facility 951-898-8555 / Fax 951-898-7646

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STERILIZATION AND SHELF LIFE

This section does not apply as the proposed device contains software only and does not require sterilization or have a shelf life identified.

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

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BIOCOMPATIBILITY

This section does not apply, as the proposed device does not contain components that come into direct or indirect contact with patients.

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

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SOFTWARE

Visix Imaging is medical imaging software that acquires, displays, enhances, stores, and prints images. The images are acquired from various hardware sources such as scanners, digital video cameras, digital image files, etc.

Software Level of Concern:

According to the *Guidance for the Submission of Premarket Notifications for Medical Image Management Devices* dated July 27, 2000, software for most medical image management devices is considered a minor level of concern.

Based on the information provided for determining the level of concern in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005, Visix Imaging is considered a minor level of concern and the following information is provided.

- A list and brief description of the functions performed by the software including revision history log;
- A description of the software development methods including changes and configuration management;
- A description of the software test methods;
- A list of hazards related to the functions performed by the software and the means taken to mitigate each of these hazards; and
- A certification statement regarding software.

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

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Functions:

The following is a list of the Visix Imaging functions with a brief description of each.

Function Number	Function	Description
1	Acquire Images	Save images taken by hardware device sources such as scanners, digital video cameras, digital sensors, etc., or import digital image files that were saved on computer media such as hard drives, floppies, CDs, DVDs, the internet, thumb drives, etc.
2	Save images in a Searchable Image Library	Store images using cross referencing database information that allows images to be located later by such information as patient name, image date, what hardware acquired the image, keywords, tooth number, etc.
3	Display Images	Present images for viewing on either a computer or TV monitor, or a paper printout.
4	Enhance Images	Make minor, non-permanent image adjustments (e.g., rotate, zoom, flip, etc.). to create the clearest and most detailed view possible of the image.
5	Link Information to Images	In database tables, link information such as the anatomical region represented by the image, keywords that describe the image, notes about the image, the date the image was taken, the hardware device used to acquire the image, and the patient that the image was taken of, to the image.
6	Delete Images	Remove images from the Visix Imaging database.
7	Print Image Copies	Print a copy of an image plus image information such as patient name, doctor name, etc.
8	Export Images	Save a copy of an image to a user specified export location.

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

Revision History Log:

(b)(4) Modifications

[redacted]

(b)(4) Modifications

(b)(4) Modifications

(b)(4) Modifications

(b)(4) Modifications

[redacted]

Software Development Methods:

(b)(4)

[redacted]

CONFIDENTIAL

(b)(4) Software Development Methods

[redacted]

Figure 1. Enhancement Request Form:

(b)(4)

[redacted]

The software development process is summarized below.

Software Development Step	Explanation	Step Performed By

(b)(4) Software Development Methods

[redacted]

(b)(4) Software Development Process

(b)(4) Software Development Process

(b)(4) Software Development Process

(b)(4) Software Development Process

(b)(4) Software Development Process

(b)(4) Software Development Process

(b)(4) Software Development Process

[redacted]

Configuration Management

(b)(4)

[redacted]

CONFIDENTIAL

(b)(4)

[redacted]

Software Testing Methods

(b)(4)

[redacted]

Hazard Analysis:

(b)(4)

[redacted]

Software Certification:

The software certification statement immediately follows this page.

CONFIDENTIAL

I hereby certify that the software development process was followed for the Visix software, good quality assurance procedures were adhered to, and test results met.

(b)(6) [redacted]

8-20-2008

Manager of Engineering
Televere Systems

Date

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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Visix Imaging Hazard Analysis

(b)(4)

[redacted]

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

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

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ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This section does not apply as the proposed device is software only and does not contain an electronic component.

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

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PERFORMANCE TESTING—BENCH

(b)(4)

[redacted]

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

(b)(4) Testing

(b)(4) Testing

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(b)(4) Testing

[redacted]

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

(b)(4) Testing

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Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

PERFORMANCE TESTING—ANIMAL

This section does not apply as no animal studies were necessary to support this 510(k) submission.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

PERFORMANCE TESTING CLINICAL

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

COVER SHEET MEMORANDUM

From: Reviewer Name Nancy Wersto

Subject: 510(k) Number K082623/S002

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%2(2%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	√	
510(k) Summary /510(k) Statement	*Attach Summary*	√	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	√	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		√
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		√	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			√
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			√
Is this device intended for pediatric use only?			√
Is this a prescription device? (If both prescription & OTC, check both boxes.)		√	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			√
Does this device include an Animal Tissue Source?			√
All Pediatric Patients age<=21			√
Neonate/Newborn (Birth to 28 days)			√
Infant (29 days -< 2 years old)			√
Child (2 years -< 12 years old)			√
Adolescent (12 years -< 18 years old)			√
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			√
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			√
Nanotechnology			√

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		√
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		√

Regulation Number	**Class***	**Product Code**
892.2050	II	LLZ

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

Additional Product Codes:

Review: (Branch Chief) (Branch Code) 2/25/09 (Date)

Final Review: (Division Director) 2/25/09 (Date)

dep

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

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

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

K082623/S002

Date: February 18, 2009

To: The Record

Office: ODE

From: Nancy Wersto

Division: DRARD

510(k) Holder: Televere Systems

Device Name: Visix Imaging

Contact: Ms. Barbara Deay
Technical Writer

Phone: (518) 384-2052

Fax: (608) 314-1084

Email: barb@tigerview.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce their Visix Imaging System into interstate commerce.

12/31/2008 The sponsor did not submit adequate documentation in support of their Moderate level of Concern software determination. Please see Section VI of this Memo for further details/CFM

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form		√	

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?	√		
Is the device sterile?		√	

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

	Yes	No	N/A
Is the device reusable (not reprocessed single use)?	√		
Are "cleaning" instructions included for the end user?		√	

The Visix Imaging System is an image management system that allows the physician to acquire, display, edit, review, store, print, and distribute medical images within a PACS environment. The minimum computer requirements for this device are listed in Section 010, Executive Summary.

The subject device is comprised of five (5) main areas:

- **Patients** – this window is divided into two sections: Patients Area (patient data is selected, added, deleted or edited) and Search Criteria (locate specific images or groups of images for the patient);
- **Images** – displays the images that belong to the currently open patient;
- **Acquire** – this input method consists of X-rays, video, flatbed scanning, and imported digital images. On page 2 of 7 in Section 010, there is a list of optional setting that allows the user to fine-tune the images;
- **Mount** – allows multiple images to be grouped together in a user specified arrangement. These images can be viewed, printed, exported, or otherwise manipulated together as one image;
- **View** – this window can be used to examine, manipulate, measure, and place notes on an image. Advanced image manipulation tools in this window provide the capability for viewing multiple images at the same time. This list is found on page 4 of 7 in Section 010.

The sponsor does not appear to claim conformance to the DICOM standard. Images are exported as bitmap, jpeg, or tiff as selected by the user in the Export function.

IV. Indications for Use – updated from S002

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Predicate devices

K061035: TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.
It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

K982422: EagleSoft's ChairSide is a clinical software program that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audio recordings, and clinical exam data. In addition, it also offers an imaging module for image acquisition, editing, and storage of digital images. It is designed to be a single-source solution for a dentist's software needs for clinical and diagnostic use when serving the general public.

Images can be acquired from standard dental imaging devices including Digital Radiographic Devices, Digital Video Capture Devices, and Generic Image Devices such as scanners. Non-diagnostic images can then be edited (i.e., resized, contrast, cropped, etc.). Images can also be easily imported and exported.

K955237: Uses for *TigerScan* and *TigerView* in the dental industry include the following:

- Scanning of film and archival storage for on-line access by patient.
- Electronic transmission of digital radiographs with insurance claims.
- Radiograph viewing and manipulation for Insurance claims adjudication
- Radiographic viewing and manipulation for diagnostic purposes.
- Radiographic viewing for patient education and consultation.
- Electronic transmission of radiographs to specialists for consultation.

When used for diagnostic purposes, the patient population will be the general public, and the diseases/conditions that the device will be used to diagnose are: dental caries, periodontal disease and bone loss, tooth fractures, jaw misalignment, and other diseases and conditions that are encountered by general practitioners and specialists in the dental care field.

Comment:

On February 20, 2009, Dr. Robert Betz, DDS, assessed the sample dental images provided in Volume 2 of this submission and found them to be adequate for diagnostic purposes. It was disillusioning to see that Charles Myers had not been mentored by either KXC or the Acting Branch Chief to seek out a clinical consult for these images. This is a questionable precedent being set which could be problematic for future submissions.

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

V. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	√		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	√		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	√		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough: The deficiencies from S001 included the removal of the "confidential" label on the IFU statement and provision of software documentation for moderate level of concern.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: The sponsor has now provided appropriate performance data per FDA request.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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VI. Deficiencies - 12/31/2008 (b)(4)

(b)(4) Deficiencies

(b)(4) Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

XVII. Contact History

12/04/08	The AI Letter is the first contact with the sponsor/CFM
12/12/08	Received response letter from the sponsor/CFM
12/19/08	A series of e-mails ensued between Mr. Myers and the sponsor contact Ms. Barbara Deay/CFM
01/02/09	The sponsor did not send in adequate documentation to answer two questions in the first AI letter. A second AI letter was prepared and will be sent to the sponsor/CFM

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

XVIII. Recommendation - SE

Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ

Nancy Weigto
Reviewer

2/24/09
Date

Branch Chief

Date

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

COVER SHEET MEMORANDUM

From: Charles F. Myers

Subject: K082623

To: The Record

Please list CTS decision code AI

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

√ Hold (**Additional Information** or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	√	
510(k) Summary /510(k) Statement	*Attach Summary*	√	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	√	
Is the device Class III?			√
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		√	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			√
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			√
Is this device intended for pediatric use only?			√
Is this a prescription device? (If both prescription & OTC, check both boxes.)		√	
Is clinical data necessary to support the review of this 510(k)?			√
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			√
Does this device include an Animal Tissue Source?			√
All Pediatric Patients age<=21			√
Neonate/Newborn (Birth to 28 days)			√
Infant (29 days -< 2 years old)			√
Child (2 years -< 12 years old)			√
Adolescent (12 years -< 18 years old)			√
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			√
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			√
Nanotechnology			√

Rev. 7/2/07

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	√
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	√

Regulation Number	**Class***	**Product Code**
21 CFR 892.2050	II	LLZ

Review: _____ RADB 1/9/09 _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K082623

Date:	01/02/2009		
To:	The Record	Office:	ODE
From:	Charles F. Myers	Division:	DRARD

510(k) Holder:	Televere Systems
Device Name:	Visix Imaging
Contact:	Barbara Deay
	Technical Support and Technical Writing
Phone:	1-800-385-9593
Fax:	1-608-314-1084
Email:	barb@tigerview.com

I. Purpose and Submission Summary.....

The 510(k) holder would like to introduce the Visix Imaging System into interstate commerce.

12/31/2008 The sponsor did not submit adequate documentation in support of their Moderate Level of Concern software determination. Please see Section XV of this Memo for further details / CFM

12/02/2008 The sponsor will need to respond to the AI letter before SE can be determined. Please see Section XV of this Memo for further explanation / CFM

II. Administrative Requirements.....

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form		√	

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

III. Device Description.....

The Visix Imaging System is an image management system that allows the physician to acquire, display, edit, review, store, print, and distribute medical images within a PACS environment. The minimum computer requirements for this device are listed in Section 010, Executive Summary.

The subject device is comprised of five (5) main areas:

- **Patients** – this window is divided into two sections: Patients Area (patient data is selected, added, deleted or edited) and Search Criteria (locate specific images or groups of images for the patient);
- **Images** – displays the images that belong to the currently open patient;
- **Acquire** – this input method consists of X-rays, video, flatbed scanning, and imported digital images. On page 2 of 7 in Section 010, there is a list of optional settings that allows the user to fine-tune the images;
- **Mount** – allow multiple images to be grouped together in s user specified arrangement. These images can be viewed, printed, exported, or otherwise manipulated together as one image;
- **View** – this window can be used to examine, manipulate, measure, and place notes on an image. Advanced image manipulation tools in this window provide the capability for viewing multiple images at the same time. This list is found on page 4 of 7 in Section 010.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?	√		
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)?	√		
Are "cleaning" instructions included for the end user?			√

IV. Indications for Use.....

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes. It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

12/31/2008 The information submitted by the sponsor was adequate to revise the IFU Statement / CFM

12/02/2008 The IFU needed to be clarified with the modalities that can be used with this device, e.g., mammography, etc. AI was requested from the sponsor. See Section XV of this Memo / CFM

V. Predicate Device Comparison.....

The sponsor claims substantial equivalence to three predicate devices:

- K061035, Televere Systems, TigerView Professional;
- K982422, EagleSoft, EagleSoft ChairSide Software Application;

- K955237, Tau Corp (purchased by Televere System), TigerScan / TigerView

The sponsor considers their device to be of Minor Level of Concern. A list of software functions is provided beginning on page 2 of 24 in Section 16 – Software. The sponsor indicates that they have provided the following software documentation within the submission:

- Software Level of concern;
- A list and brief description of the functions performed by the software including revision history log;
- A description of the software development methods including changes and configuration management;
- A description of the software test methods;
- A list of hazards related to the functions performed by the software and the means taken to mitigate each of these hazards; and
- A certification statement regarding software.

(b)(4) Deficiencies

[redacted]

VI. Labeling.....

The sponsor has provided the following Labeling documentation:

- Visix Imaging Manual;
- Visix Imaging Administration Manual;
- Visix Imaging CD Label;
- Web site about Visix Imaging with the documents printed from that web site;
- Visix Imaging marketing document.

VII. Sterilization/Shelf Life/Reuse.....

N/A

VIII. Biocompatibility.....

N/A

IX. Software.....

The sponsor claims Minor Level of Concern software. Not all elements were submitted for Minor LOC. In addition, this device should be considered Moderate LOC software.

(b)(4) Deficiencies

[redacted]

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

Version: 2.1

Level of Concern: **Minor**

	Yes	No
Software description:	√	
Device Hazard Analysis:	√	
Software Requirements Specifications:		√
Architecture Design Chart:		√
Design Specifications:		√
Traceability Analysis/Matrix:		√
Development:	√	
Verification & Validation Testing:	√	
Revision level history:	√	
Unresolved anomalies:		√

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety.....

The sponsor indicated that this is a software only device.

XI. Performance Testing – Bench.....

Bench testing was performed in order to determine software LOC / CFM

XII. Performance Testing – Animal.....

N/A

XIII. Performance Testing – Clinical.....

N/A

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

XIV. Substantial Equivalence Discussion.....

The sponsor claims that this device is substantially equivalent to the three predicate devices listed in the submission.

12/31/2008 A second AI letter is being sent to the sponsor. Please see Section XV of this Memo / CFM

12/02/2008 The Lead Reviewer cannot determine SE based on the information provided by the sponsor in the submission. AI was requested from the sponsor. Please see Section XV of this Memo for further explanation / CFM

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. **Explain how the new indication differs from the predicate device's indication:**
   N/A

2. **Explain why there is or is not a new effect or safety or effectiveness issue:**
   N/A

3. **Describe the new technological characteristics**:
   N/A

4. **Explain how new characteristics could or could not affect safety or effectiveness:**
   N/A

5. **Explain how descriptive characteristics are not precise enough:**
   N/A

6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**
   N/A

7. **Explain why existing scientific methods can not be used:**
N/A

8. **Explain what performance data is needed:**
N/A

9. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
N/A

XV. Deficiencies.....

(b)(4) Deficiencies

[redacted]

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(b)(4) Deficiencies

[redacted]

XVI. Contact History.....

12/04/2008 The AI Letter is the first contact with the sponsor / CFM
12/12/2008 Received response letter from the sponsor / CFM
12/19/2008 A series of e-mails ensued between Mr. Myers and the sponsor contact Ms. Barbara Deay / CFM
01/02/2009 The sponsor did not send in adequate documentation to answer two questions in first AI letter. A second AI letter was prepared and will be sent to the sponsor / CFM

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

XVII. Recommendation……..

Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archive and communication system
Regulatory Class: Class II
Product Code: LLZ

Reviewer (Charles F. Myers) — Date: 01/02/2009

Branch Chief — Date: 1/9/09

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Myers, Charles F

From: Myers, Charles F
ent: Monday, December 29, 2008 10:46 AM
o: 'barb@tigerview.com'
Subject: RE: FDA 510(k) submission K082623

Good morning Barbara,

As it has been several days since we have been in touch, let me give you my timelines and summarize the exact information I need in order to complete your submission and send it up-line for clearance:

Timeline: Please have all of the requested documentation to me (you may send it to me electronically) no later than close of business Wednesday, 12/31/2008. If I receive your documentation later, I will need to place your submission on Telephone Hold and at that point, you will need to send your documentation through the FDA Document Mail Center.

Required information:

(b)(4) Deficiencies

[redacted]

Please let me know if you have any questions regarding this correspondence.

Regards,
Charles

Charles F. Myers
Reviewer
Radiology Branch
FDA/CDRH/ODE
Phone: 240-276-3657

From: Myers, Charles F
Sent: Monday, December 22, 2008 1:23 PM
To: 'barb@tigerview.com'
Subject: RE: FDA 510(k) submission K082623

Hi Barbara,

nk you for your response below. I am off-site today and will not have your file available until tomorrow. Let me ntact you tomorrow and give you my timelines.

Thanks,
Charles

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Charles F. Myers
Reviewer
Radiology Branch
A/CDRH/ODE
one: 240-276-3657

From: Barb [mailto:barb@tigerview.com]
Sent: Monday, December 22, 2008 12:26 PM
To: Myers, Charles F
Subject: RE: FDA 510(k) submission K082623

Hi Charles,

Below is a rewrite of my response to the third issue from your first email from early Dec (I called you and asked you to ignore the response I initially sent for number 3).

(b)(4) Deficiencies

[redacted]

What's our deadline for finishing this? I remember you saying we have a certain number of days.

If you have any questions, feel free to call me at 1-800-385-9593 x128 or email me.

Thank you for your time and patience.

Barbara Deay
evere Systems
.b@tigerview.com

-----Original Message-----
From: Myers, Charles F [mailto:charles.myers@fda.hhs.gov]

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Sent: Friday, December 19, 2008 3:16 PM
To: barb@tigerview.com
Subject: FDA 510(k) submission K082623

(b)(4) Deficiencies

[redacted]

Hi Barbara,

I received your written correspondence dated 12/12/2008, which was in response to our additional information letter dated 12/04/2008. I need the following information sent to me electronically which should allow me to complete my review:

(b)(4) Deficiencies

[redacted]

Thank you for your time and attention to this matter.

gards,

Charles

Charles F. Myers
Reviewer
Radiology Branch
FDA/CDRH/ODE
Phone: 240-276-3657

No virus found in this incoming message.
Checked by AVG.
Version: 7.5.552 / Virus Database: 270.9.19/1857 - Release Date: 12/19/2008 10:09 AM

No virus found in this outgoing message.
Checked by AVG.
Version: 7.5.552 / Virus Database: 270.9.19/1860 - Release Date: 12/21/2008 3:08 PM

1/2/2009 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

CONFIDENTIAL

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes. It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

CONFIDENTIAL

510(k) SUMMARY

General Information

Submitted by:

Televere Systems
1611 Center Avenue
Janesville, WI 53545

Phone: 800-385-9593
Fax: 608-314-1084

Contact Person:

Barbara Deay
471 Stage Road
Charlton, NY 12019

Phone: 800-385-9593 x128
Fax: 408-762-2760
Email: barb@tigerview.com

Date Prepared: August 29, 2008

Device Name

Trade Name: Visix Imaging
Common Name: Picture archiving and communications system
Classification Name: System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp. (purchased by Televere Systems)	TigerScan/TigerView	K955237

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card, or SCSI card.

Intended Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Visix Imaging has been demonstrated to perform as intended.

Conclusions

Visix Imaging is substantially equivalent to legally marketed Picture Archiving and Communications Systems.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

COVER SHEET MEMORANDUM

From: Charles F. Myers

Subject: K082623

To: The Record

Please list CTS decision code 41

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

√ Hold (**Additional Information** or Telephone Hold).

Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	√	
510(k) Summary /510(k) Statement	*Attach Summary*	√	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	√	
Is the device Class III?			√
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		√	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			√
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			√
Is this device intended for pediatric use only?			√
Is this a prescription device? (If both prescription & OTC, check both boxes.)		√	
Is clinical data necessary to support the review of this 510(k)?			√
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			√
Does this device include an Animal Tissue Source?			√
All Pediatric Patients age<=21			√
Neonate/Newborn (Birth to 28 days)			√
Infant (29 days -< 2 years old)			√
Child (2 years -< 12 years old)			√
Adolescent (12 years -< 18 years old)			√
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			√
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			√
Nanotechnology			√

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	√
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	√

Regulation Number	**Class***	**Product Code**
21 CFR 892.2050	II	LLZ

Review: _____ RADB 12/4/08
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

K082623
PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

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

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

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K082623

Date:	12/02/2008		
To:	The Record	Office:	ODE
From:	Charles F. Myers	Division:	DRARD

510(k) Holder:	Televere Systems
Device Name:	Visix Imaging
Contact:	Barbara Deay
	Technical Support and Technical Writing
Phone:	1-800-385-9593
Fax:	1-608-314-1084
Email:	barb@tigerview.com

I. Purpose and Submission Summary.....

The 510(k) holder would like to introduce the Visix Imaging System into interstate commerce.

The sponsor will need to respond to the AI letter before SE can be determined. Please see Section XV of this Memo for further explanation / CFM

II. Administrative Requirements.....

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form		√	

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

III. Device Description.....

The Visix Imaging System sis an image management system that allows the physician to acquire, display, edit, review, store, print, and distribute medical images within a PACS environment. The minimum computer requirements for this device are listed in Section 010, Executive Summary.

The subject device is comprised of five (5) main areas:

- **Patients** – this window is divided into two sections: Patients Area (patient data is selected, added, deleted or edited) and Search Criteria (locate specific images or groups of images for the patient);
- **Images** – displays the images that belong to the currently open patient;
- **Acquire** – this input method consists of X-rays, video, flatbed scanning, and imported digital images. On page 2 of 7 in Section 010, there is a list of optional settings that allows the user to fine-tune the images;
- **Mount** – allow multiple images to be grouped together in s user specified arrangement. These images can be viewed, printed, exported, or otherwise manipulated together as one image;
- **View** – this window can be used to examine, manipulate, measure, and place notes on an image. Advanced image manipulation tools in this window provide the capability for viewing multiple images at the same time. This list is found on page 4 of 7 in Section 010.

12/02/2008 The Lead Reviewer has requested additional information from the sponsor regarding two specific functions of the software. See Section XV of this Memo / CFM

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?	√		
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)?	√		
Are "cleaning" instructions included for the end user?			√

IV. Indications for Use.....

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical notes. It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

(b)(4) Deficiencies

[redacted]

V. Predicate Device Comparison.....

The sponsor claims substantial equivalence to three predicate devices:

- K061035, Televere Systems, TigerView Professional;
- K982422, EagleSoft, EagleSoft ChairSide Software Application;
- K955237, Tau Corp (purchased by Televere System), TigerScan / TigerView

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

The sponsor considers their device to be of Minor Level of Concern. A list of software functions is provided beginning on page 2 of 24 in Section 16 – Software. The sponsor indicates that they have provided the following software documentation within the submission:

- Software Level of concern;
- A list and brief description of the functions performed by the software including revision history log;
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- A description of the software test methods;
- A list of hazards related to the functions performed by the software and the means taken to mitigate each of these hazards; and
- A certification statement regarding software.

(b)(4) Deficiencies [redacted]

VI. Labeling.....

The sponsor has provided the following Labeling documentation:

- Visix Imaging Manual;
- Visix Imaging Administration Manual;
- Visix Imaging CD Label;
- Web site about Visix Imaging with the documents printed from that web site;
- Visix Imaging marketing document.

VII. Sterilization/Shelf Life/Reuse.....

N/A

VIII. Biocompatibility.....

N/A

IX. Software..... (b)(4) Deficiencies [redacted]

(b)(4) Deficiencies [redacted]

Version: 2.1

Level of Concern: **Minor**

	Yes	No
Software description:	√	
Device Hazard Analysis:	√	
Software Requirements Specifications:		√

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

Architecture Design Chart:		√
Design Specifications:		√
Traceability Analysis/Matrix:		√
Development:	√	
Verification & Validation Testing:	√	
Revision level history:	√	
Unresolved anomalies:		√

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety.....
The sponsor indicated that this is a software only device.

XI. Performance Testing – Bench.....
Bench testing was performed in order to determine software LOC / CFM

XII. Performance Testing – Animal.....
N/A

XIII. Performance Testing – Clinical.....
N/A

XIV. Substantial Equivalence Discussion.....
The sponsor claims that this device is substantially equivalent to the three predicate devices listed in the submission.

(b)(4) Deficiencies [redacted]

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please

complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. **Explain how the new indication differs from the predicate device's indication:**
   N/A

2. **Explain why there is or is not a new effect or safety or effectiveness issue:**
   N/A

3. **Describe the new technological characteristics:**
   N/A

4. **Explain how new characteristics could or could not affect safety or effectiveness:**
   N/A

5. **Explain how descriptive characteristics are not precise enough:**
   N/A

6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**
   N/A

7. **Explain why existing scientific methods can not be used:**
   N/A

8. **Explain what performance data is needed:**
   N/A

9. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
   N/A

XV. Deficiencies.....

Please see the deficiencies listed below as identified in the AI letter sent to the sponsor / CFM

(b)(4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(b)(4) Deficiencies

[redacted]

XVI. Contact History.....

The AI Letter is the first contact with the sponsor / CFM

XVII. Recommendation.....

Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archive and communication system
Regulatory Class: Class II
Product Code: LLZ

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Reviewer (Charles F. Myers) — Date: 12/02/2008

Branch Chief — Date: 12/4/08

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 15, 2008

TELEVERE SYSTEMS
471 STAGE RD.
CHARLTON, NEW YORK 12019
UNITED STATES
ATTN: BARBARA DEAY

510k Number: K082623

Product: VISIX IMAGING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

K082623/S1

Barbara Deay
Televere Systems
471 Stage Road
Charlton, NY 10219

Dec 12, 2008

FDA CDRH DMC
DEC 15 2008
Received

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

Re: K082623
Trade Name: Visix Imaging
Dated: August 20, 2008
Received: September 29, 2008
Page 1

K-33

Dear Mr. Myers:

This document is in response to our phone conversation of Dec 11, 2008 and your written questions regarding our 510(k) submission.

(b)(4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(b)(4) Deficiencies

[redacted]

I hope this clarifies the issues you had with our 510(k) submission. If you have any questions, feel free to call me at 1-800-385-9593 x128.

Thank you for your time and patience.

Barbara Deay
Televere Systems

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

January 15, 2009

TELEVERE SYSTEMS
471 STAGE RD.
CHARLTON, NEW YORK 12019
UNITED STATES
ATTN: BARBARA DEAY

510k Number: K082623

Product: VISIX IMAGING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

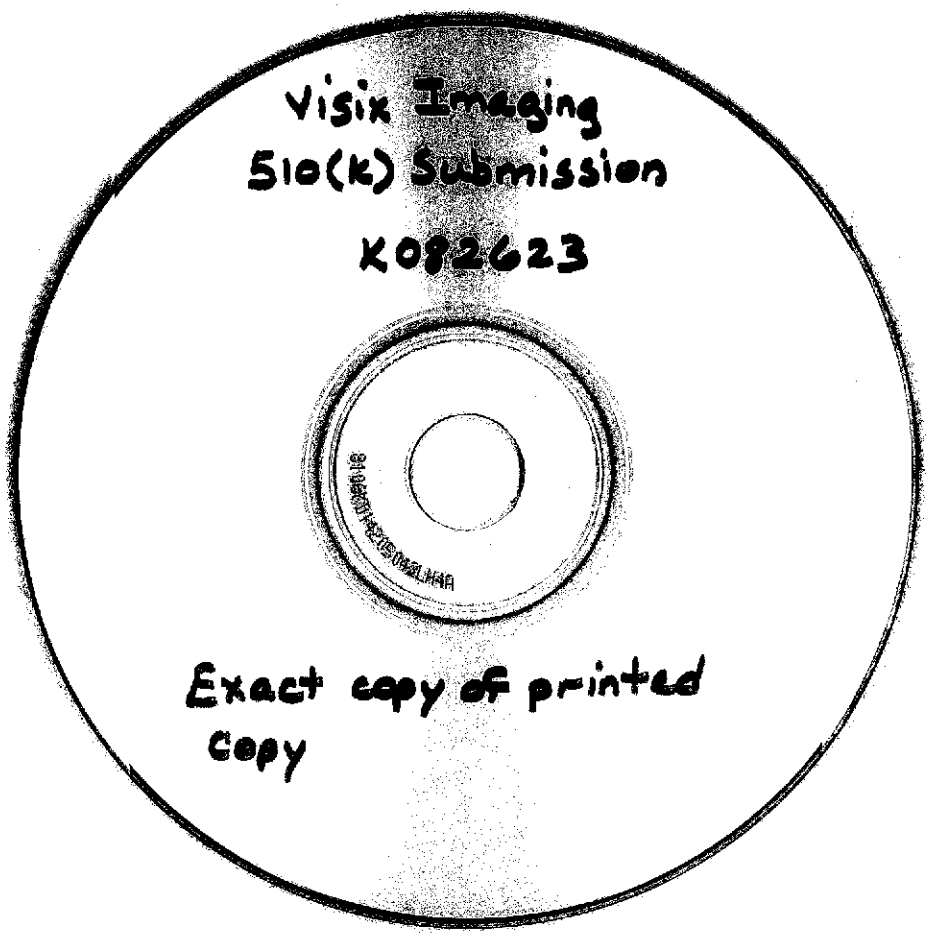
If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016



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

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510(k) Sumission K082623

Proprietary Name: Visix Imaging

Submitted By: Televere Systems

1/13/09

K 36

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

K082623/S2

Mr. Charles F. Myers
Food and Drug Administration
Center for Devices and Radiological Health
240-276-3657

Re: K082623
Trade Name: Visix Imaging
Dated: August 20, 2008
Received: September 29, 2008

JAN 14 2009

January 11, 2009

Dear Charles,

Accompanying this letter is the complete Visix 510(k) submission, revised as you requested. The following sections have changed:

Section	Change
(b)(4) Deficiencies	[redacted]

I'm including a CD that has exactly the same documents that you're receiving printed out (we're printing them from the cd). I'm including the updated device description for the Spectra that the manufacturer wrote up. I sent this to you by email so this is included just in case the submission gets turned over to someone else.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Thanks for all your help and your prompt phone responses. You've been great to work with. Good luck on your new position!

Take care,

Barbara Deay
Televere Systems
Technical Writer
471 Stage Road
Charlton, NY 12019
518-384-2052
800-385-9593 x128

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Barbara Deay
Televere Systems
471 Stage Road
Charlton, NY 10219

Dec 12, 2008

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

FDA CDRH DMC
JAN 14 2009
Received

Re: K082623
Trade Name: Visix Imaging
Dated: August 20, 2008
Received: September 29, 2008
Page 1

Dear Mr. Myers:

This document is in response to our phone conversation of Dec 11, 2008 and your written questions regarding our 510(k) submission.

(b)(4) Deficiencies

[redacted]

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

(b)(4) Deficiencies

[redacted]

I hope this clarifies the issues you had with our 510(k) submission. If you have any questions, feel free to call me at 1-800-385-9593 x128.

Thank you for your time and patience.

Barbara Deay
Televere Systems

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Medical Device User Fee Cover Sheet

Site: null

Page 1 of 1

Form Approved: OMB No 0910-513 Expiration Date: January 31, 2010. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

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

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

TELEVERE SYSTEMS LLC
1611 Center Ave.
Janesville WI 53545
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
752692534

2. CONTACT NAME
Jill Davieswhite

2.1 E-MAIL ADDRESS
jill@ligerview.com

2.2 TELEPHONE NUMBER (Include Area code)
800-3859593

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
408-7624441

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

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

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under 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

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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] 14-Aug-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?ordnum=6038023 8/26/2008

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
9/08	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Televere Systems	Establishment Registration Number *(if known)*: 2954358		
Division Name *(if applicable)*	Phone Number *(including area code)*: 1-800-385-9593		
Street Address: 1611 Center Avenue	FAX Number *(including area code)*: 1-608-314-1084		
City: Janesville	State / Province: Wisconsin	ZIP/Postal Code: 53545	Country: USA
Contact Name: Barbara Deay			
Contact Title: Technical Support and Technical Writing	Contact E-mail Address: barb@tigerview.com		

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

Company / Institution Name: Televere Systems			
Division Name *(if applicable)*	Phone Number *(including area code)*: (800) 385-9593 x128 or (518) 384-2052		
Street Address: 471 Stage Road	FAX Number *(including area code)*: (408) 762-2760		
City: Charlton	State / Province: NY	ZIP/Postal Code: 12019	Country: USA
Contact Name: ·bara Deay			
Contact Title: Technical Support and Writing	Contact E-mail Address: barb@tigerview.com		

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

BSC Media Arts (301) 443-2454 EF

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

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

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

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

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

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

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

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

- [ ] Response to FDA correspondence:

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

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

- [ ] Other Reason *(specify)*:

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LLZ	2		3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K061035	1	TigerView Professional	1	Televere Systems
2	K955237	2	TigerScan/TigerView	2	Televere Systems
3	K982422	3	EagleSoft ChairSide Software Application	3	EagleSoft, A Patterson Co.
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Image Processing System (PACS)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Visix Imaging	1	
2		2	
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
K955237	K061035				
7	8	9	10	11	12

Data Included in Submission

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

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LLZ	21 CFR 892.2050	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Radiology

Indications *(from labeling)*

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video ture devices, and generic image devices such as scanners). In addition, Visix Imaging enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

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

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 2954358	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Televerc Systems		Establishment Registration Number: 2954358
Division Name *(if applicable)*		Phone Number *(including area code)*: 800-385-9593
Street Address: 1611 Center Avenue		FAX Number *(including area code)*: 608-314-1084
City: Janesville	State / Province: WI	ZIP/Postal Code: 53545 / Country: USA
Contact Name: Barbara Deay	Contact Title: Technical Support and Technical Writer	Contact E-mail Address: barb@tigerview.com

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

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

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

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SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

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CERTIFICATION OF COMPLIANCE WITH CLINICAL TRIALS

This new section (included per instructions on the FDA web site) does not apply since no clinical studies were necessary to support this 510(k) submission.

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

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August 29, 2008

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: 510(k) Submission for Visix Imaging

Dear Document Control Clerk:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, two copies of this 510(k) Notification are being submitted at least 90 days prior to the date when Televere Systems proposes to introduce this product into interstate commerce for commercial distribution. One copy of this 510(k) Notification is a paper copy. Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

The proposed product is a modification (an expansion of the indications for use) of the TigerView Professional product that was developed by Televere Systems.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: System, Image Processing, Radiological

   Common/Usual Name: Picture Archiving and Communications System
   Trade/Proprietary Name: Visix Imaging

2. The registration number for Televere Systems is 2954358.

3. Picture archiving and communications systems have been classified as Class II (special controls) devices under 21 CFR 892.2050. Panel designation for similar devices is under Radiology, with Product Classification Code: LLZ.

4. No mandatory performance standards under Section 514 have been developed by the FDA for picture archiving and communications systems.

5. Proposed labeling for Visix Imaging is described in Section 13.

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6. Visix Imaging is substantially equivalent to other marketed devices previously cleared under Section 510(k). These include:

Manufacturer	Product Name	510(k) Number
Televere Systems	TigerView Professional	K061035
Televere Systems	TigerView Classic	K955237
Patterson Dental	Patterson EagleSoft (formerly known as EagleSoft ChairSide)	K982422

7. Table of Contents and Page Explanation
The header on each page indicates the 510(k) section on the left and the page within the section on the right. The additional section, Certification of Compliance With Clinical Trials listed in the Device Advice document "How To Prepare a Traditional 510(k)" located at http://www.fda.gov/cdrh/devadvice/3143.html has been placed between section 2 and section 3.

Section 1.0 Medical Device User Fee Cover Sheet (Form FDA 3601)
Section 2.0 CDRH Premarket Review Submission Cover Sheet
Section 2X Certification of Compliance With Clinical Trials
Section 3.0 510(k) Cover Letter
Section 4.0 Indications for Use Statement
Section 5.0 510(k) Summary
Section 6.0 Truthful and Accuracy Statement
Section 7.0 Class III Summary and Certification
Section 8.0 Financial Certification or Disclosure Statement
Section 9.0 Declarations of Conformity and Summary Reports
Section 10.0 Executive Summary
Section 11.0 Device Description
Section 12.0 Substantial Equivalence Discussion
Section 13.0 Proposed Labeling
Section 14.0 Sterilization and Shelf Life
Section 15.0 Biocompatibility
Section 16.0 Software
Section 17.0 Electromagnetic Compatibility and Electrical Safety
Section 18.0 Performance Testing – Bench
Section 19.0 Performance Testing – Animal
Section 20.0 Performance Testing – Clinical
Section 21.0 Software Requirements Specification
Section 22.0 Architecture Design Chart
Section 23.0 Software Design Specification
Section 24.0 Traceability Analysis and Unresolved Anomalies

Should you have any questions or require further information, please feel free to contact me at phone number (800) 385-9593 x128, or at the following address: 471 Stage Road, Charlton, NY 12019.

Sincerely,
Barbara Deay
Barbara Deay
Technical Writer, Televere Systems August 29, 2008

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

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INDICATIONS FOR USE

510(k) Number (if known): K082623

Device Name: Visix Imaging

Sponsor Name: Televere Systems

Indications for Use:
Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Prescription Use [X] And/Or Over-The-Counter Use [ ]
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

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CONFIDENTIAL

510(k) SUMMARY

General Information

Submitted by:	Televere Systems 1611 Center Avenue Janesville, WI 53545 Phone: 800-385-9593 Fax: 608-314-1084
Contact Person:	Barbara Deay 471 Stage Road Charlton, NY 12019 Phone: 800-385-9593 x128 Fax: 408-762-2760 Email: barb@tigerview.com
Date Prepared:	August 29, 2008

Device Name

Trade Name:	Visix Imaging
Common Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
EagleSoft	EagleSoft ChairSide Software Application	K982422
Tau Corp. (purchased by Televere Systems)	TigerScan/TigerView	K955237

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

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Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card, or SCSI card.

Intended Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Technological Comparison

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Visix Imaging has been demonstrated to perform as intended.

Conclusions

Visix Imaging is substantially equivalent to legally marketed Picture Archiving and Communications Systems.

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

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that as a responsible representative of Televere Systems, I believe, to the best of my knowledge and understanding, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Randall Quaal 8/29/08

Randall Quaal
General Manager
Televere Systems

Date

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

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PREMARKET NOTIFICATION

CLASS III SUMMARY AND CERTIFICATION

This section does not apply as the proposed device is classified as Class II (special controls) under 21 CFR 892.2050.

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PREMARKET NOTIFICATION

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

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PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section does not apply since declaration of conformances to recognized standards are not being provided.

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

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EXECUTIVE SUMMARY

1.1 Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., brighten, adjust contrast, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging utilizes the same programming routines to capture the images as TigerView Professional (K061035). The minimum computer requirements for the Visix Imaging software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher Hard Drive: 70MB or more of free space for the program Monitor: 1024x786 setting minimum Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, black and white laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology. Microsoft. Network speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database and images

Visix Imaging is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card or SCSI card. Examples of capture devices that are compatible are the ScanX scanner from Air Techniques, the Expression 1680 Pro Scanner from Epson, and the Acclaim camera from Air Techniques.

Visix is comprised of five (5) main areas: Patients, Images, Acquire, Mount, and View. Additionally, there is an Export Image function and a Print function.

Visix includes software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

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Patients

The Patients window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

Images

The Images bar displays the images that belong to the currently open patient. Images are stored in date order with the newest image at the top.

Acquire

Images are acquired into Visix through one of the devices listed in the Acquire area. The input methods consist of x-rays, video, flatbed scanning, and imported digital images.

The optional settings for the attached hardware device are displayed in settings windows. The following is an overall list of options available to the user to fine-tune the images. Not every option is available for every hardware device.

Optional Device Settings

- Edge Enhancement
- Smoothing
- Brightness
- Contrast
- Gamma / Gray Shift
- Trim
- Film Mask
- Auto Flip
- Auto Re-arm
- Timeout Value
- Advanced Settings
- Allow Scan Edit
- Auto Optimize
- Auto-Segment
- DEMS
- Image Orientation
- Prompt for Date
- Display Size
- Image Resolution
- Network Settings
- Shared / Exclusive Use

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- X-ray
  Various x-ray devices (e.g. ScanX scanner, Accent sensor) are compatible with Visix Imaging. Associated with x-ray acquisition are a number of options, such as the scan setting and exposure mode, which are specific to the attached hardware device, plus automatically mounting acquired images.

- Video
  Still pictures from video camera devices are acquired in the Acclaim window. Video options include such things as the specific video camera device from which to capture images, where the input is coming from, the size the live input is displayed at, the option to change device-specific video camera settings, and automatically mounting acquired images.

- Laser Fluorescence Detection Aid System
  Still pictures from fluorescence detection devices are acquired in the Spectra window. Options include detection (of bacteria) and analysis (amount of bacteria), and automatically mounting acquired images.

- Flatbed Scanning
  Images from a flatbed scanner are acquired in the Scan Film window. Flatbed scanner options include such things as selecting the appropriate TWAIN driver that matches the connected scanner, storing the image with a date specified by the user, and automatically mounting acquired images.

- Import
  Digital images and documents may be acquired through the import of various file types in the Import window. The user specifies the location of the files, and then selects the specific files to import. Import options include such things as automatically mounting the imported images.

Mount

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing photographs in a cardboard mat that has multiple openings. Mounted images are viewed, printed, exported, or otherwise manipulated together as one image. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function which automatically places newly acquired images into an existing mount.

View

The View window may be used to examine, manipulate, measure, and place notes on an image. The View window provides advanced image manipulation tools and

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has the capability for viewing multiple images at once. Various tools are available to the user in the View window such as:

- Zoom In and Out
- Full Screen
- Reset Zoom
- Rotate
- Flip
- Reset Orientation
- Automatically Arrange Images
- Manually Arrange Images
- Measure
- Annotate
- Magnifying Glass
- Print Image
- Negate
- Colorize Image
- Pseudo 3D
- Sharpen Image Edges
- Reset Original Image
- Brightness and Contrast
- Gray Shift (Gamma)

Export

Images are exported in a user selected file type of bitmap, jpeg or tiff in the Export function.

Print

A predefined report containing images and data prints in the Print function.

Dynamic Exposure Monitoring System (DEMS)

The Dynamic Exposure Monitoring System is an aid to the user in quickly identifying images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data made available by the acquisition device to render the object being imaged. The amount of data (measured in terms of bits acquired from the hardware device) required to meet the criteria for determining these status colors is specific to each hardware device supported by Visix Imaging based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software displays a yellow or red light that prompts the user to check the image and

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possibly retry image acquisition. Each hardware device has threshold bit levels set by default on installation. Whether the image displays a green (good) light or a yellow or red light, the user makes the decision to either accept the image or change imaging hardware settings and reacquire the image.

1.2 Indications for Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

1.3 Technological Comparison

Visix Imaging is substantially equivalent to TigerView Pro (K061035), EagleSoft ChairSide Software Application (K982422) and TigerScan/TigerView Classic (K955237). Visix Imaging, TigerScan/TigerView Classic, TigerView Pro and EagleSoft ChairSide are each software applications that have similar indications for use and overall functions, and perform in a similar manner with respect to image processing systems (i.e. PACS). Visix Imaging is compatible with similar types of hardware devices (e.g. scanners, digital sensors, digital video cameras, etc.) and has similar options for displaying, editing, and printing/sending images as the predicate devices.

A comparison of the features and performance of these devices is provided in the following table.

Parameters	Visix Imaging Televere Systems	TigerView Pro Televere Systems K061035	TigerScan/TigerView Tau Corp. (Televere Systems) K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Patient/Image Management	Yes	Yes	Yes	Yes
Acquire Images				
X-Ray	Yes	Yes	Yes	Yes
Video	Yes	Yes	No	Yes
Photos	Yes	Yes	No	Yes
Laser Fluorescence	Yes	No	No	No

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Detection Documents Import	Yes Yes	Yes Yes	No Yes	Yes Yes
Display Images	Yes	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes	Yes
Print/Send/Export Images	Yes	Yes	Yes	Yes
Enhance Images	Yes	Yes	Yes	Yes

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1.4 Performance Testing

(b)(4)

[redacted]

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INDICATIONS FOR USE AND DEVICE DESCRIPTION

11.1 Indications for Use

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

11.2 Device Description

Visix Imaging is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, etc.), review, store, print, and distribute images within a Picture Archiving and Communication System (PACS) environment. Visix Imaging utilizes the same programming routines to capture the images as TigerView Professional (K061035). The minimum computer requirements for the Visix software application are as follows:

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher Hard Drive: 70MB or more of free space for the program Monitor: 1024x786 setting minimum Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, black and white laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology, Microsoft, network speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database and images

Visix Imaging is compatible with capture devices which attach to the computer using a USB port, parallel port, S-video port on a video capture card or SCSI card. Examples of capture devices that are compatible are provided in the table below.

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Devices that attach to the computer in the following manner:	Device Examples
USB Port	Phosphor plate scanners such as the ScanX from Air Techniques
	Video cameras such as the Acclaim Intra-oral camera from Air Techniques
	Digital cameras such as the M305 digital camera from HP
	Flatbed scanners such as the Epson 1680
	Sensors such as the Accent from Air Techniques
	Fluorescence detection aid devices such as the Spectra from Air Techniques
Parallel Port	Phosphor plate scanners such as the ScanX from Air Techniques
S-video port on a video capture card	Video cameras such as the Acclaim Intra-oral camera from Air Techniques
SCSI Card	Various flatbed scanners such as: Perfection 4870 Photo Scanner from Epson Expression 1680 Pro Scanner from Epson ScanMaker 9800XL Scanner from Microtek

Visix Imaging is comprised of five (5) main areas: Patients, Images, Acquire, Mount, and View. Additionally, there is an Export Image function and a Print function.

Visix Imaging includes software logic called Dynamic Exposure Monitoring System (DEMS) to aid in the acquisition of high quality images.

Further description of the windows and additional software functionality is as follows:

11.2.1 Patients

The Patients window is divided into two sections: the Patients area, where patient data is added, selected, deleted, and/or edited, and a Search Criteria area, which is used to locate specific images or groups of images for the patient.

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11.2.2 Images

Images on the Image bar are displayed based on their age, i.e., the newest image will be displayed first. Images can be deleted, opened in the View window for viewing and manipulation, mounted, or printed.

Additionally, by right clicking on a specific image, the user will be able to copy an image, archive an image, export an image, print a report, view/designate the anatomical region of the image, add/delete keywords, flip the image, rotate the image, and view image properties such as where the image is stored and how large it is.

Exported image files save to the local hard drive or a network hard drive as a jpeg, bitmap or tiff image file (the type of file is selected by the user).

11.2.3 Acquire

Images are entered into Visix through one of the devices listed in the Acquire area. The input methods consist of x-rays, video, photos/documents/images acquired by a flatbed scanner, and imported digital images.

Optional Software Settings for Devices
The following is an overall list of options available to the user to fine-tune images. Not every option is available for every hardware device.

- Advanced Settings
  Advanced settings are specified by the device manufacturer.

- Allow Scan Edit
  When enabled, this option permits the user to draw selection boxes around images, or edit the selection boxes Visix Imaging draws automatically if the Auto-Segment option is enabled. Allow Scan Edit is only available for flatbed scanners.

- Auto-Flip
  When an image is Auto Flipped the view is as though the user is sitting on the other side of the item being x-rayed looking toward the x-ray head.

- Auto-Optimize
  This option is only available for flatbed scanners. When enabled, Auto-Optimize is used to make a flatbed scanner image a true 8-bit image with its greater range of grayscale values. See section 11.2.7 for more detail.

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- Auto Re-arm
  When enabled, as soon as one x-ray is taken, the device (typically a sensor) will automatically become ready to take another x-ray.

- Auto-Segment
  When enabled, Visix attempts to recognize separate items on a scanner bed as separate images. For example, when scanning standard size negatives, a green box is placed around each negative indicating that the area within the box is recognized as a standard size negative. A blue box is placed around an item that is not recognized as a standard size negative but is recognized as a separate item to scan.

- Brightness
  Raises or lowers the lightness of every pixel in the image.

- Contrast
  Makes white areas whiter and black areas blacker in an image. This has the effect of making details more noticeable in the image.

- DEMS
  Allows specification of threshold values for the Dynamic Exposure Monitoring System. See section 11.2.8 for more detail.

- Display Size
  This option is only available for video cameras. Display size allows the user to determine how large the image from the camera displays on the screen.

- Edge Enhancement
  When Edge Enhancement is enabled, edges within an image will appear more defined. Edge Enhancement tends to give an image a "salt and pepper" look.

- Extra-oral Settings
  Extra-oral images are much larger images than intra-oral images. Extra-oral settings are the same settings as intra-oral settings except that they are applied against larger images.

- Film Mask
  A Film Mask is a black border around the image similar to a mat around a photograph. The border can make the edges of the image appear sharper.

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- Gamma / Gray Shift
  Raises or lowers the lightness of the mid-range grayscale values without changing the whitest or blackest values on an image.

- Image Orientation
  This option lists each size of phosphor plate and sensor along with the default acquisition orientation - vertical or horizontal - for each size. The user may change image orientation at any time before or after acquisition.

- Image Resolution
  Image resolution (e.g. very high, high, standard) determines the amount of detail that an image will have. Selecting a high or very high resolution will result in a greater amount of detail in the resulting image. It will also save a larger digital image file that requires more hard drive space. For most images, a standard resolution is acceptable.

- Network Settings
  Some devices may be controlled by computers other than the computer the device is physically connected to. Network settings identify the computer and the ports used to acquire images from these devices.

- Prompt for Date
  If enabled, the user is prompted to specify the date the image was taken. If disabled, the current date is used as the image date.

- Reset
  Restores the default settings that came with Visix Imaging.

- Shared / Exclusive
  If more than one computer can control a device, the device can be set to either Shared mode or Exclusive mode. When in Shared mode, multiple computers can acquire images from the device. When in Exclusive mode, only one computer can acquire images from the device.

- Smoothing
  Smoothing attempts to remove any extra "noise" (miscellaneous black dots) from the image that was caused by applying edge enhancement.

- Timeout Value
  Timeout Value specifies how much time a sensor should wait before placing itself in low energy mode.

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- Trim
  Removes extraneous black dots from the outside edges of the image.

Software enabled setting options for the different types of hardware devices vary and are listed in the following Device Specific Settings chart:

Device Specific Settings	Phosphor plate scanners such as the ScanX	Video Cameras such as the Acclaim	Sensors such as the Accent	Flatbed Scanners	Fluorescence detection devices such as the Spectra
Advanced Settings		x			x
Allow Scan Edit				x	
Auto Flip	x		x		
Auto-Optimize (Adaptive Image Processing or AIP)				x	
Auto Rearm			x		
Auto-Segment				x	
Brightness	x		x	x	
Contrast	x		x	x	
DEMS	x			x	
Display Size		x			
Edge Enhancement	x		x		
Extra-oral Settings	x				
Film Mast	x			x	
Gamma / Gray Shift	x		x	x	
Image Orientation	x		x	x	
Image Resolution	x		x		
Network Settings	x				
Prompt for Date				x	
Shared / Exclusive Use	x				
Smoothing	x		x		
Timeout Value			x		
Trim	x				

Chart 1

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Image activities after an image has been acquired into Visix

- Auto or Manual Mounting
  When enabled, the auto-mount function automatically places acquired images into a previously created mount in the order in which they are acquired. Alternatively, images may be manually placed in mounts through dragging and dropping the desired images into image placeholders on a mount. See section 11.2.4 below for more information.

- Image Buttons
  After images have been acquired, single or multiple images may be selected and then deleted, viewed, or saved.

- Open an Image into the View window
  Images may be opened into the View window by:
  - Double-clicking on one image
  - Single clicking on one or more images and then clicking on the View button
  - Single clicking on one or more images and then right clicking once on one of the selected images and selecting View from the Right Click Menu

  See section 11.2.6 below for more information on the View window.

- Print an Image Report
  The Image Report may be printed from the main Visix window, the View window or the Right Click Menu. See section 11.2.5 below for more information.

- Right-Click Image Menu
  Some image manipulation functionality is available via the right-click image menu, including:
  - Mounting an image
  - Opening an image into the View window
  - Printing an image
  - Deleting an image
  - Copying an image to the clipboard
  - Moving an image to a user specified archive location
  - Exporting an image outside of Visix Imaging
  - Moving an image to a different patient
  - Specifying the anatomical region of the image
  - Assigning keywords to an image
  - Changing the orientation of an image (flip or rotate)
  - Viewing image properties

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11.2.3.1 Acquire X-ray Images

Various x-ray devices, such as the ScanX scanner and the Accent sensor, are compatible with Visix Imaging. X-rays from phosphor plate scanners such as the ScanX are acquired in the ScanX window, and x-rays from sensors such as the Accent are acquired in the Accent window. See the Device Specific Settings chart (Chart 1) above for user specified device settings for each.

11.2.3.2 Acquire Video Images

Various video cameras, such as the Acclaim intra-oral camera, are compatible with Visix Imaging. Video images from video camera devices are acquired in the Acclaim window using the Freeze function and the Save function. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, video options include the specific video camera device from which to capture images and the specific type of input such as S-Video.

11.2.3.3 Acquire Fluorescence Detection Images

Fluorescence detection images are acquired in the Spectra window (a fluorescence detection aid device) using the Freeze function and the Save function. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, options include Detection and Analysis.

11.2.3.4 Acquire images from a Flatbed Scanner

Images from a flatbed scanner are acquired in the Scan Film window. In addition to the user specified device settings listed in the Device Specific Settings chart (Chart 1) above, the only option for Flatbed Scanning is selecting the appropriate TWAIN driver that matches the scanner that is connected to the computer.

11.2.3.5 Acquire Imported Images

Digital images, documents, and photos may be acquired through the import of various file types in the Import window. The only import option is the user specified name and location of the file to import.

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11.2.4 Mount Window

The Mount function allows multiple images to be grouped together in a user specified arrangement similar to placing photographs in a cardboard mat that has multiple openings. Mounted images can be viewed, printed, exported, or otherwise manipulated together as one image. The images contained in the mount can also be viewed and manipulated individually. The user may create new mounts or edit existing mounts, including mounts used for auto-mounting, a function that automatically places newly acquired images into an existing mount.

Using the right-click menu on an image holder in the mount, the user is able to perform the following functions:

- Automatically assign a specific anatomical region to the image that is moved to that mount location
- Automatically assign specific keywords to the image that is moved to that mount location
- Change the image holder orientation from vertical to horizontal or from horizontal to vertical
- Automatically flip any image placed in that image holder
- Delete the image holder

Using the right-click menu on an image in an image holder, the user is able to perform the following functions:

- Open the image into the View window
- Place a copy of the mounted image in the area below the Mount box
- Copy the image to the clipboard
- Show or hide any annotations that have already been placed on the image
- Remove the image from the Mount

Additionally, basic image manipulation functionality is available via the Right Click Menu, including copying, archiving, exporting, assignment of an anatomical region, addition of keywords, image flip, rotation, viewing of properties, and printing.

11.2.5 Print

A predefined report that includes one or more images accompanied by patient, practice, and provider information will print. A sample of the report appears on the last page of this section.

11.2.6 View Window

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The View Window may be used to examine, manipulate, and place measurements and annotations on an image. The View Window provides the capability of manipulating multiple images at once. Various tools are available for use in the Viewer Window:

- Zoom
  Narrows or broadens the view of an image. Zooming in (enlarging) focuses on a specific area of an image that has been enlarged. Zooming out (reducing the size of an enlarged image) broadens the view until the image is returned to its original size.

- Full Screen
  Fills the Viewer Window with the selected image.

- Reset Zoom
  Resets the image to its original size.

- Rotate
  Allows the image to be turned by either 90° or 180° at a time.

- Flip
  Allows flipping of the image, either left-to-right or top-to-bottom.

- Reset Orientation
  Returns the image to the original orientation.

- Automatically Arrange Images
  Places images in the View window in the position they occupied when the View window was originally opened.

- Manually Arrange Images
  Allows images to be manually moved to any position in the View window. Also allows the image size to be manually adjusted.

- Measure
  Allows the measurement of the distance between points or the angle between intersecting lines. For some devices, calibration is required before measurements are made. Measurement lines may remain on the image and be displayed, may remain on the image and be hidden from sight, or may be deleted.

- Annotate
  Provides tools with which to add, edit or delete annotations on the image, including text, shapes, lines, arrows, freehand drawing, and options to customize each of these including size, font, and color.

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Annotations may remain on the image and be displayed, may remain on the image and be hidden from sight, or may be deleted.

- Magnifying Glass
  Permits closer visual inspection of a particular region of an image using different-sized areas and shapes of magnification, different magnification amounts, and the application of effects such as increased contrast, inversion, or colorization.

- Print Image
  Opens the Microsoft Print window in order to print the image in a pre-setup report that includes the image plus some patient, provider and practice information.

- Negate
  Converts image areas that are black to white, and areas that are white to black.

- Colorize Image
  Substitutes colors for grayscale values in an image.

- Pseudo 3D
  Applies a 3-D effect to the image.

- Sharpen Image Edges
  Increases contrast on edges in the image, causing the edges to be more easily seen.

- Reset Original Image
  Resets the image to its original state when the View Window was opened.

- Remove From Viewer
  Removes the image from the View window. This function does not delete the image from Visix Imaging.

- Brightness and Contrast
  Changes the brightness and contrast levels of the image.

- Gray Shift (Gamma) Slide Bar
  Leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker.

11.2.7 Adaptive Image Processing (AIP) / Auto-Optimize

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Flatbed scanners cannot properly interpret what should be pure white or pure black, since the film being scanned is not completely transparent or opaque in these areas. Auto-Optimize, the flatbed scanner version of AIP, takes the lightest white and makes it pure white, and the darkest black and makes it pure back. It then adjusts the grayscale values of the image to fall between those values, increasing the sharpness of the image and using a full 8-bit grayscale that would otherwise be lost by the scanner.

For x-ray images, Adaptive Image Processing (AIP) takes into account the medical use of the image and removes unnecessary information to reduce the size of the image file. For example, Visix Imaging removes image information relating to the cheek in front of the teeth being x-rayed.

11.2.8 Dynamic Exposure Monitoring System (DEMS)

The Dynamic Exposure Monitoring System is an aid to the user in quickly identifying x-ray images that are of potentially lower quality than what the particular hardware is capable of acquiring. DEMS provides a green, yellow, or red light to indicate the amount of data made available by the acquisition device to render the object being imaged. The amount of data (measured in terms of bits) required to meet the criteria for determining these status colors is specific to each hardware device supported by Visix Imaging based on input from the hardware device manufacturer and testing. Should the image data obtained from a device contain fewer bits of information than desired for a quality image, the software displays a yellow or red light that prompts the user to check the image and possibly retry image acquisition. Each hardware device has threshold bit levels set by default on installation, and users are advised not to change these values without consulting a Visix Imaging representative.

The DEMS system of indicator lights is not intended to serve as a diagnostic tool, but rather provide a quick visual to the user that an image may need to be retaken. Threshold values affect how many warnings a user may receive during image acquisition; higher thresholds will require higher quality images that may prompt the user to reacquire images more frequently. Lower thresholds may not prompt the user to reacquire an image frequently enough.

Whether prompted or not, the user makes the decision to accept the image or change the x-ray hardware settings and reacquire the image.

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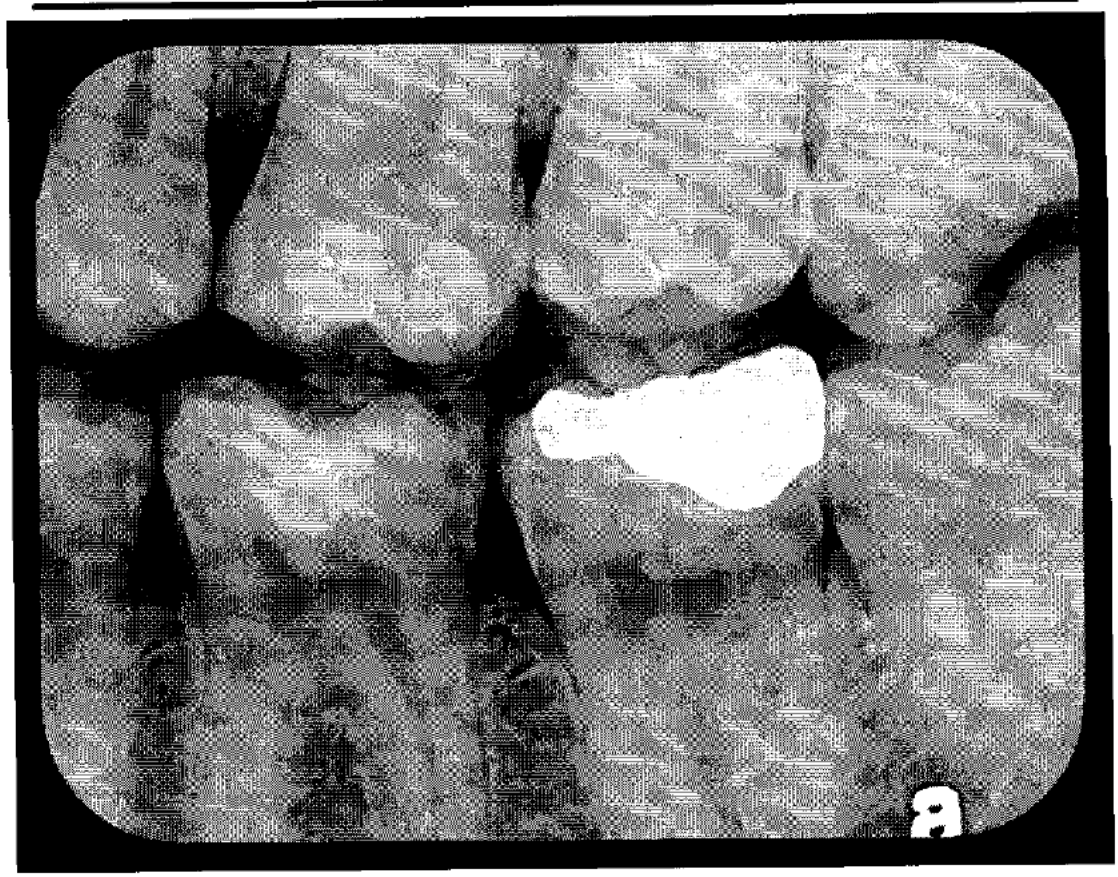
(1) Image Report

(b)(4) [redacted]

Visix Imaging



(b)(4), (b)(6) [redacted]

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SUBSTANTIAL EQUIVALENCE AND PREDICATE COMPARISON

Visix Imaging is substantially equivalent to the following predicate devices:

Manufacturer	Product Name	510(k) No.
Televere Systems	TigerView Professional	K061035
Tau Corp. (Televere Systems)	TigerScan/TigerView	K955237
EagleSoft	EagleSoft ChairSide Software Application	K982422

This conclusion is based on the following aspects:

Indications for Use:

Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.

Technological Comparison:

Visix Imaging, TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS). Visix Imaging is compatible with similar types of hardware devices (e.g. scanners, digital video camera, etc.) and has similar options for displaying, editing, and printing images as the predicate devices.

A more detailed comparison of the features and performance of these devices is provided in the following table.

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Indications for Use	Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images, plus store clinical notes in the form of annotations and measurements,	TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data. It is intended for use by radiologists, clinicians, and physicians to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store,	Uses of TigerScan and TigerView in the dental industry include the following: - Scanning of film and archival storage for on-line access by patient - Electronic transmission of digital radiographs with insurance claims. - Radiograph viewing and manipulation for diagnostic purposes, patient education and consultation, and insurance claims adjudication. - Electronic transmission	EagleSoft's ChairSide is a clinical software program that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audio recordings, and clinical exam data. In addition, it also offers an imaging module for image acquisition, editing, and storage of digital images. It is designed to be a single-source solution for a dentist's software needs for clinical and diagnostic use when serving the general public. Images can be acquired from standard dental imaging devices including Digital Radiographic Devices, Digital Video Capture Devices, and Generic Image

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
	using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.	print, and distribute images using standard PC hardware.	of radiographs to specialists for consultation.	Devices such as scanners. Non-diagnostic images can then be edited (i.e. resized, contrast, cropped, etc.). Images can also be easily imported and exported.
Patient/Image Management	Yes	Yes	Yes	Yes
Acquire Images				
X-ray (i.e., Phosphor Plate, Digital Sensor, Digital Panaromic)	Yes	Yes	Yes	Yes
Fluorescence Detection	Yes	No	No	No

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Video	Yes	Yes	No	Yes
Photos	Yes	Yes	No	Yes
Documents	Yes	Yes	No	Yes
Import	Yes	Yes	Yes	Yes
Display Images	Yes	Yes	Yes	Yes
Save/Store Images	Yes	Yes	Yes	Yes
Produce Reports	Yes	Yes	Yes	Yes
Print/Export Images	Yes	Yes	Yes	Yes

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Enhance Images:				
Brightness	Yes	Yes	Yes	Yes
Contrast	Yes	Yes	Yes	Yes
Colorize	Yes	Yes	Yes	Yes
Crop	No	Yes	Yes	Yes
Rotate	Yes	Yes	Yes	Yes
Zoom In/Out	Yes	Yes	Yes	Yes
Invert	Yes	Yes	Yes	Yes
Sharpen	Yes	Yes	Yes	Yes
Measure	Yes	Yes	Yes	Yes
Over/Under	Yes	Yes	Yes	Yes

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Parameters	Visix Imaging Televere Systems	TigerView Professional Televere Systems K061035	TigerScan/TigerView Tau Corp. K955237	EagleSoft ChairSide Software Application EagleSoft, A Patterson Co. K982422
Exposure Annotate	Yes	Yes	Yes	Yes
Run on standard PC-compatible computers	Yes	Yes	Yes	Yes

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PRODUCT LABELING

The labeling for the proposed device, Visix Imaging, follows this page. The labeling includes:

Part 1 This document, 1 page
Part 2 Visix Imaging Manual, 157 pages
Part 3 Visix Imaging Administration Manual, 27 pages
Part 4 Visix Imaging CD label, 1 page
Part 5 A web site about Visix Imaging with the documents printed from that web site, 22 pages
Part 6 A Visix Imaging marketing document, 1 page

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Perfecting Your Practice...

Visix Imaging Manual

Dental Imaging Software

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Indications for Use

Visix is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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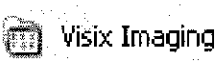
How To Open Visix

On your desktop, double click on the Visix icon.

Or

On your desktop, click on the Start button

Go to All Programs

Select Visix Imaging 

Then select Visix again.

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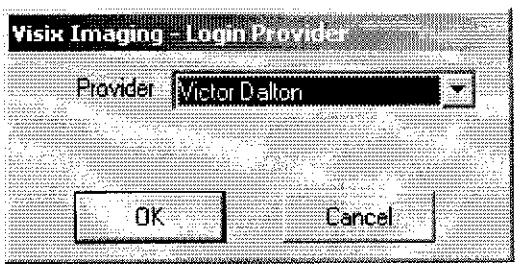
Select a Provider

The first Visix window that opens is the Select Provider Window.



A provider is a doctor. If the name that displays is the correct provider click on the Login button. Otherwise, click on the Provider down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, click on the cancel button to exit Visix then open Visix Administration and enter a new provider. For instructions on how to use Visix Administration, please refer to the Visix Administration manual.

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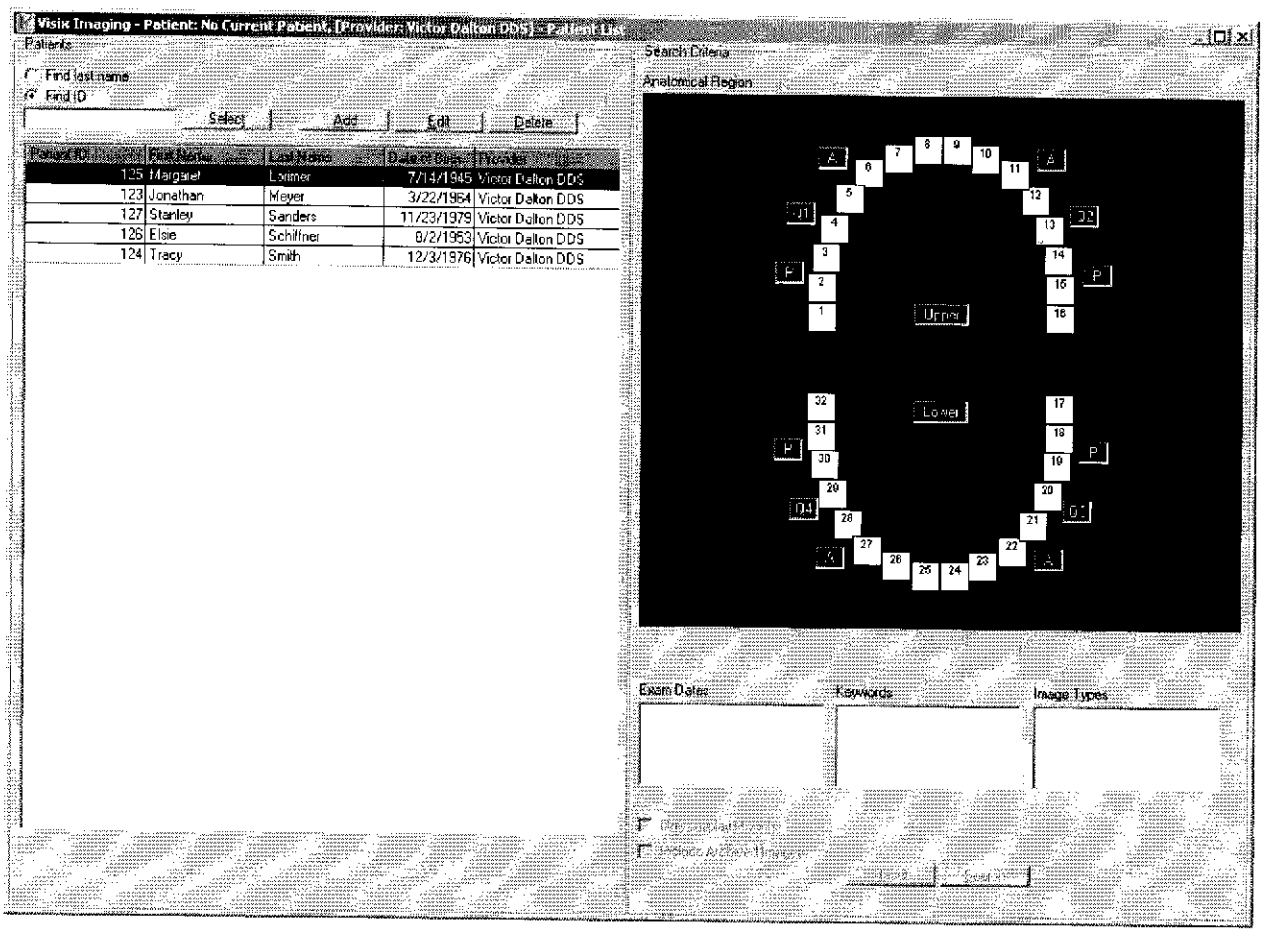
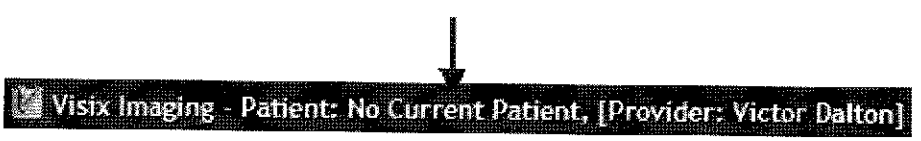
Patients Window



The Patient window is broken up into two sections: a Patients area where a patient is selected, added, deleted, or has his information edited, and a Search Criteria area which is used to locate specific images.

Patients Area

The Patient window initially opens without a patient selected. Notice on the top bar of the window where the provider, Visix icon, and Visix name display, the message "No Current Patient" also displays.



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After a patient is selected the patient's name will display here.

Always check this area of the screen to make sure that the correct patient is selected before starting an activity in Visix.

Display Existing Patients

Patients

Find last name
Find ID

Select | Add | Edit | Delete

Patient List →

Patient ID	First Name	Last Name	Date of Birth	Provider
125	Margaret	Lorimer	7/14/1945	Victor Dalton
123	Jonathan	Meyer	3/22/1964	Victor Dalton
127	Stanley	Sanders	11/23/1979	Victor Dalton
126	Elsie	Schiffner	8/2/1953	Victor Dalton
124	Tracy	Smith	12/3/1976	Victor Dalton

In the Patient List inside Visix, patients are listed in alphabetical order by last name.

Find a Patient

Click on the Find Last Name radio button to find patients by their last name, or on the Find ID radio button to find patients by their ID, then enter either the patient's last name or ID into the Find Patient box.

Patients

Find last name
Find ID

Find Patient box →

As information is entered into the Find Patient box, Visix will advance through the list of patients, moving to the first patient whose last name or ID is the same as the entry in the Find Patient box.

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Patients

Find last name
Find ID

m | Select | Add | Edit | Delete

Patient ID	First Name	Last Name	Date of Birth	Provider
125	Margaret	Lorimer	7/14/1945	Victor Dalton
128	Lauren	Mainner	2/15/1958	Victor Dalton
123	Jonathan	Meyer	3/22/1964	Victor Dalton
127	Stanley	Sanders	11/23/1979	Victor Dalton
126	Elsie	Schiffner	8/2/1953	Victor Dalton
124	Tracy	Smith	12/3/1976	Victor Dalton

In the example above, the patient is being found by their last name and the letter "m" was entered into the Find Patient box. Visix moved to the first patient in the Visix Patient List whose last name begins with the letter "m".

Patients

Find last name
Find ID

me | Select | Add | Edit | Delete

Patient ID	First Name	Last Name	Date of Birth	Provider
125	Margaret	Lorimer	7/14/1945	Victor Dalton
128	Lauren	Mainner	2/15/1958	Victor Dalton
123	Jonathan	Meyer	3/22/1964	Victor Dalton
127	Stanley	Sanders	11/23/1979	Victor Dalton
126	Elsie	Schiffner	8/2/1953	Victor Dalton
124	Tracy	Smith	12/3/1976	Victor Dalton

In this second example, the letters "me" were entered into the Find Patient box. Visix moved past "Mainner" whose second letter is an "a" to "Meyer" whose second letter is an "e" which matches the Find Patient criteria.

Select a Patient

To select a patient, double click anywhere on the patient's information in the patient list (Patient Name, ID, Date of Birth, or Provider) or click on the Select button. The patient's name will display in the top bar of the Visix window letting you know which patient has been selected.

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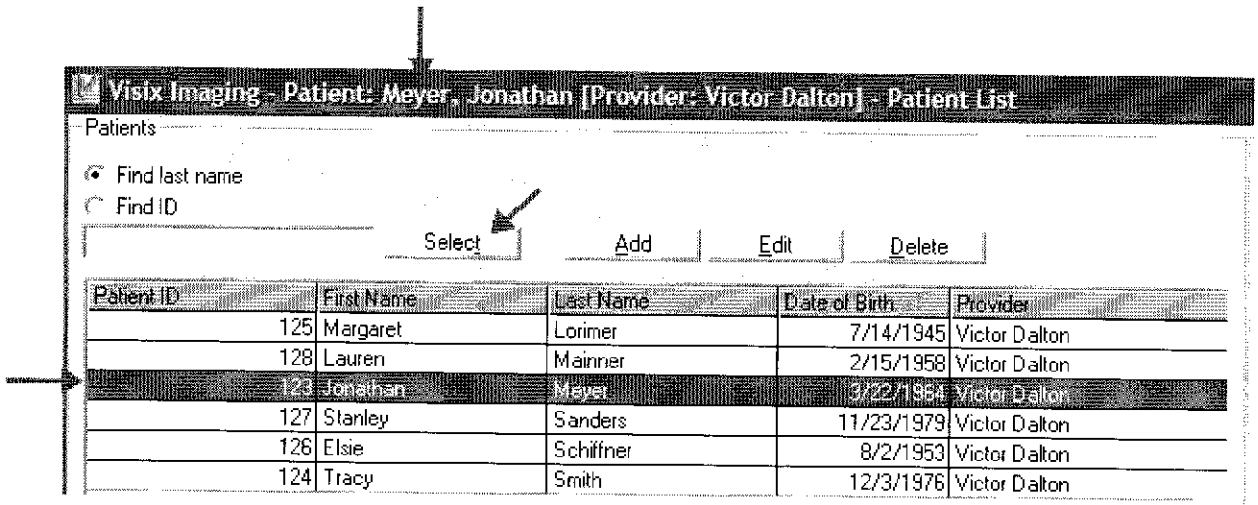
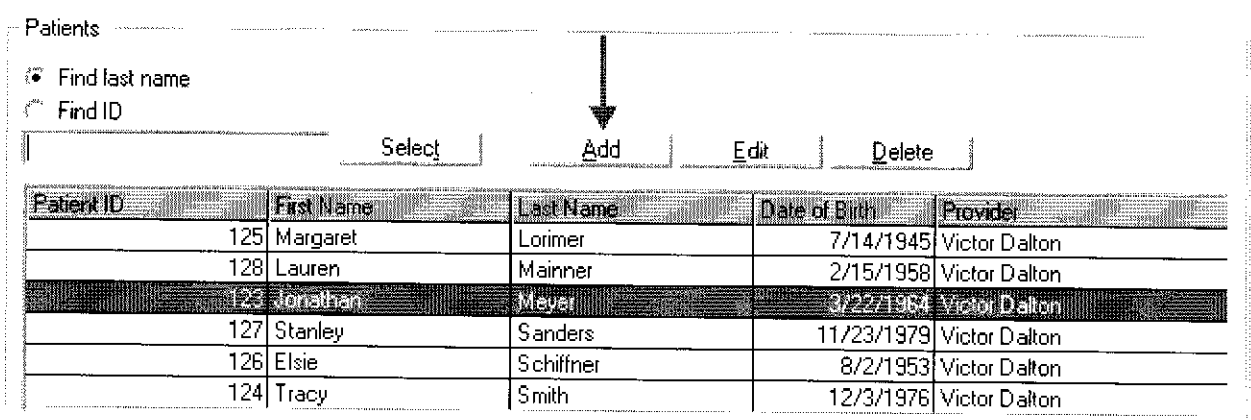


Once the patient has been selected, the main Visix window appears with the patient's images displayed on the right hand side in the Images window.

Add a Patient

To add a new patient, click on the Add button at the top of the Patients window.



The Add Patient window will display.

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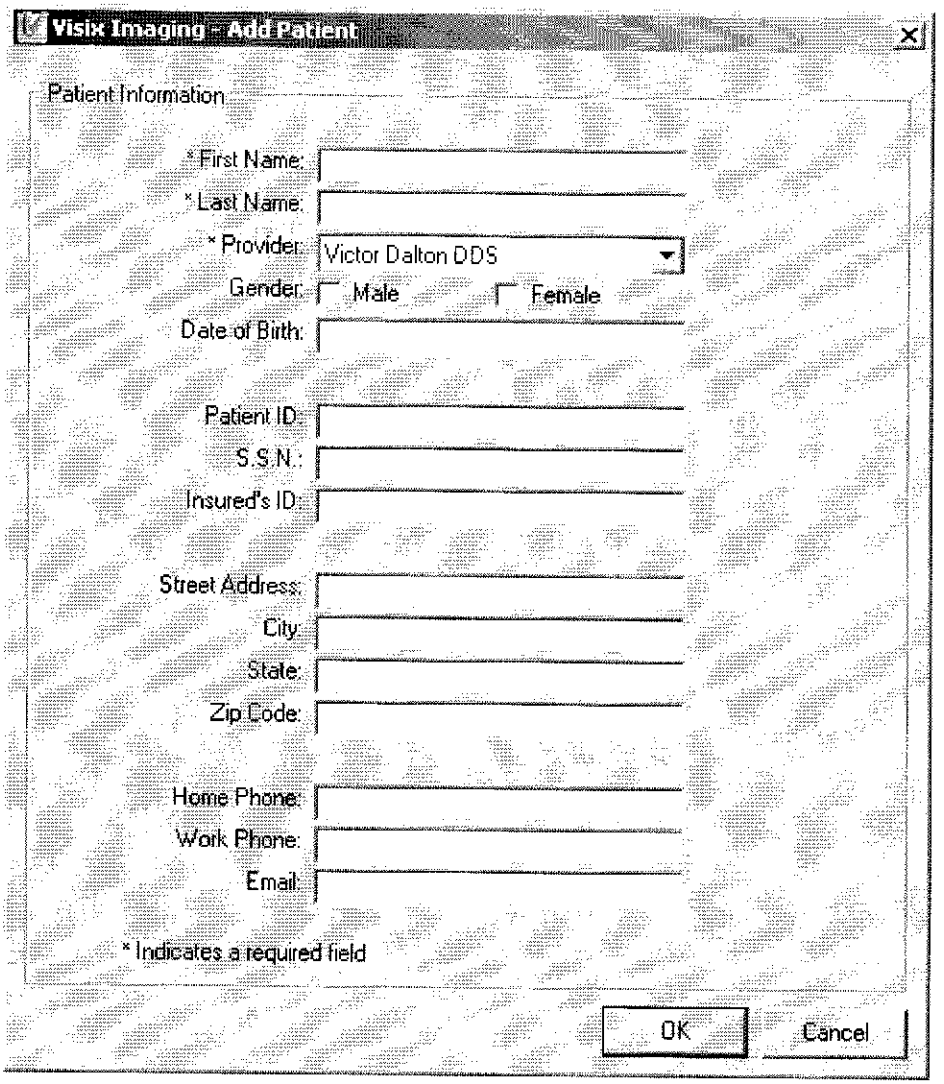

First Name

Enter the first name of the patient. This is required to save the record.

Last Name

Enter the last name of the patient. This is required to save the record.

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Provider

Select the correct provider from the drop down box. This is required to save the record.

Gender

Select Male or Female to specify the gender of the patient.

Date of Birth

Enter the date the patient was born. Include slashes as a separator and a four-digit year. (ex. 11/23/1985)

Patient ID

Enter the ID this patient will use in Visix.

S.S.N.

Enter the patient's Social Security Number. All X's can be substituted.

Insured's ID:

If applicable, enter the ID for the Insured party for the patient.

Street Address

Enter the street address of the patient.

City

Enter the city the patient lives in.

State

Enter the state the patient lives in.

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Zip Code

Enter the zip code the patient lives in.

Home Phone

Enter the home phone number of the patient. If you would like the phone number to display with separators for ease of viewing, such as dashes, enter them.

Work Phone

Enter the phone number where the patient works. If you would like the phone number to display with separators for ease of viewing, such as dashes, enter them.

Email

Enter the e-mail address the patient uses.

OK

Click on the OK button [OK] at the bottom of the Add New Patient window to save the patient record. The patient record can be saved at any point after the patient's name and providers' name have been entered. Once saved, the patient record will appear in its alphabetical position by last name.

Cancel

Click on the Cancel button [Cancel] at the bottom of the Add New Patient window to close the window without any further saving.

Edit a Patient

To change information in a patient record, left click once on the patient in the Patient List, and then click on the Edit button at the bottom of the Patients section of the Patients window.

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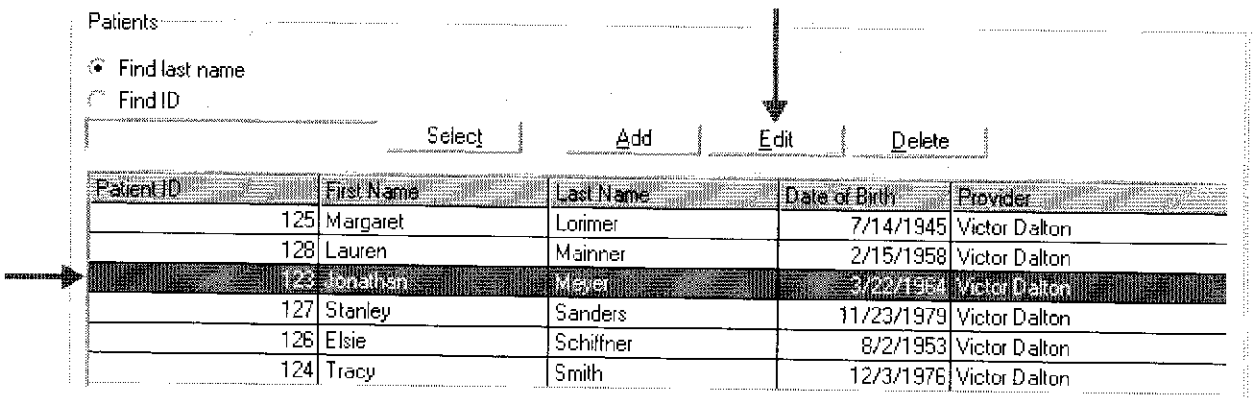
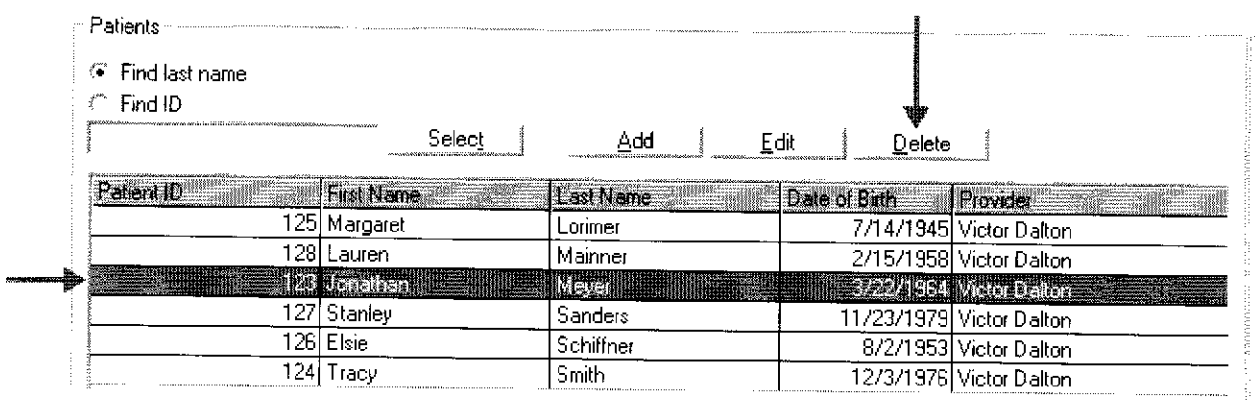


The Edit Patient Info window will display. The Edit Patient Info window contains the same information fields as the Add New Patient window. For an explanation of each entry please refer to the Add A Patient section of this manual.

Delete A Patient

To delete a patient, left click once on the patient in the Patient List, and then click on the Delete button at the bottom of the Patients section of the Patients window.



A window that asks if you are sure that you want to delete the patient and all of the patient's images will appear. Check the patient name at the top of the Visix window to make sure this is the correct patient before proceeding.

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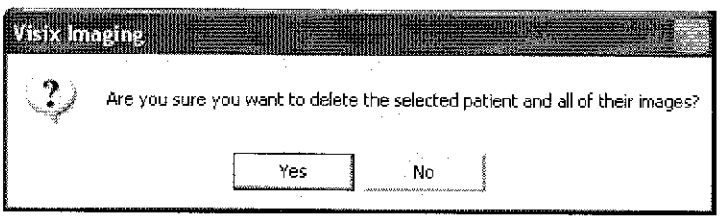

Click on yes if you are sure that you want to delete the currently selected patient with all of his or her images. Click on No if you are not sure.

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Search Criteria Area

The Search Criteria section of the Patient window is used to find a specific image, or group of images, from among a potentially large number of images.

The search decision involves the information that is displayed in the Anatomical Region, Exam Dates, Image Types, and Keywords list boxes in the Search Criteria section of the Patients window. Click on any information in each list box that can be used to narrow the image search.

The anatomical region diagram allows you to search for images that have the selected teeth displayed in the image. If any images have anatomical information specified, the Anatomical Region diagram will color the corresponding teeth green. To search for images of a specific tooth or teeth, click on the green teeth to turn them blue. To search for standard sets of teeth click on "A" for anterior, "P" for posterior, "Q1", "Q2", "Q3" and "Q4" buttons for a quadrant, and "Upper" and "Lower" buttons for all teeth in either the Upper or Lower Arch.

When "Only Display Mounts" is checked, clicking the Search button will filter out all single images and display only mount images.

Click on the Include Archived Images check box if there are any archived images that should also be searched.

Double-clicking on the patient's name in the Patient List will over-ride the search criteria and display all of the patient's images.

For example, referring to the Search Criteria window section pictured above, a search could be narrowed to only those images that have teeth with amalgam fillings where the x-ray was taken on 11/28/2006 or 12/7/2006 using a ScanX Phosphor Plate. To do this, the Amalgam Filling entry in the Keywords list box would be clicked on, the ScanX Phosphor Plate entry in the Image Types list box would be clicked on, and the 11/28/2006 and 12/7/2006 dates in the Exam Dates list box would be clicked on. When the Search button is then clicked, only those images that were of an Amalgam Filling that were taken on 11/28/2006 and 12/7/2006 using a ScanX would display.

The anatomical region for an image can be assigned using the Right Click Image Menu (see the Right Click On An Image section of this manual) or by assigning an anatomical region to a mount hole in the Mount window (see the Mount Window section of this manual).

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Keywords can be assigned to an image in the same ways the anatomical region can be assigned.

The information in the Exam Dates and Image Types list boxes in the Search Criteria area is automatically entered when the image is acquired.

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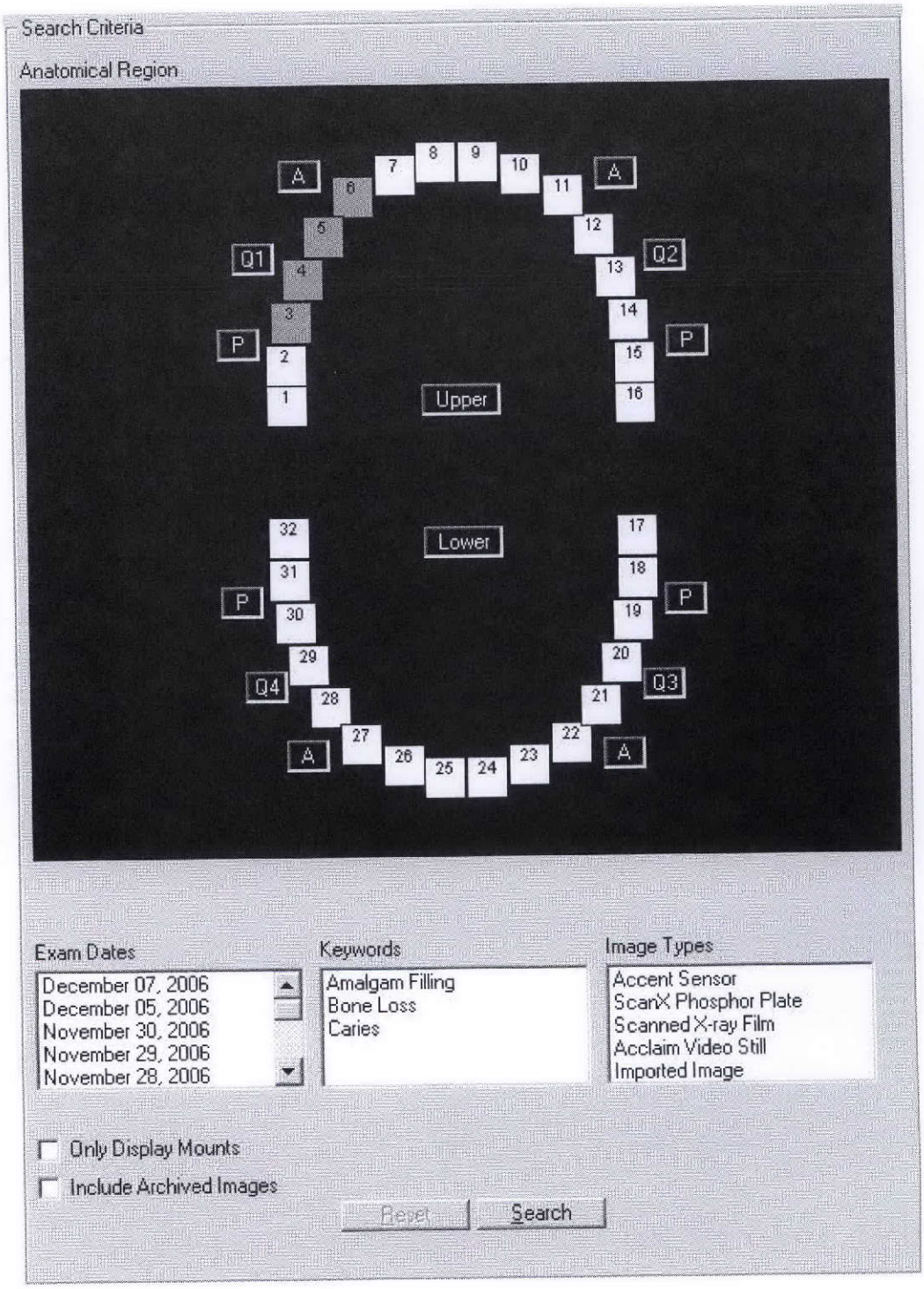
Patients Window



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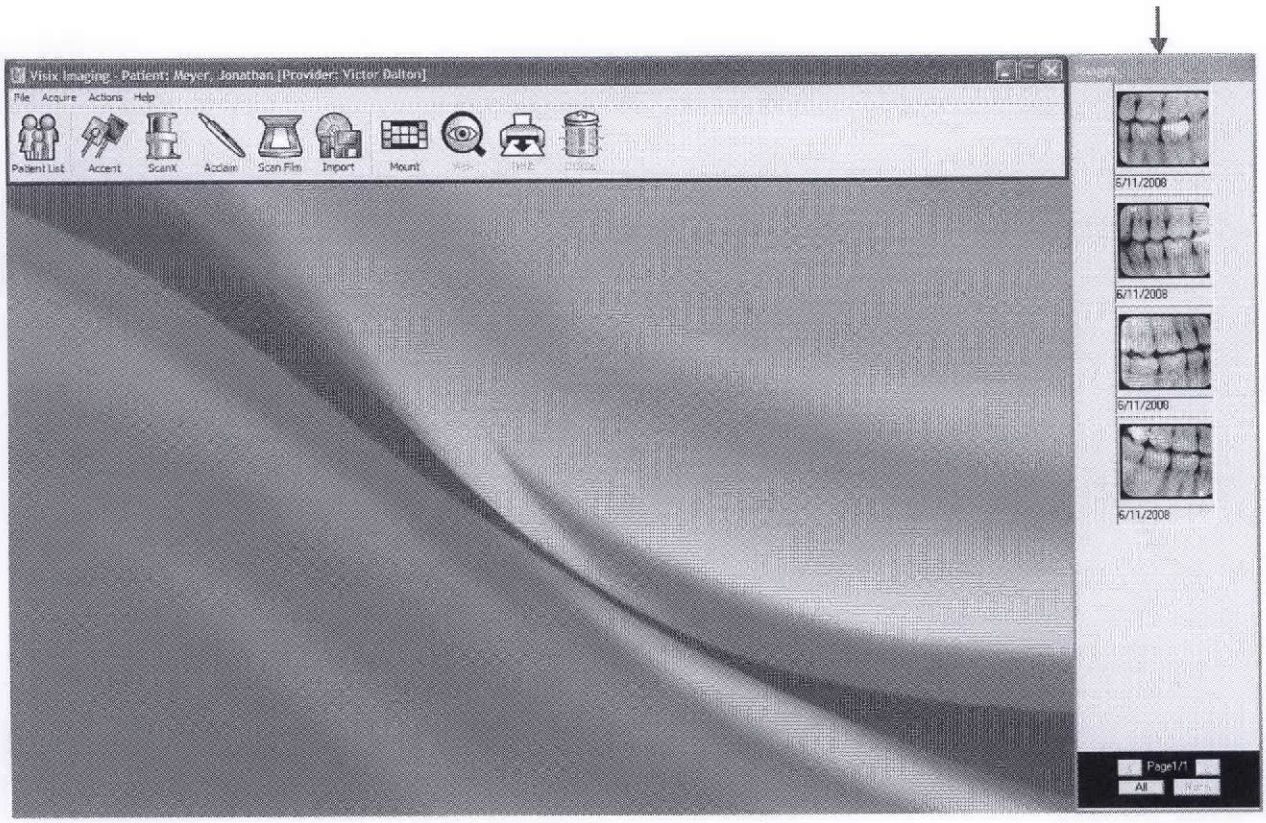
Images Window



The Images window is the vertical window on the right side of Visix. The images displayed on the Images window belong to the patient whose name appears at the top of the Visix window. To learn how to change patients see the Select A Patient section of this manual.

The images in the Image window will display based on their age. The newest images display first. Images can be deleted, exported, opened into the View window for viewing and manipulation, sent to the Mount window for viewing and mounting, or printed.

Select an Image

To manipulate an image in any fashion the image must be selected first.

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images, click on the All button at the bottom of the Images window.

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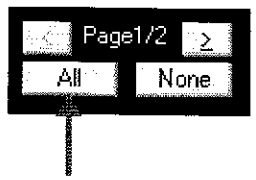
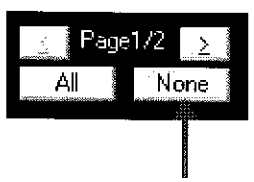


Deselect an Image

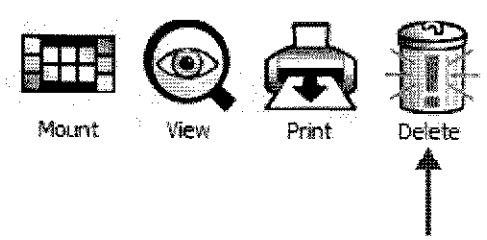
To deselect an image, click on it again. To deselect all of the selected images, click on the None button at the bottom of the Images window.



Delete an Image

To delete an image, first select the image or images to be deleted, and then perform ONE of the following steps:

- Click on the Delete button on the top Visix toolbar.



- Right click on one of the selected images and select Delete from the Right Click Menu that appears.

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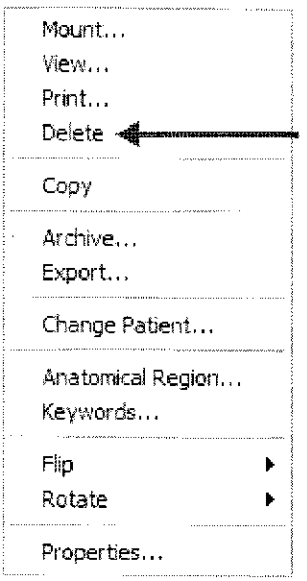
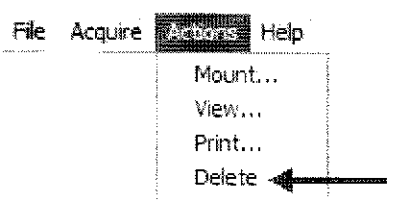
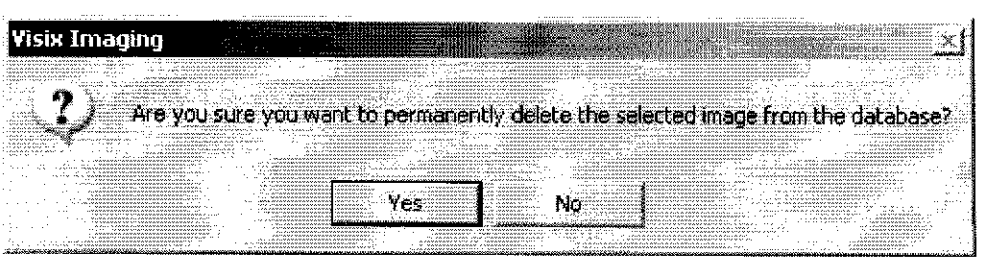


- Click on the Actions Menu on the top Visix toolbar and then select Delete from the drop down menu that appears.



Once the delete option is selected, the following window will open:



Note: If the Yes button is clicked, the image will be deleted. A deleted image is NOT recoverable.

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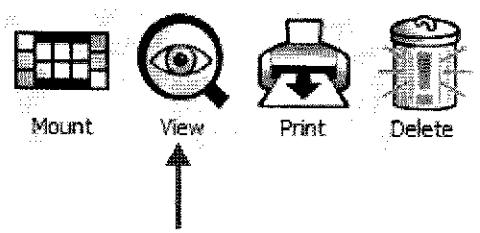
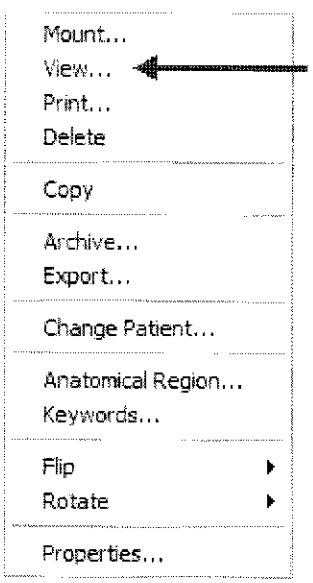
View an Image

A single image may be opened in the View window by left clicking twice on it. To open multiple images in the View window, first select the image or images to be viewed, and then perform ONE of the following steps:

- Click on the View button on the top Visix toolbar.



- Right click on one of the selected images and select View from the Right Click Menu that appears.



- Click on the Actions Menu on the top Visix toolbar and then select View from the drop down menu that appears.

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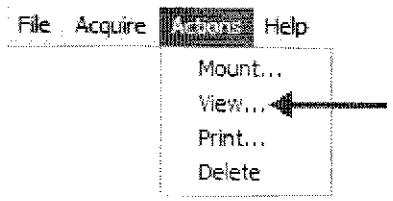
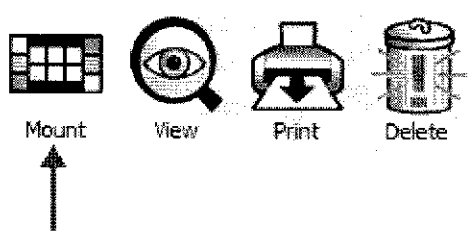


For instructions on how to use the View window, please refer to the View Window section of this manual.

Mount an image

To mount an image or work with an already created mount, click on the mount and/or images that are needed then perform ONE of the following steps:

- Click on the Mount button on the top Visix toolbar.



- Right click on one of the selected images and select Mount from the Right Click Menu that appears.

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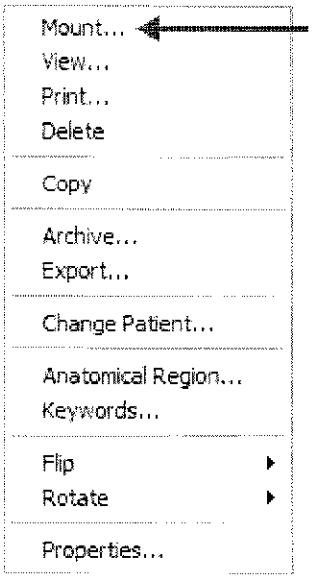
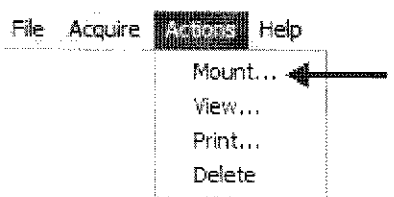


- Click on the Actions Menu on the top Visix toolbar and then select Mount from the drop down menu that appears.



For instructions on how to use the Mount window, please refer to the Mount Window section of this manual.

Print an Image

To print an image in a report, click on the image or images that need to be included then perform ONE of the following steps:

- Click on the Print button on the top Visix toolbar.

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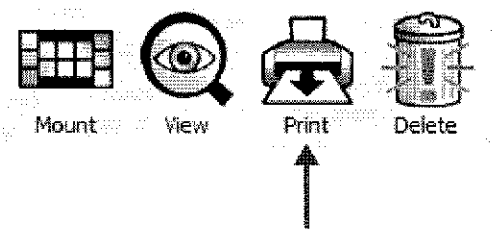
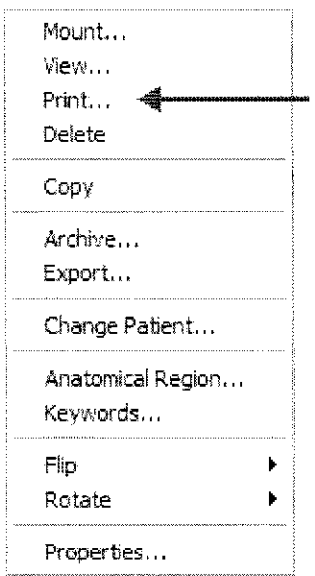
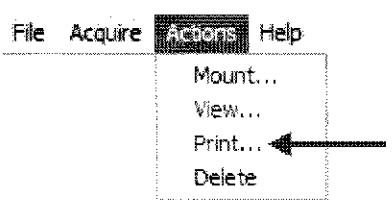


- Right click on one of the selected images and select Print from the Right Click Menu that appears.



- Click on the Actions Menu on the top Visix toolbar and then select Print from the drop down menu that appears.



The Windows Print window will open to allow the user to select the printer to send the report to, the number of copies to print, etc. The report that prints will display patient, doctor and practice information in addition to the selected images.

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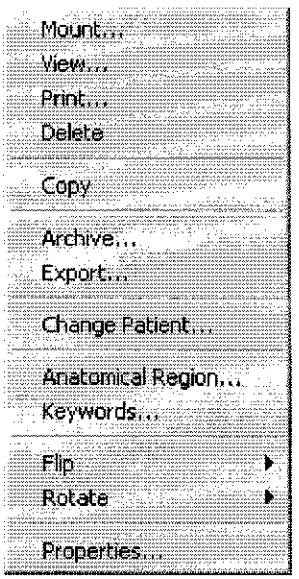
Right Click on an Image Menu

When you right click on an image the Right Click Menu will appear:



Mount

The selected images will be opened in the Mount window. For instructions on how to use the Mount window, please refer to the Mount Window section of this manual.

View

The selected images will display in the View window. For instructions on how to use the View window, please refer to the View Window section of this manual.

Print

The selected image or images will be printed along with the patient's name, ID, gender, and date of birth, the provider's name and phone number, the practice name, address and phone number and the date the image was taken.

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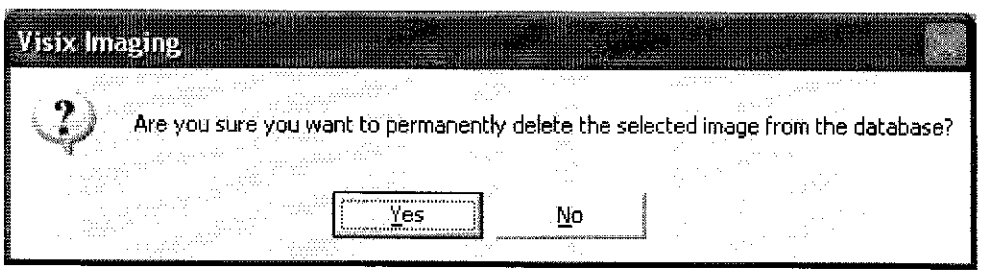
Delete

When Delete is selected the following window will display:

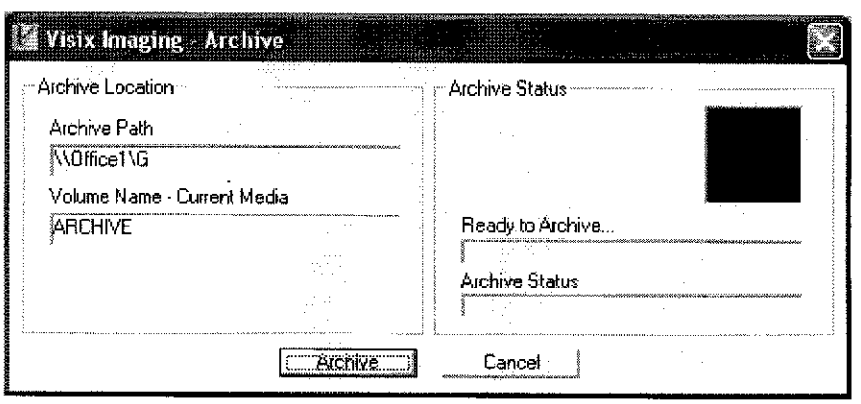


Click on Yes to remove the image from Visix. Click on No to cancel the delete. A deleted image can not be recovered.

Copy

The selected image will be copied to the clipboard. The image can then be pasted into another program that uses the clipboard such as Microsoft Word.

Archive



When an image is archived, the full size image is removed from Visix and placed in the archive location specified in Visix Administration. The thumbnail version of the image remains in Visix. The thumbnail version will not open in the View window. To restore an archived image, right click on the thumbnail version and select Restore.

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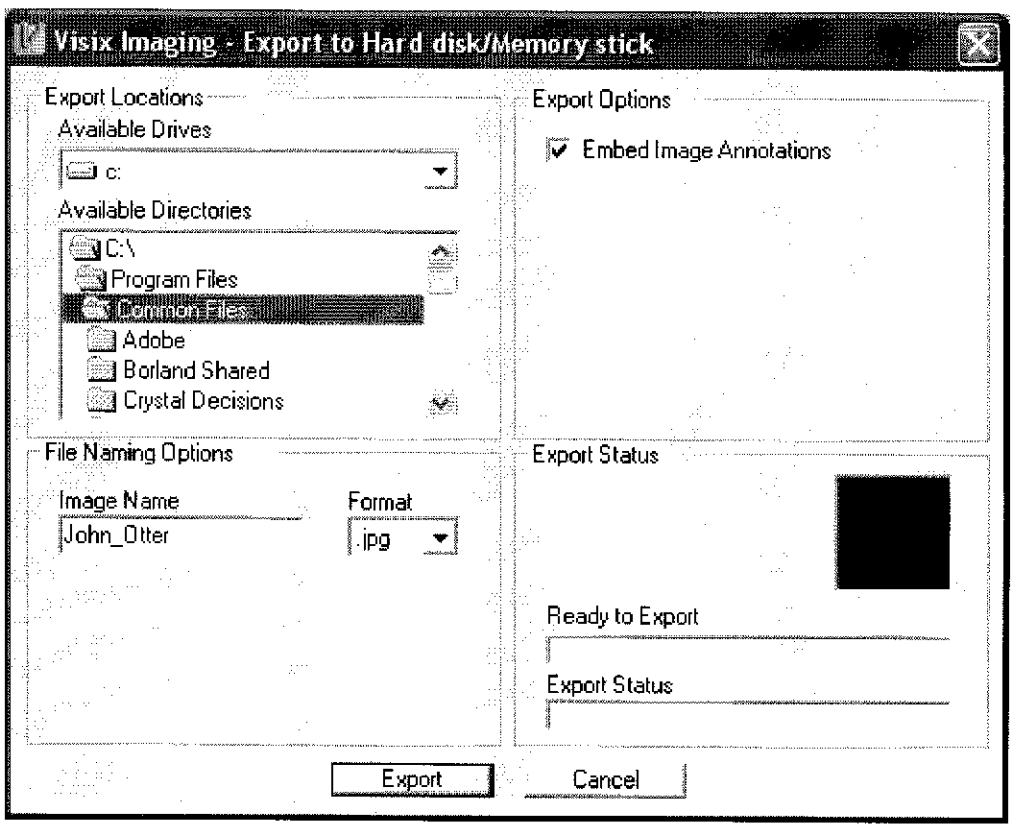
Export

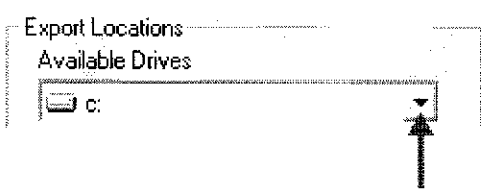
Exporting is the process by which an image is copied from within Visix to a file outside of Visix. When Export is selected the following window will display:

Export to Hard disk/Memory stick:



Export Location - Available Drives

To export the image to a hard drive or memory stick that is accessible by this computer, click on the Available Drives down arrow then select the drive from those displayed.



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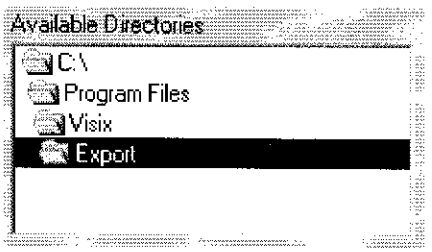
Export Location – Available Directories

The directories (also known as folders) within the selected drive will display. Double click on a folder to display any folders that might be within it.



Select the directory (folder) to copy the export file to.

File Naming Options

The default name for the exported file is the patient's name.

If multiple images are exported at the same time, a number that increases by 1 for each exported image will follow the image name. For example:

John_Smith1.jpg
John_Smith2.jpg
John_Smith3.jpg

Export Options

Click on Embed Image Annotations to place a check in the checkbox if the annotations on this image should be included with the exported image.

Export

Click on the Export button to export the file.

Change Patient (Move Images From One Patient To Another)

The ability to move an image from one patient to another patient is available only from the Right Click Image Menu.

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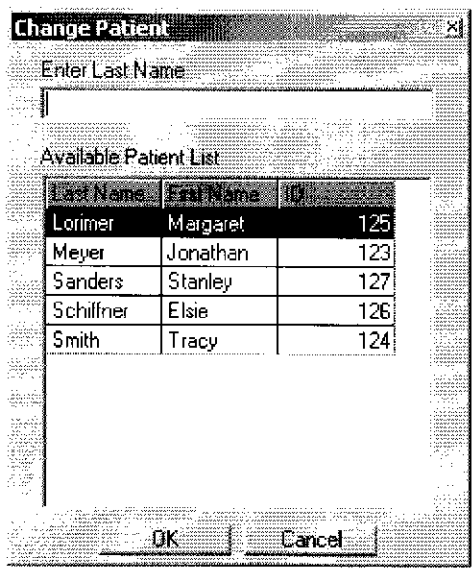
To move an image from one patient to another, perform the following steps:

- Open the patient the image was incorrectly saved to
- Right click on the image to open the Right Click Menu
- Select Change Patient. The Change Patient window will open.



- Double left click on the name of the patient who should have received the image, or type in the last name of the patient who should have received the image for Visix to locate it for you
- Click on the OK button.

Anatomical Region

When Anatomical Region is selected the following window will display:

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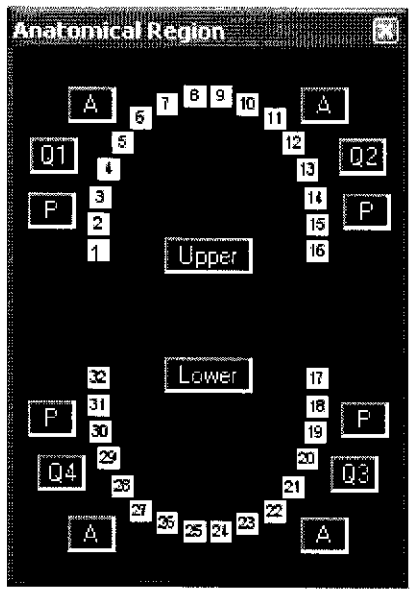

This is identical to the Anatomical Region section of the Patient Window. Select the teeth in the diagram that correspond with the teeth in the image by clicking on them. Clicking on "A", "P", "Q1", "Q2", "Q3", "Q4", "Upper" or "Lower" will select sets of teeth. Individual teeth can be selected by left clicking on each individual tooth. Clicking on selected teeth will un-select them. Changes to this window are saved when the window's close button ☒ is clicked.

Saving the anatomical region allows this image to appear (or not appear) in response to a search by anatomical region. The search is performed on the Patient Window.

Keywords

When Keywords is selected the Keywords window will display:

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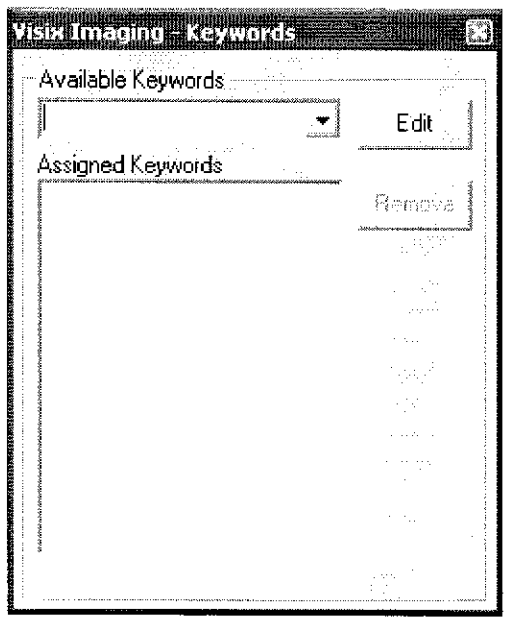
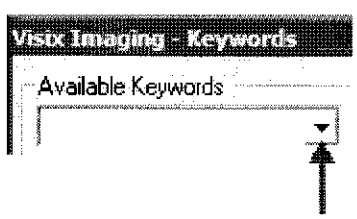


The Keywords window allows two actions:

- Keywords can be added or deleted from the main Keywords List that supplies keywords to all of the images in Visix.
- Specific Keywords can be associated with the currently selected image

Add Keywords to the Main Keyword List

To add or delete Keywords from the main Keywords List, click on the Edit button on the right of the Available Keywords drop down box.



The following window will display:

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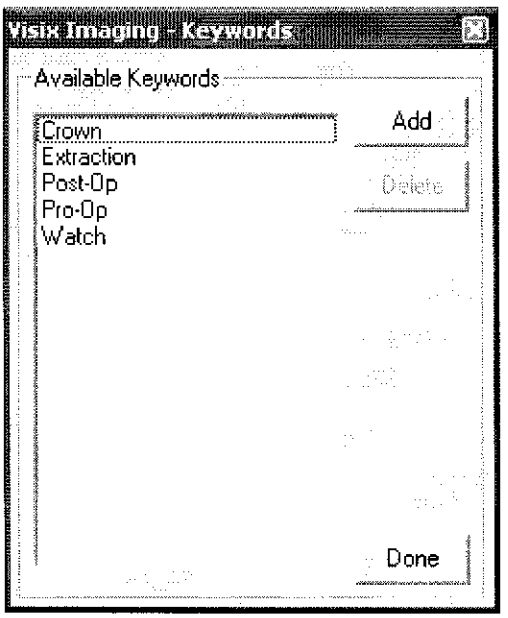
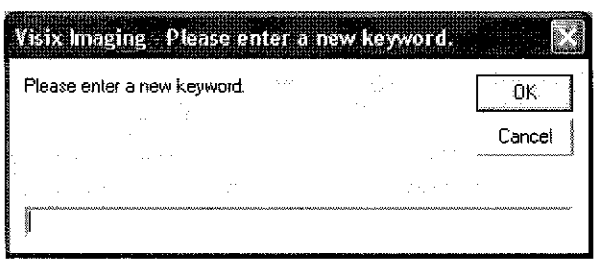


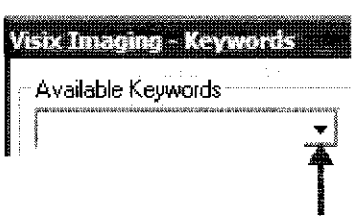
To Add a Keyword, click on the Add button at the top of the window then enter the keyword into the New Keyword window. Click on the OK button to save the new keyword.



Click on the Done button to close the Add Keyword window.

Assign a Keyword to an Image

To assign a keyword to a selected image, click on the down arrow of the Available Keywords drop down box



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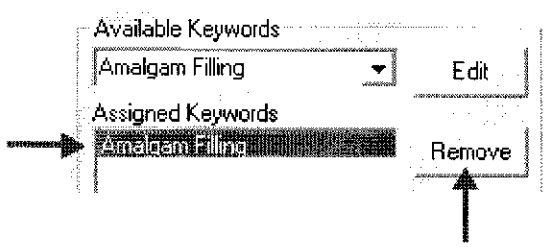
then select the keyword. The keyword must exist in the Main Keyword List before it can be assigned to an image.

Multiple Keywords can be assigned to an image. When all of the applicable Keywords have been assigned to the image, click on the window's Close button ☒ to close the Keywords window. Note: If the keyword to assign does not appear in the drop down box, add the keyword to the main Keyword List following the Add Keywords To The Main Keyword List instructions above.

Remove a Keyword from an Image

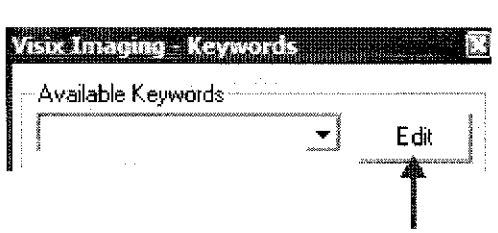
To Remove a Keyword that was assigned to an image, click on the Keyword then click the Remove Button.



When finished, click on the window's Close button ☒ to close the Keywords window.

Delete a Keyword from the Main Keyword List

To Delete a Keyword from the Main Keyword List, click on the Edit button on the Keyword window.



In the window that opens click on the Keyword to delete, and then click on the Delete button.

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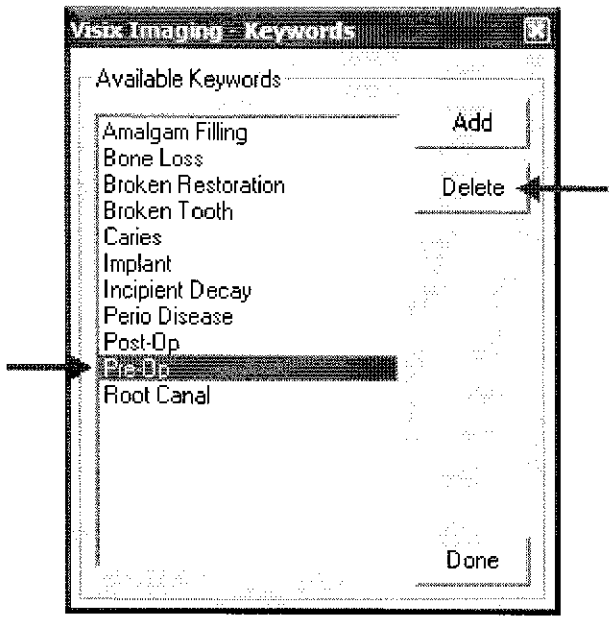

Click on the Done button to close the Edit Keywords window then on the window's Close button ☒ to close the main Keywords window.

Flip

When Flip is selected the following window will display:

Left/Right

Selecting Left/Right will create a horizontally mirrored image. What was on the left side of the image will now be on the right side, and what was on the right side of the image will now be on the left side.

Top/Bottom

Selecting Top/Bottom will create a vertically mirrored image. What was on the top of the image will now be on the bottom, and what was on the bottom of the image will now be on the top.

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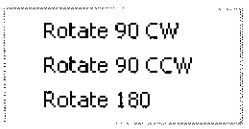
Rotate

When Rotate is selected the following window will display:



Rotate 90 CW

Selecting Rotate 90 CW will cause the selected image to turn 90 degrees clockwise (CW).

Rotate 90 CCW

Selecting Rotate 90 CCW will cause the selected image to turn 90 degrees counter clockwise (CCW).

Rotate 180

Selecting Rotate 180 will cause the selected image to turn 180 degrees.

Properties

When Properties is selected the following window will display:

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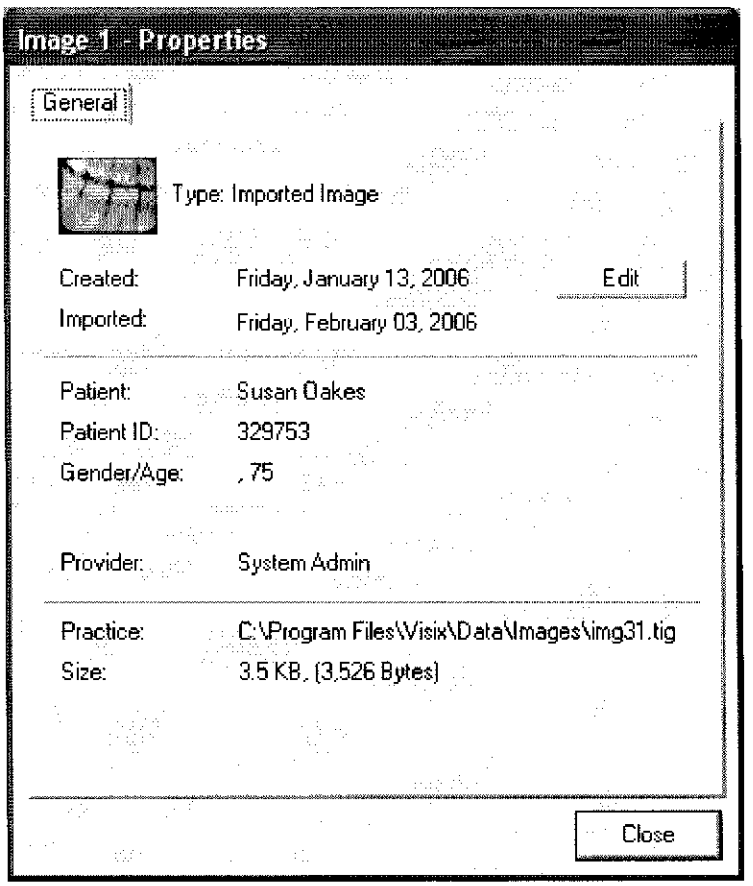

The information displayed on the General tab includes the type of equipment used to capture the currently selected image, the name, ID, gender, and age of the patient the image was taken of, the name of the provider for this patient, the date the image was acquired, where the image is stored, what the stored image is called, and how large the image is.

Change the Created Date for Images acquired from a flatbed scanner or imported

If the image was acquired from a flatbed scanner or imported, an Edit button Edit... will appear on the Properties window that will allow the Created Date for the image to be changed.

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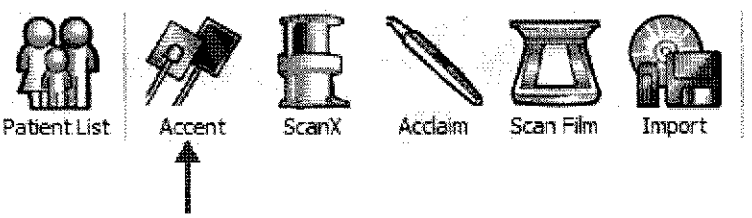
Acquisition Windows

Accent Sensor

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

Accent Acquisition Window

Click on the Accent button on the Visix toolbar to open the Accent Acquisition window.



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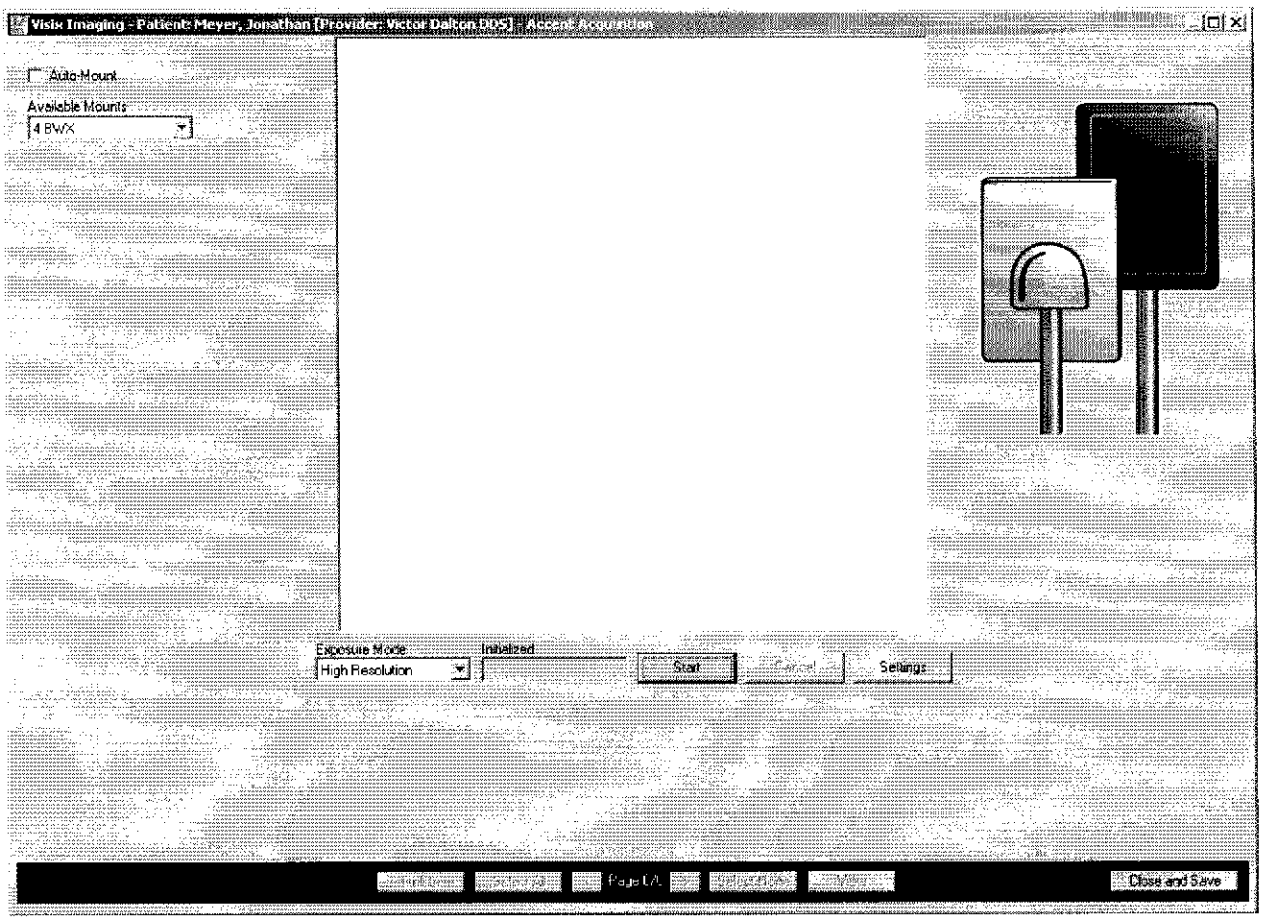

Acquiring Images from an Accent Sensor

When the Accent Acquisition window opens, the status bar will flash and then change to a solid green. This indicates the sensor has been initialized and is ready to acquire images.

Settings Button for an Accent Sensor

The Settings button will display windows that hold optional settings for the sensor that is connected to this computer. These settings are advanced and will apply to <u>all</u> of the future images acquired by this sensor.

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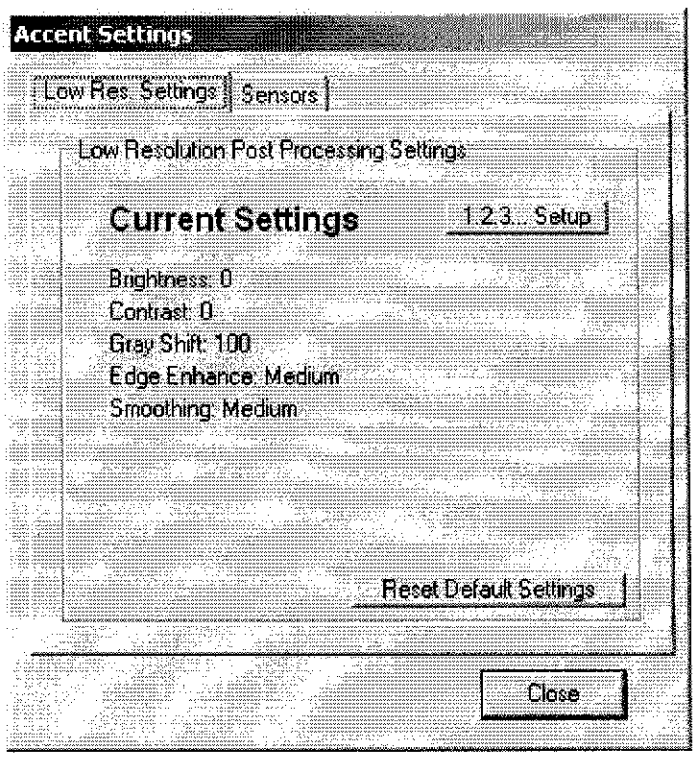
Settings Button – Low Res. Settings – Accent sensor



The current settings for the Accent sensor are displayed in the center of the Settings window under the heading "Current Settings". The settings for a low-resolution image will display if the last image taken was a low-resolution image. The settings for a high-resolution image will display if the last image taken was a high-resolution image.

1, 2, 3... Setup is a tool that will help obtain the best image quality possible. Click on the 1.2.3...Setup button to change the Brightness, Contrast, Gray Shift, Edge Enhancement, or Smoothing settings for future low-resolution or high-resolution images taken by this sensor. At least one image must be acquired before using the 1, 2, 3...Setup tool.

Clicking on the Reset Default Settings button [Reset Default Settings] will change the settings back to the original settings Visix came with.

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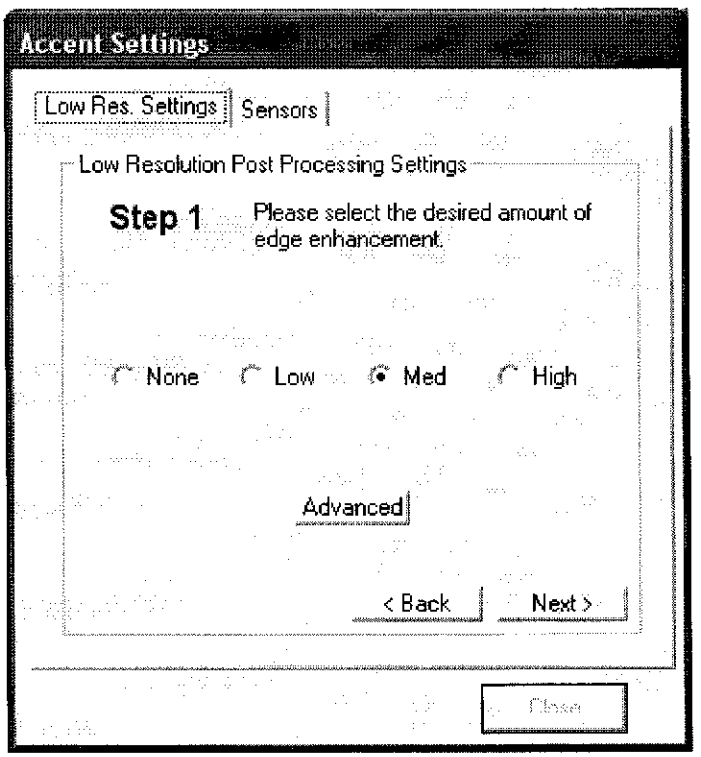
Settings Button – Accent sensor



1, 2, 3... Setup Step 1

Click on the amount of Edge Enhancement desired. Edge Enhancement will make the first few pixels on the dark side of an edge darker and the first few pixels on the white side of an edge whiter. This causes more contrast at the edges, which makes the edges more defined, giving them a sharper look.

As the level of Edge Enhancement is changed, the change is reflected on the last image that was acquired, allowing the user to decide the amount of Edge Enhancement that is appropriate.

The Advanced button should only be accessed by trained service personal. Changing its values may adversely affect image quality.

Click on the Back button to exit out of the 1, 2, 3...Setup tool. Click on the Next button to advance to the Step 2 window.

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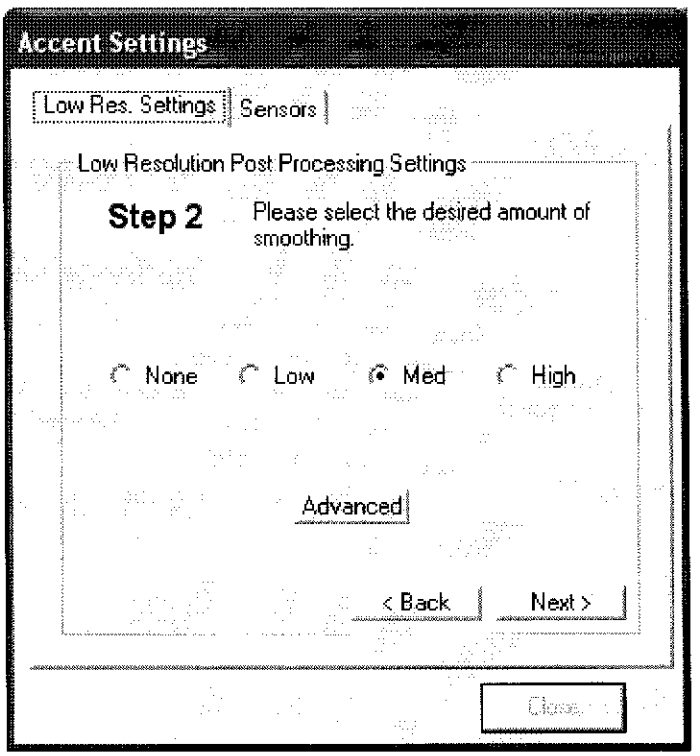
1, 2, 3... Setup Step 2



Click on the amount of Smoothing to apply to all future Low Resolution or High Resolution images. Smoothing attempts to remove any extra "noise" or graininess from the image caused by the Edge Enhancement applied in Step 1.

As the level of Smoothing is changed, the change is reflected on the last image that was acquired, allowing the user to decide the amount Smoothing that should be applied.

The Advanced button should only be accessed by trained service personal! Changing its values may adversely affect image quality.

Click on the Back button to return to Step 1, Edge Enhancement. Click the Next button to move to Step 3

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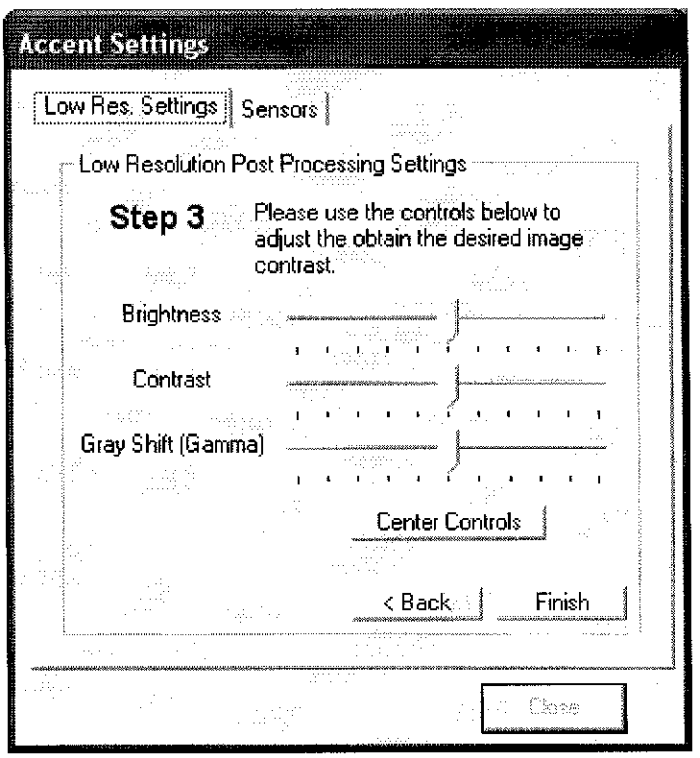
1, 2, 3... Setup Step 3



Step 3 allows the user to set the amount of brightness, contrast and gray shift (also called gamma) that is applied to all future Low Resolution images.

The default values are shown in the screen shot above and can be set by clicking the Center Controls button below the sliders.

As the levels of brightness, contrast or gray shift are adjusted, the changes will be reflected on the last acquired image so that the user can determine which setting is appropriate.

Brightness

Changing the Brightness setting can make up for an x-ray device that takes images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

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Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gray Shift (Gamma)

A Gray Shift change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. If the Gamma level gets moved up the Contrast level should be moved down. Changing the Gamma setting can result in an image that is very dark.

Back or Finish

Click on the Back button to return to Step 2, Smoothing. Click on the Finish button to complete the 1, 2, 3...Setup.

A summary of the new settings that will be applied to every Low Resolution or High Resolution image taken with the Accent sensor will appear on the first 1.2.3...Setup window under the heading "Current Settings".

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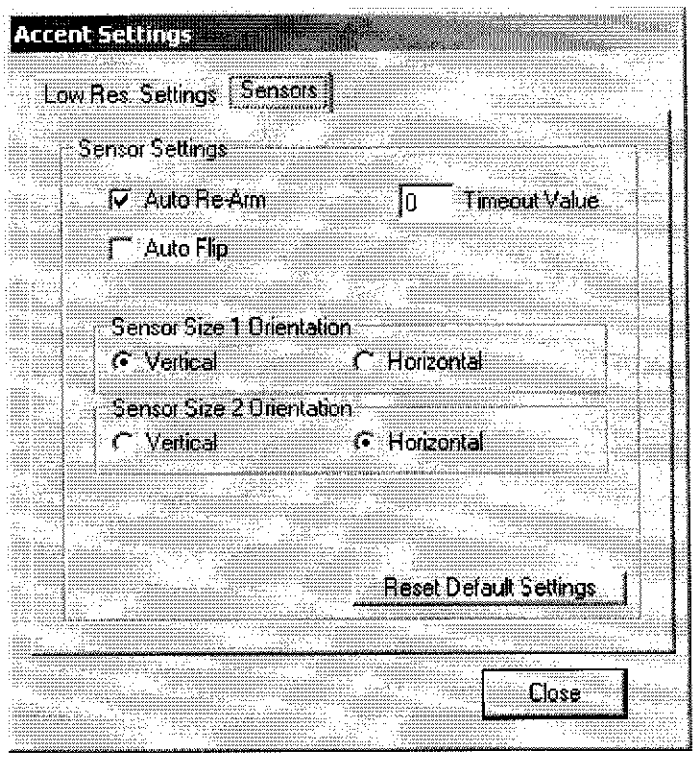
Settings Button – Sensors Window – Accent sensor



Sensors Tab Settings

Auto Re-Arm

Place a check in the Auto Re-Arm checkbox to have the sensor automatically reset itself for another picture as soon as the previous picture has been taken.

Auto Flip

By default, each image the sensor takes is viewed as if the viewer is on the outside of the mouth looking in. Place a check in the Auto Flip checkbox to change the view to look like the viewer is on the inside of the mouth looking out.

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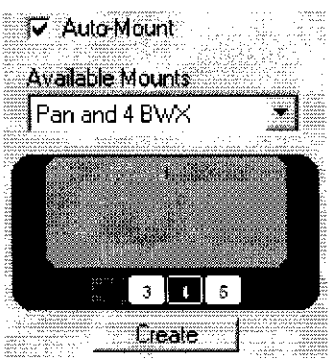
Timeout Value

The Timeout Value is the amount of time the sensor will wait for an x-ray to be taken before going into low power mode. The default value of 0 will cause the sensor to never time out.

Sensor Orientation

The Sensor Orientation lists each size of Accent sensor and whether the image taken by that sensor should be displayed in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed

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above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

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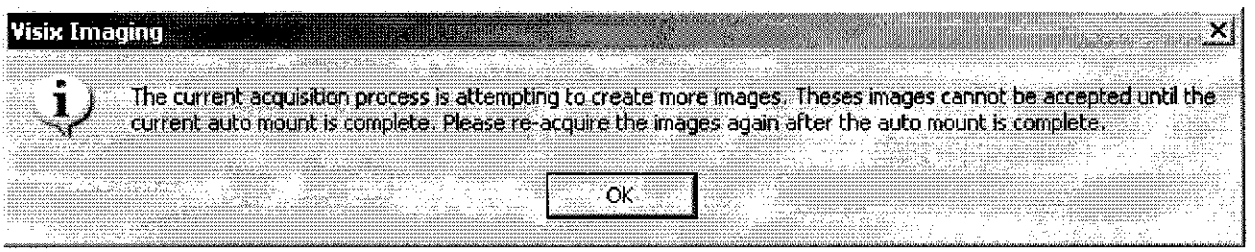
If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Sensor Indicator Bar

Once the Accent Sensor is ready to be used, the bar next to the Start button will display the word "Initialized" then will flash green and the words "Waiting for Exposure" will display. After the sensor button has been pressed to take the x-ray the bar will flash red and "Processing Image" will display.

During the Acquire Process

Visix will automatically capture the image from the sensor.

If the Cancel button [Cancel] is clicked during the acquire process, the acquire process will be aborted.

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After the Acquire Process

Once an image has been acquired it will appear in the area under the Start button as a thumbnail image.

To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the Close Window box in the upper right corner of the window and either continue acquiring images or move on to selecting the images and saving them into Visix.

If the image quality is not acceptable, close the View window, and reacquire the image. Once the image is acceptable, select the image then click on the Save button to save the image into Visix.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

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View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window.
Close and Save The images will save to the currently selected patient.

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Acquisition Windows

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

ScanX

The ScanX scanner uses small, flexible, reusable phosphor plates to acquire images instead of film. The ScanX can be setup in an office in two ways: Direct Connect Mode and Intelligent Track Control Mode.

Direct Connect Mode is the traditional method of setting up a ScanX. In Direct Connect Mode the ScanX is directly connected to one computer with a cable. Although all of the workstations on the network that have Visix installed on them can display saved ScanX images, only the copy of Visix on the computer the ScanX is directly connected to can acquire the images from the ScanX.

Intelligent Track Control Mode, also known as ITC mode, allows up to two workstations that have Visix installed to acquire images from the ScanX. The workstations will use the ScanX in either Exclusive or Shared Mode. In Exclusive Mode only one workstation will be allowed to acquire images from the ScanX. In Shared Mode, the tracks on the ScanX will be shared equally between two workstations allowing each workstation to independently acquire images from the plates that are fed into their assigned tracks.

Direct Connect Mode

Installation Overview

To use the ScanX in Direct Connect Mode install the ScanX and Visix on one workstation then use the Visix Administration program on that workstation to activate the ScanX. Install the remaining copies of Visix that were purchased on other network workstations. Each copy of Visix will request an activation code the first time it's opened. Please refer to the ScanX Drivers and Utilities cd for instructions about installing the ScanX. Refer to the Visix Installation instructions and the Visix Administration

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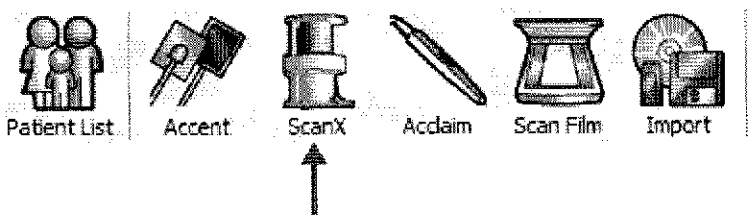
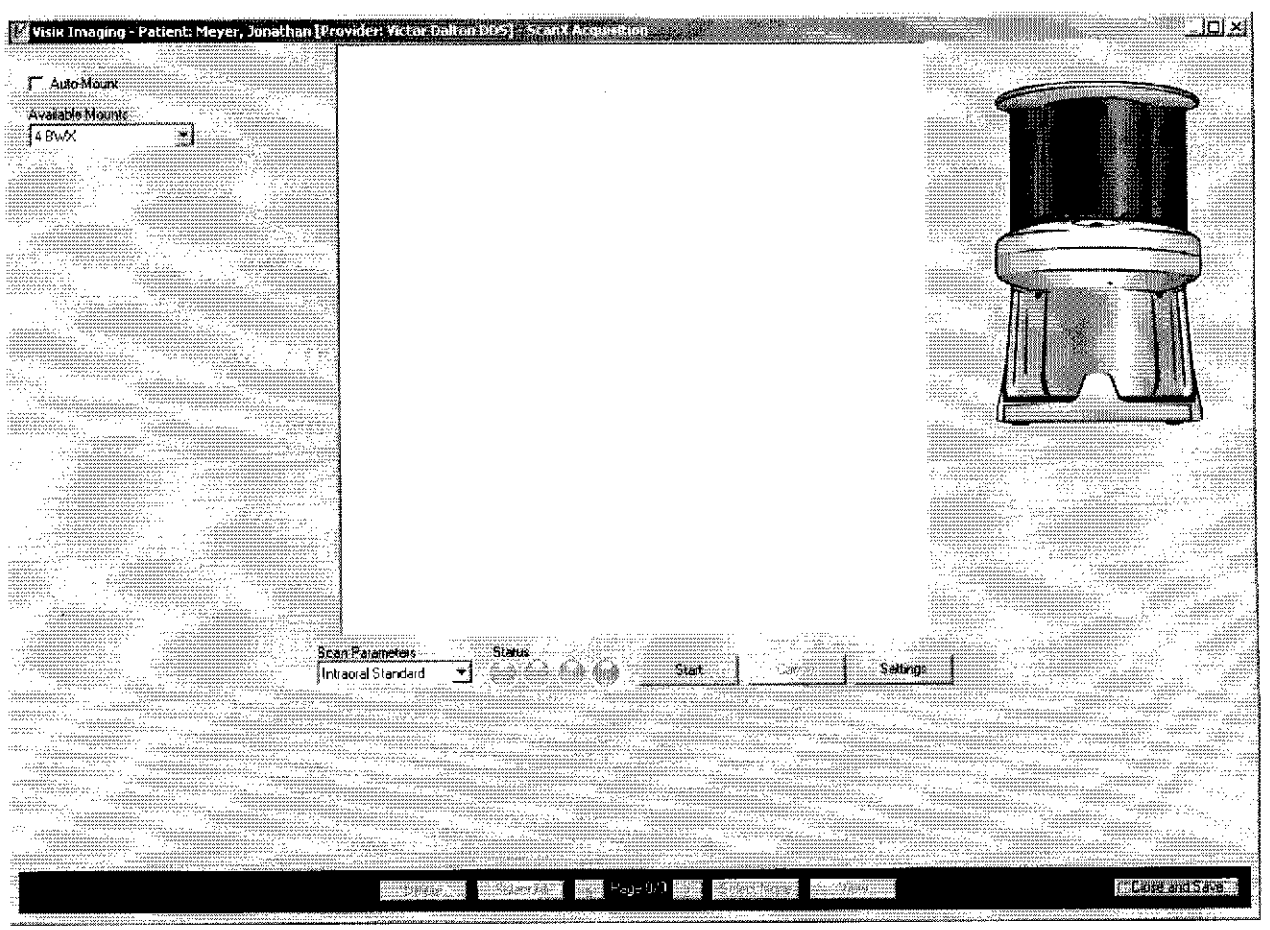
manual for instructions about installing Visix and activating Visix and the ScanX.

ScanX Acquisition Window

Click on the ScanX button on the Visix toolbar to open the ScanX Acquisition window.



ScanX Acquisition window when Direct Connect Mode is used



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Scan Parameters

The Scan Parameters for the ScanX phosphor plate scanner specify the type of image being x-rayed and the resolution for the resulting digital image.

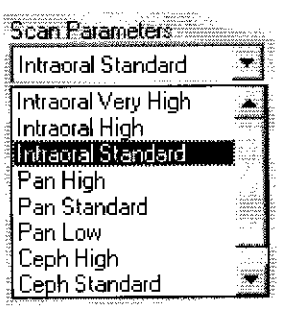
Image Type

Image types include:

- Intraoral, where a phosphor plate is placed inside the patient's mouth and an x-ray is taken of a small group of teeth.
- Pan, where a panoramic x-ray machine takes a picture of the patient's entire jaw.
- Ceph, where a cephalometric x-ray machine takes an x-ray of the side of the patient's head.

Resolution

Selecting a high or very high resolution will result in an image with a greater amount of detail along with a larger file size that requires more hard drive space. For most x-rays, a Standard resolution scan setting is appropriate.



Status Lights

Before beginning a scan check the color of the four Status lights. The four Status lights in Visix correspond to the four Track Status Lights on the ScanX.

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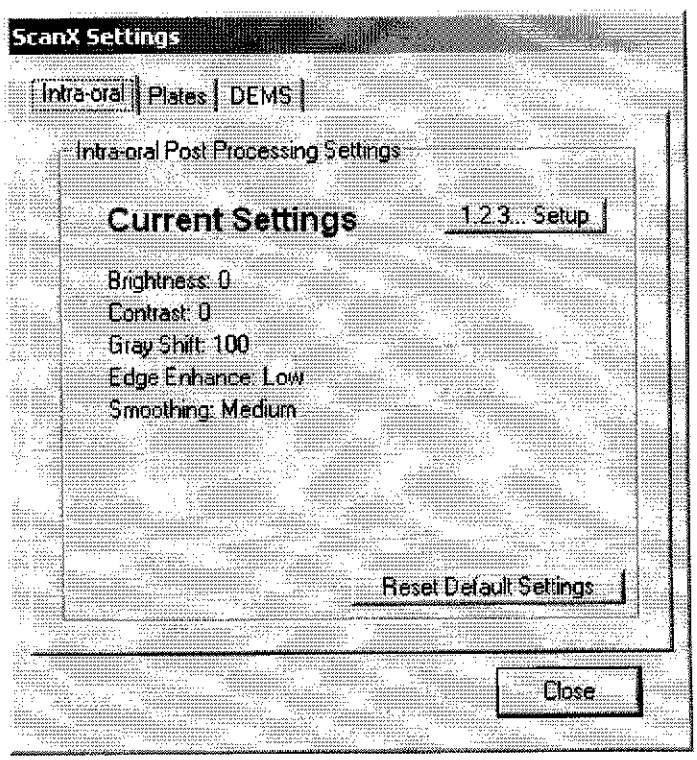
If a track is available for use its Status light will be green. If a track is currently scanning a phosphor plate its Status light will be red. If the Status lights are gray, the computer has lost its connection to the ScanX. For connection issues please call Visix technical support.

Settings Button for a ScanX Scanner Settings...

The Settings button will display windows that hold optional scan settings for the ScanX scanner. These settings are advanced and will affect the future images acquired by the ScanX scanner.

Settings Button – Intra-Oral Window – ScanX scanner



The Intra-oral settings window will display if the last image scanned was an intra-oral image. The intra-oral tab displays the Current Settings that are applied to every intra-oral phosphor plate that is scanned by the ScanX scanner. The default settings are displayed above. Clicking the "Reset Default Settings" button will return the settings on that window to the manufacturer's default settings.

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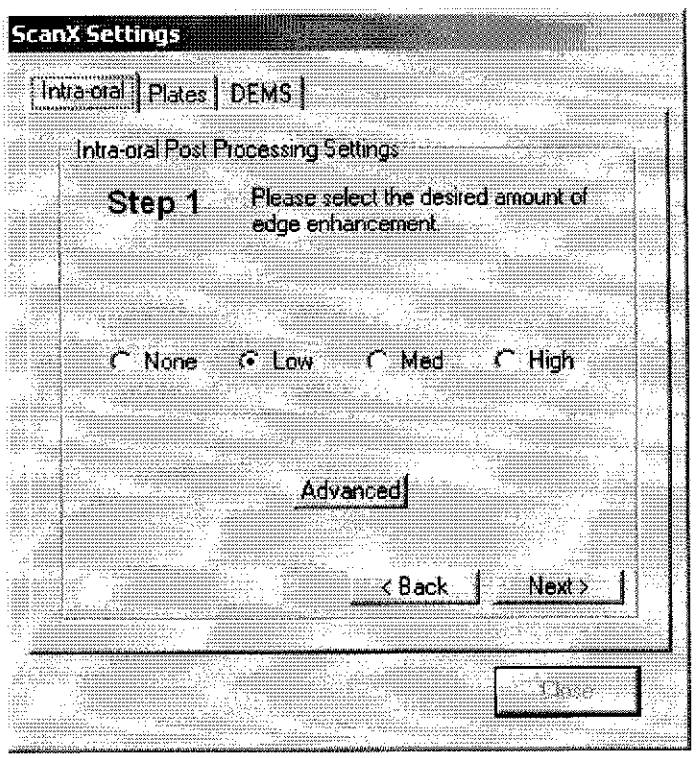
Intra-oral Window 1, 2, 3... Setup

1, 2, 3... Setup is a tool that will help determine the settings necessary for capturing the best image possible. At least one image must be scanned before using the 1, 2, 3...Setup tool. Changes made in 1, 2, 3...Setup on the Intra-oral tab will affect all future intra-oral images.

Step 1



Step 1 determines the amount of edge enhancement that will be applied to an image, ranging from None to High. Edge enhancement increases the sharpness of the edges and structure of the teeth.

As different levels of edge enhancement are selected, the image displayed in the Waterfall window will change to show what the application of that level of edge enhancement will look like.

The Advanced button should only be accessed by trained service personnel! Changing a value on the

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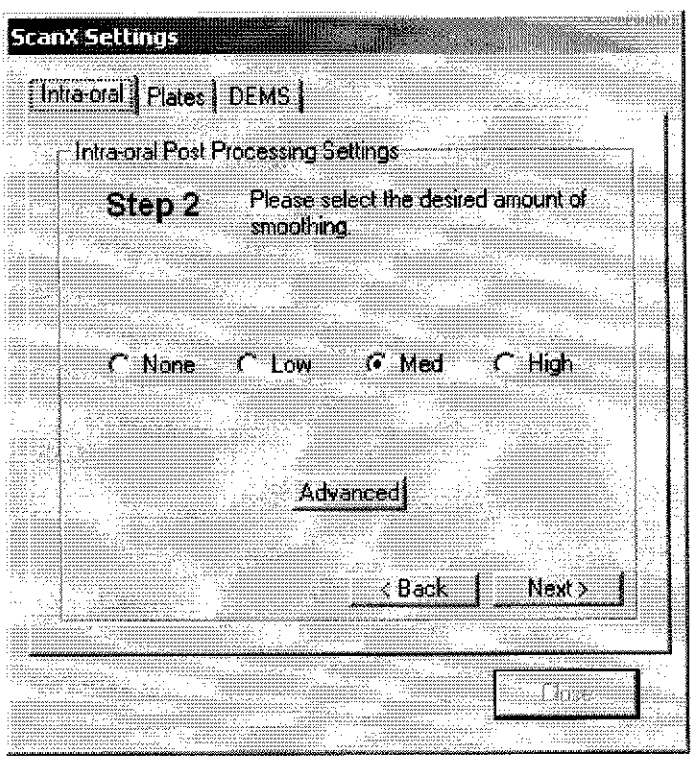
Advanced window may adversely affect image quality.

Click the Back button to exit out of the 1, 2, 3...Setup tool. Click the Next buttonto move to Step 2.

Step 2



Step 2 determines the amount of smoothing that should be applied to future images, ranging from None to High. Smoothing will attempt to remove any extra "noise" or graininess from the image caused by the edge sharpening applied.

As different levels of smoothing are selected, the image displayed in the Waterfall window will change to show what the application of that level of smoothing will look like.

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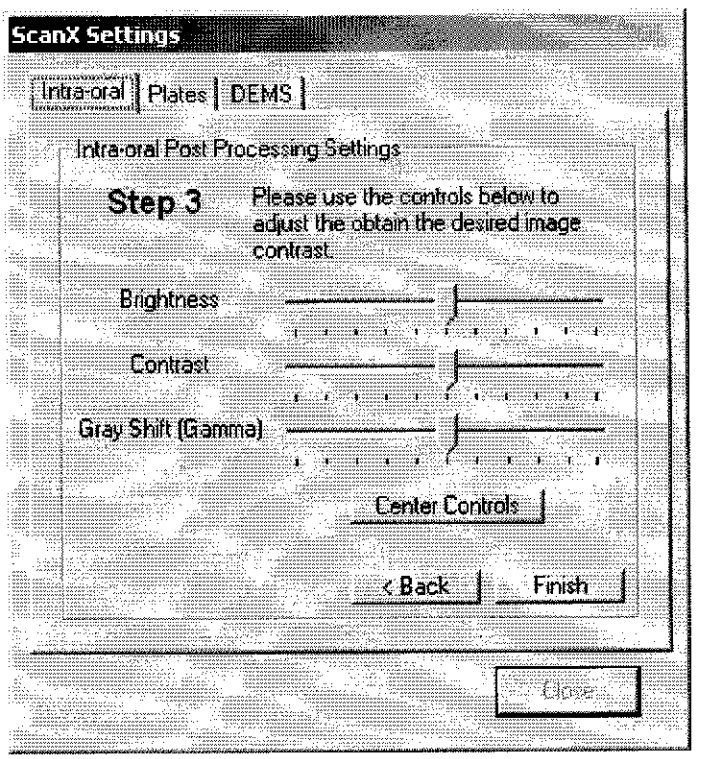
The Advanced button should only be accessed by trained service personnel! Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to return to Step 1. Click the Next button to move to Step 3.

Step 3



Step 3 determines the amount of brightness, contrast, and gray shift (or gamma) that will be applied to future intra-oral images.

The default value for each slider is shown in the above window and can be set by clicking the Center Controls button Center Controls.

As the levels of brightness, contrast and gray shift are adjusted, the image displayed in the Waterfall window will change to reflect the adjustment.

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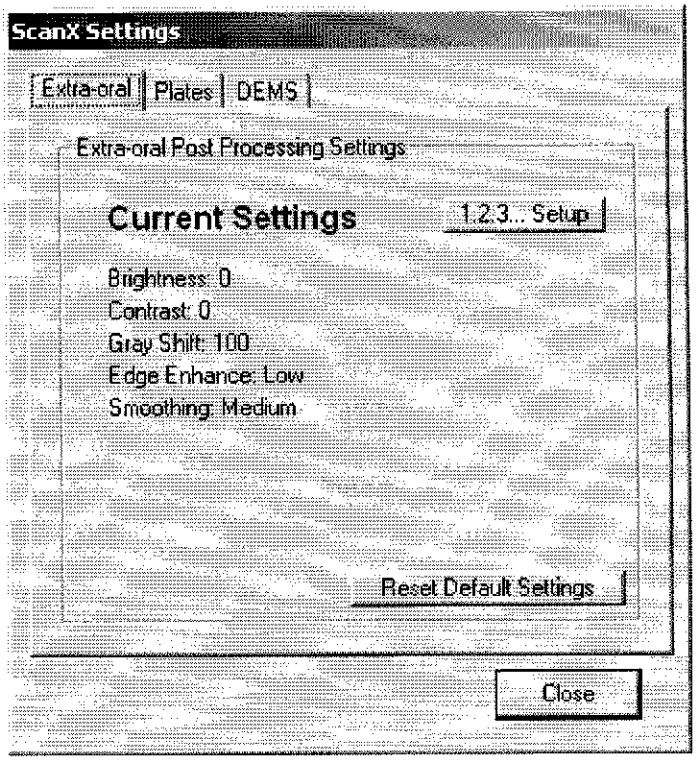
Click the Back button to return to Step 2. Click the Finish button to move to complete the 1,2,3... Setup steps. The new settings will display on the Intra-oral window under the Current Settings heading.

Settings Button – Extra-oral Window – ScanX scanner



Extra-oral Window 1, 2, 3... Setup

The Extra-oral settings window will display if the last image scanned was an extra-oral image. The Extra-oral settings are the same as the Intra-oral settings except that they refer to extra-oral images instead of intra-oral images. For an explanation of each setting please refer to the Intra-oral settings explanations listed before this section.

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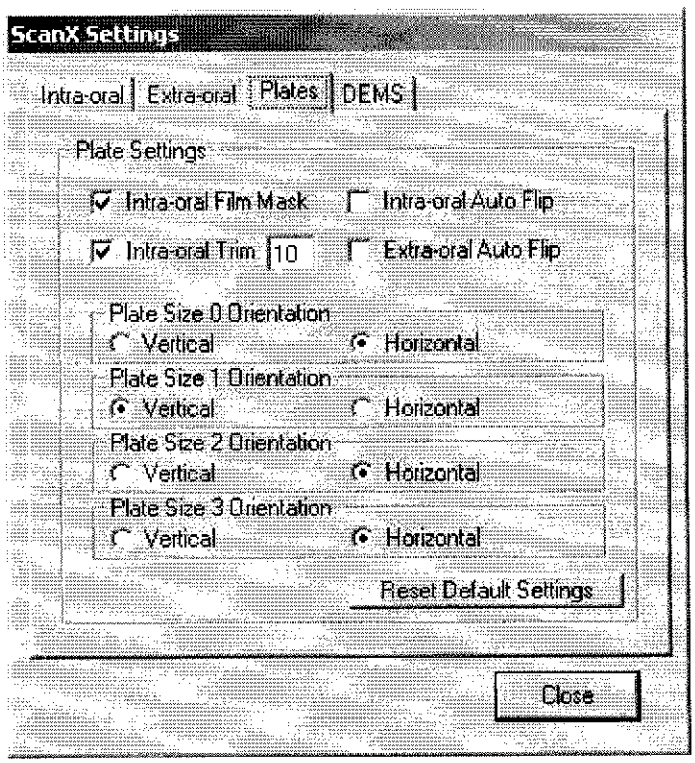
Settings Button – Plates Window – ScanX scanner



Intra-oral Film Mask

A Film Mask is a black border around an image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

Intra-oral Auto Flip

When an image is Auto Flipped the view is as though sitting on the tongue looking out at the x-ray head.

Intra-oral Trim

By default this option will be set to 10 which is the highest trim value. Instances where intra-oral trim would be used include cone-cut images and images that have "scatter" (extraneous black dots) around their edges. These types of images have

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white borders that the Intra-oral trim will delete, creating a cleaner image.

Extra-oral Auto Flip

When an extra-oral image is Auto Flipped, it's flipped left right.

Plate Orientation

The Plates window lists each size of intra-oral phosphor plates and whether it is to be displayed in Visix in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Reset Default Settings

Clicking the Reset Default Settings button will restore the original settings for this window.

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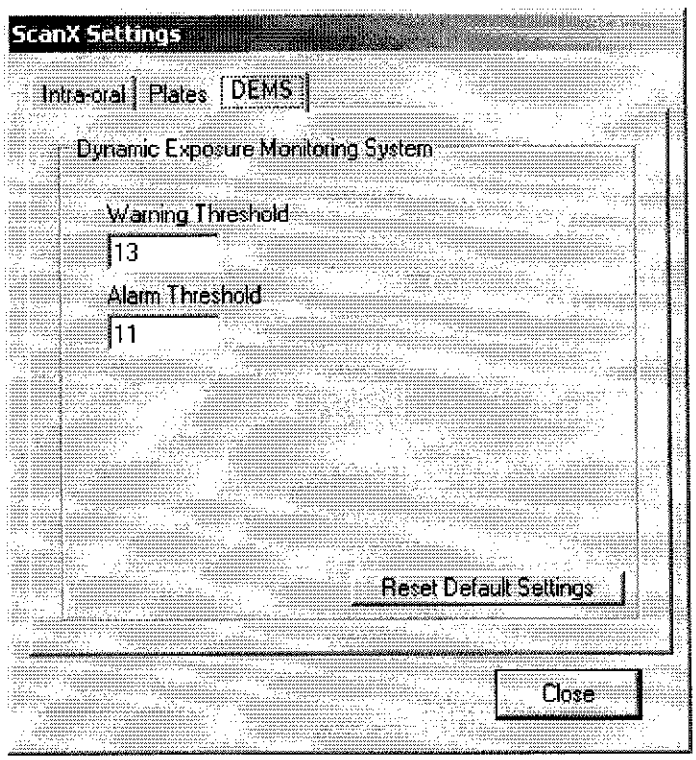
Settings Button – DEMS Window – ScanX scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset Default Settings button will restore the original settings.

The Dynamic Exposure Monitoring System lets the user know if the image being captured was shot with a less than optimum x-ray exposure setting.

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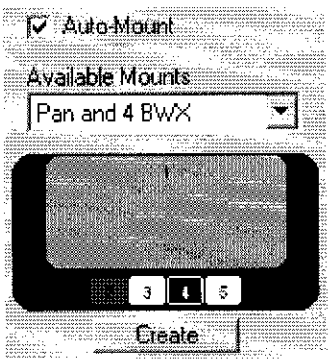
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

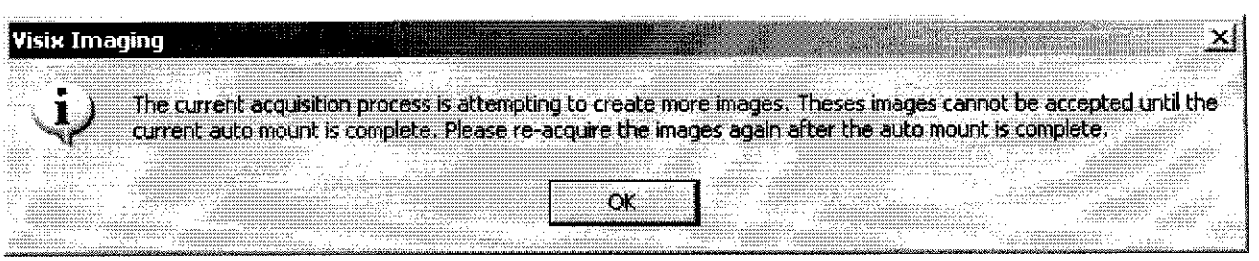
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

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Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Start button

Click on the Start button [Start] on the ScanX Acquisition window to tell Visix a scan is ready to begin.

At the ScanX Scanner

Load the phosphor plate or plates according to the manufacturer's directions into a ScanX track that displays a green light.

During the Scanning Process

Visix will automatically capture the image from the ScanX scanner. As the phosphor plate or plates advance through the ScanX scanner they will drop down the Visix Current Image box on the Acquisition window in a waterfall effect. As the plate is being scanned, the Status light on the ScanX and the corresponding light in Visix will turn red. A red light indicates that an image is being processed in that track. When a light turns green another phosphor plate can be inserted into that track to begin another scan. If the Cancel Button is clicked during the scanning process, the scan will be aborted. [Cancel]

Please note that the Current Image box (the waterfall) on the Acquisition Window is not a diagnostic quality image. The Current Image box is only used to show the image's progression through the scanner.

After the Scanning Process

Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the ScanX window. A DEMS light on each image will be green

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if Visix is satisfied with the x-ray machine settings used to acquire this image, yellow if Visix thinks the x-ray settings could be slightly better, and red if Visix thinks the x-ray settings are poor and the image should be checked.

To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the Close Window box ☒ in the upper right corner of the window. If the image quality is not acceptable, close the View window and consider either rescanning the plate, if it hasn't been erased, or retaking the x-ray.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

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View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window. View

Save an Image

To save images, click the Close and Save button at the bottom of the ScanX Acquisition window. Close and Save The images will save, no matter what color their DEMS lights are, to the currently selected patient.

Intelligent Track Control Mode

Intelligent Track Control Setup Options

Intelligent Track Control Mode has three setup options that use different combinations of Visix workstations to control and acquire images from the ScanX.

Option 1	The ScanX is connected to a USB port on this workstation. The copy of Visix running on this workstation will acquire images from the ScanX.
Option 2	Although the ScanX is not physically connected to this workstation, the copy of Visix running on this workstation will acquire images from it.
Option 3	Although the ScanX is physically connected to this workstation, one or two other workstations will acquire images from it.

Installation Overview

To use the ScanX in ITC Mode, install the ScanX and Visix on one workstation first, then use the Visix Administration program on that workstation to change Visix to ITC Mode

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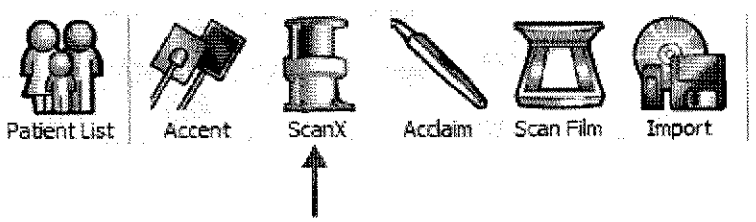
and to activate the ScanX. Next, install Visix on any additional workstations that will be acquiring images from the ScanX and use the Visix Administration program on those workstations to set Visix to ITC Mode. Finally install the remaining copies of Visix that were purchased on other network workstations. Each copy of Visix will request an activation code the first time it's opened. Please refer to the ScanX Drivers and Utilities cd for instructions about installing the ScanX. Refer to the Visix Installation instructions and the Visix Administration manual for instructions about installing Visix, changing to ITC Mode, and activating Visix and the ScanX.

ScanX Acquisition Window

Click on the ScanX button on the Visix toolbar to open the ScanX Acquisition window.



Intelligent Track Control – Setup Option 1 or 2

The copy of Visix running on this workstation will acquire images from the ScanX.

The ScanX Acquisition window looks the same when Visix is setup in ITC Mode and either Option 1 or Option 2 is selected to show where the ScanX will be located and which workstations will be acquiring images from it.

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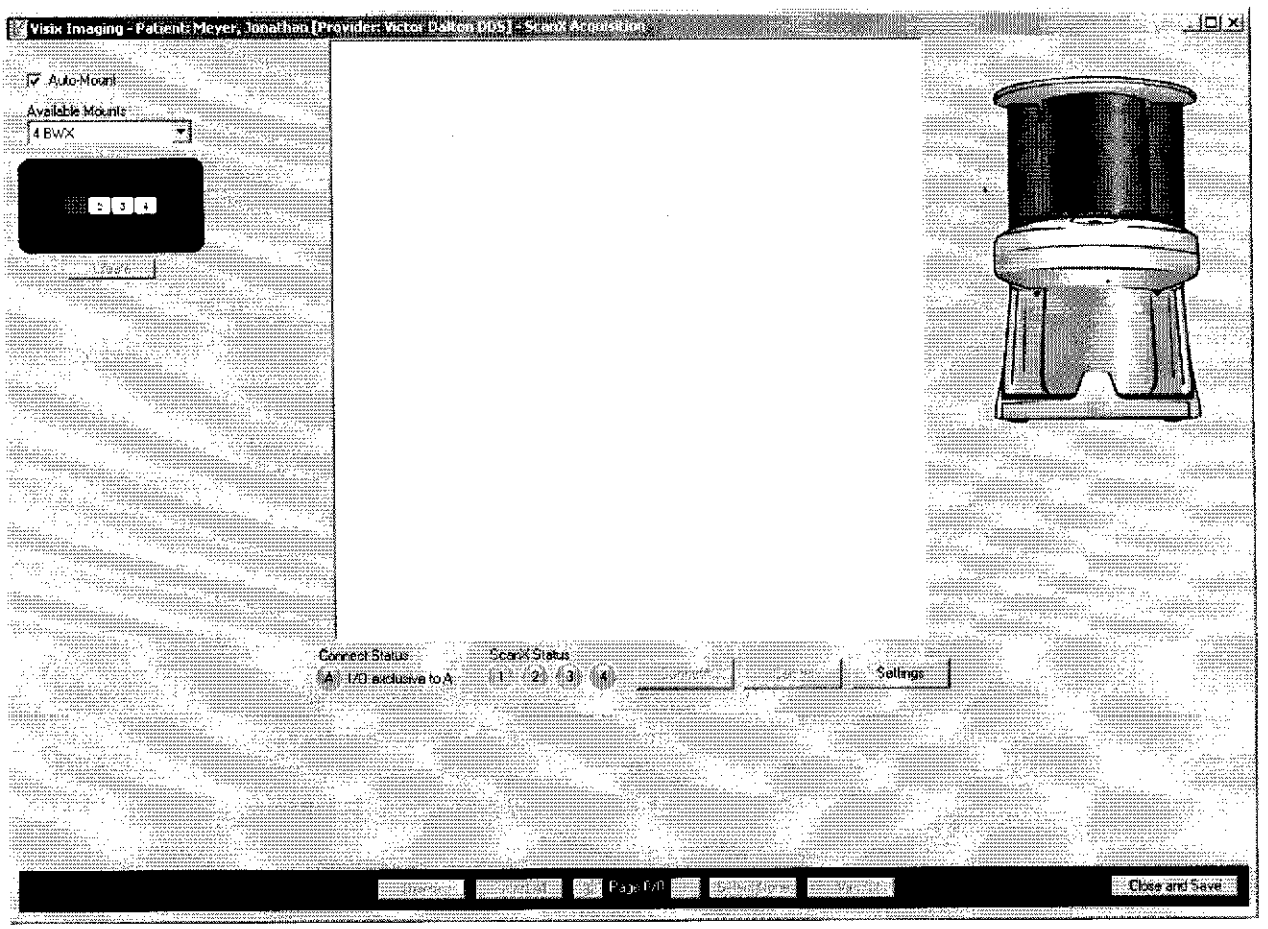
ScanX Acquisition window when Setup Option 1 or 2 of ITC Mode is selected:
The copy of Visix running on this workstation will acquire images from the ScanX



Connect Status

The Connect Status light will be green if this Visix workstation is currently connected to the ScanX scanner. The letter on the Connect Status light will indicate if the ScanX recognizes this Visix workstation as workstation A or workstation B.

The label next to the Connect Status light tells if the ScanX is being used in Shared mode or Exclusive Mode, and, if it's in Exclusive Mode whether workstation A or workstation B has control.

This is workstation A. Workstations A and B both acquire images from the ScanX.

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This is workstation A. Only workstation B acquires images from the ScanX.

If this Visix workstation has failed to connect to the ScanX the Connect Status light will be red, and the Connect button will be available for use. Click on the Connect button to establish the connection to the ScanX scanner.

ScanX Status

Before beginning a scan, check the color of the four ScanX Status lights. The four ScanX Status lights in Visix correspond to the four Track Status Lights on the ScanX.

- If a track is available for use its corresponding Status light will be green.
- If a track is currently scanning a phosphor plate its Status light will be red.
- If half of the Status lights are gray, this Visix workstation is controlling the tracks that correspond to the green or red Status lights and the other Visix workstation that is sharing control of the ScanX computer is controlling the tracks that correspond with the gray Status lights.
- If all of the Status lights are gray, the Visix Controller has lost its connection to the ScanX. Please refer to the instructions in the ScanX Controller section of this manual to reconnect the ScanX Controller and the ScanX.

Settings Button for a ScanX Scanner

The Settings button will display windows that hold optional scan settings for the ScanX scanner. These settings are advanced and will affect the future images acquired by the ScanX scanner.

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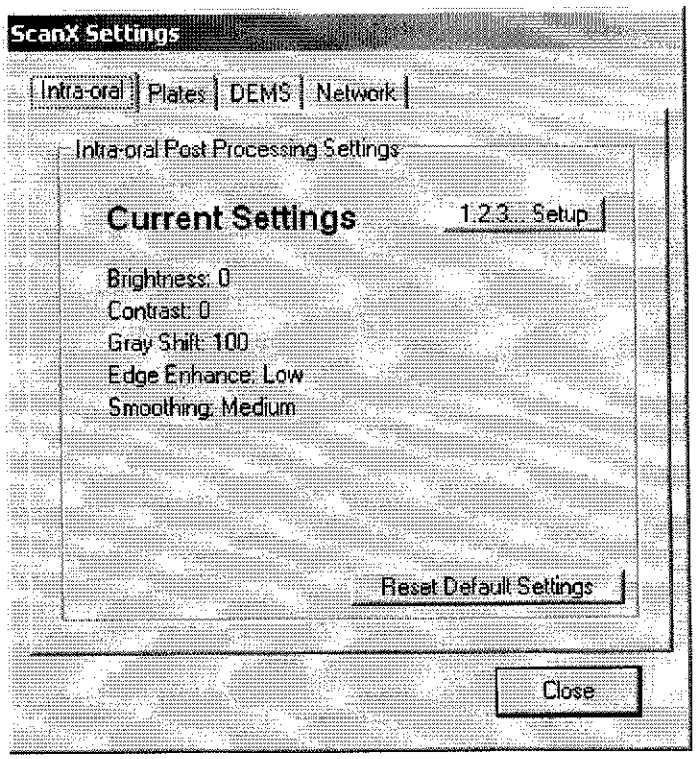
Settings Button – Intra-Oral Window – ScanX scanner



The Intra-oral settings window will display if the last image scanned was an intra-oral image. The intra-oral tab displays the Current Scan Settings that are applied to every intra-oral phosphor plate that is scanned by the ScanX scanner. The default settings are displayed above. Clicking the "Reset Default Settings" button will return the settings on that window to the manufacturer's default settings.

Intra-oral Window 1, 2, 3... Setup

1, 2, 3... Setup is a tool that will help determine the settings necessary for capturing the best image possible. At least one image must be scanned before using the 1, 2, 3...Setup tool. Changes made in 1, 2, 3...Setup on the Intra-oral tab will affect all future intra-oral images.

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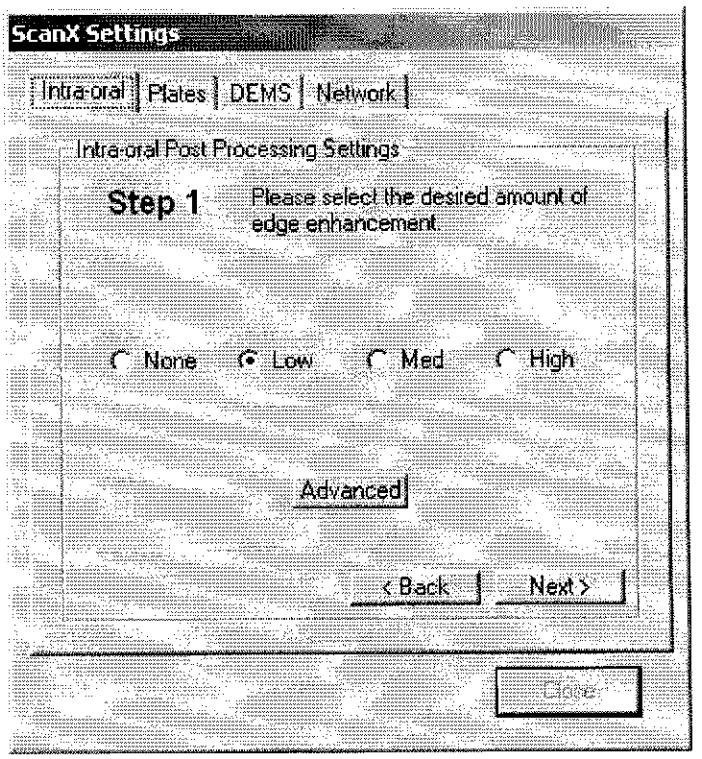
Step 1



Step 1 determines the amount of edge enhancement that will be applied to an image, ranging from None to High. Edge enhancement increases the sharpness of the edges and structure of the teeth.

As different levels of edge enhancement are selected, the image displayed in the Waterfall window will change to show what the application of that level of edge enhancement will look like.

The settings on the Advanced button should only be changed by trained service personnel. Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to exit out of the 1, 2, 3...Setup tool. Click the Next button to move to Step 2.

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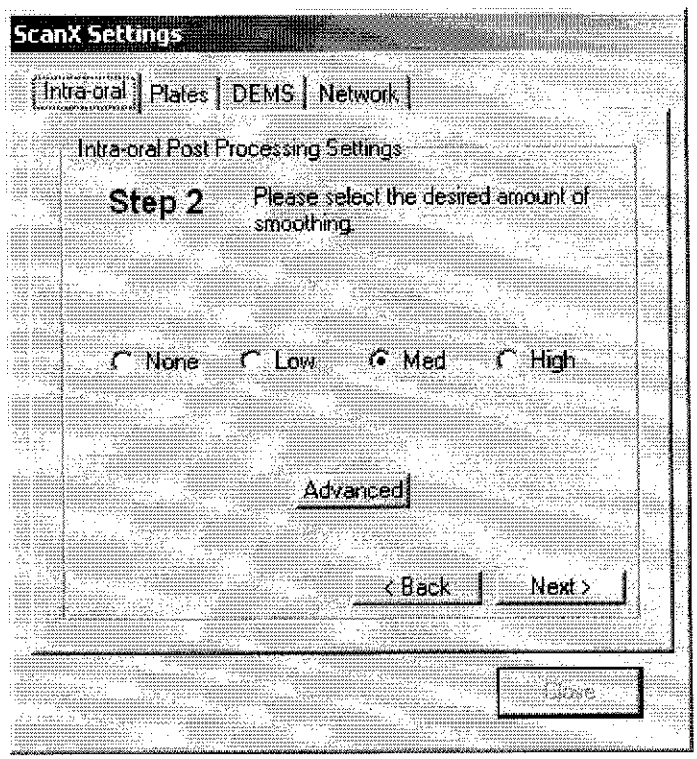
Step 2



Step 2 determines the amount of smoothing that should be applied to future images. Smoothing amounts range from None to High. Smoothing will attempt to remove any extra "noise" or graininess from the image caused by the edge sharpening applied.

As different levels of smoothing are selected, the image displayed in the Waterfall window will change to show what the application of that level of smoothing will look like.

The settings on the Advanced button should only be changed by trained service personnel. Changing a value on the Advanced window may adversely affect image quality.

Click the Back button to return to Step 1. Click the Next button to move to Step 3.

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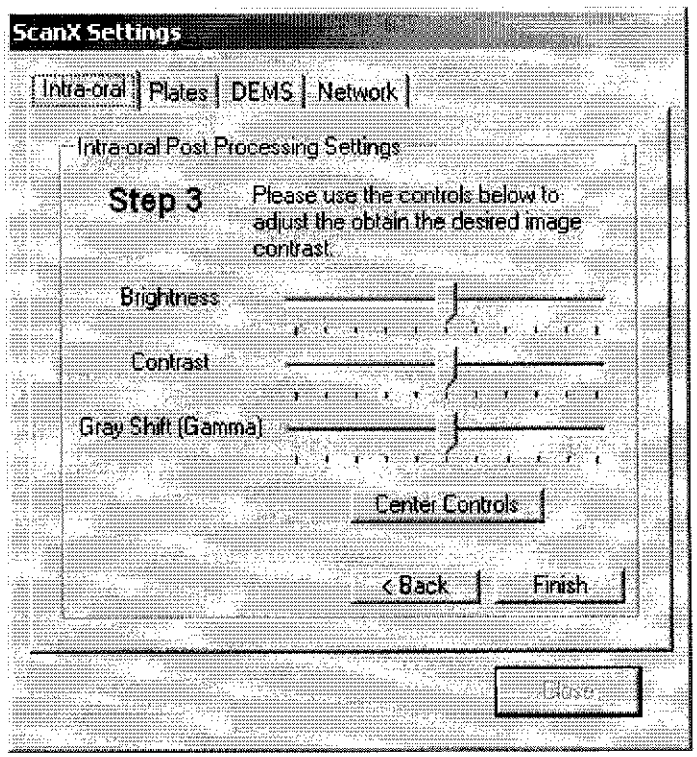
Step 3



Step 3 determines the amount of brightness, contrast, and gray shift (or gamma) that will be applied to future intra-oral images.

The default value for each slider is shown in the above window and can be set by clicking the Center Controls button Center Controls.

As the levels of brightness, contrast and gray shift are adjusted, the image displayed in the Waterfall window will change to reflect the adjustment.

Click the Back button to return to Step 2. Click the Finish button to move to complete the 1,2,3... Setup steps. The new settings will display on the Intra-oral window under the Current Settings heading.

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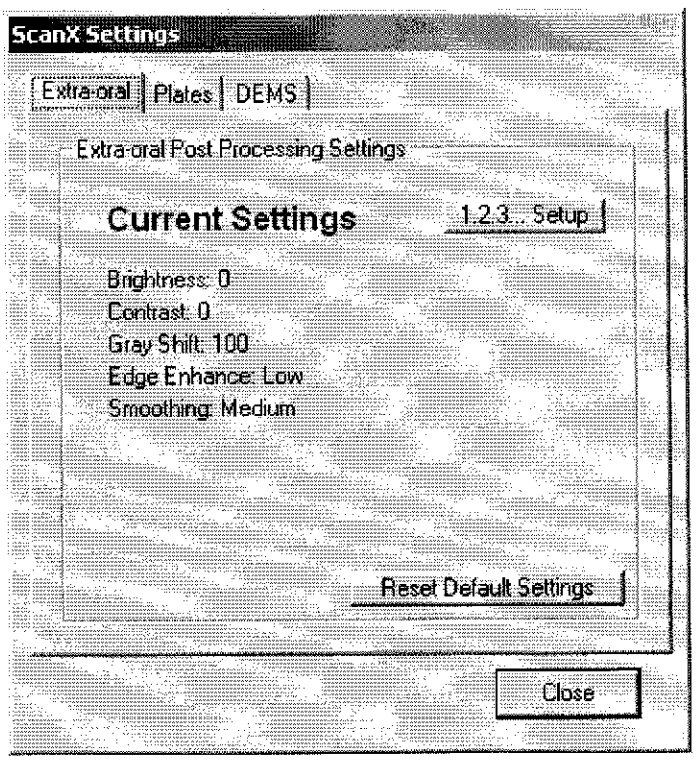
Settings Button – Extra-oral Window – ScanX scanner



Extra-oral Window 1, 2, 3... Setup

The Extra-oral settings window will display if the last image scanned was an extra-oral image. The Extra-oral settings are the same as the Intra-oral settings except that they refer to extra-oral images instead of intra-oral images. For an explanation of each setting please refer to the Intra-oral settings explanations listed before this section.

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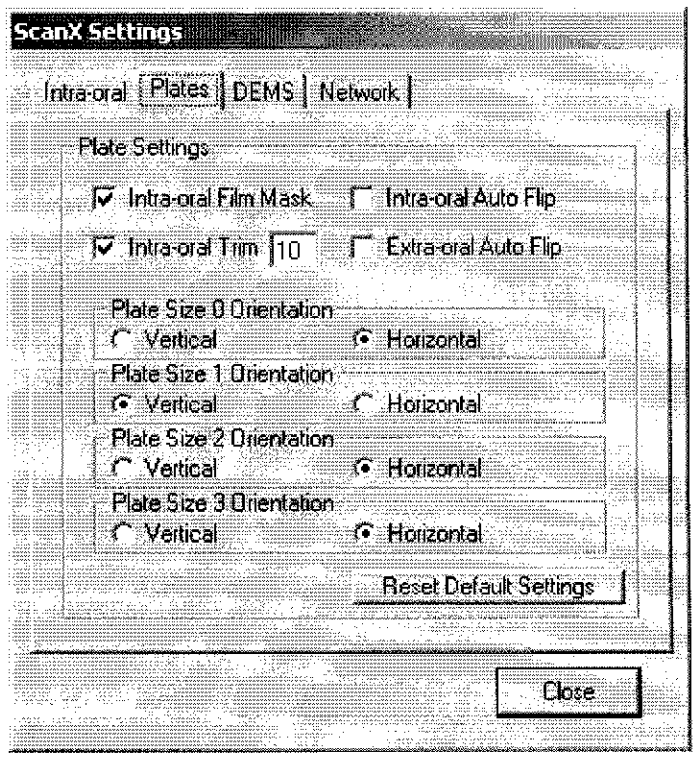
Settings Button – Plates Window – ScanX scanner



Intra-oral Film Mask

A Film Mask is a black border around an image that is similar to a mat around a picture. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future ScanX scanned images.

Intra-oral Auto Flip

When an image is Auto Flipped the view is as though sitting on the tongue looking out at the x-ray head.

Intra-oral Trim

By default this option will be set to 10 which is the highest trim value. Instances where intra-oral trim would be used include cone-cut images and images that have "scatter" (extraneous black dots) around their edges. These types of images have

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white borders that the Intra-oral trim will delete, creating a cleaner image.

Extra-oral Auto Flip

When an extra-oral image is Auto Flipped, it's flipped left right.

Plate Orientation

The Plates window lists each size of intra-oral phosphor plates and whether it is to be displayed in Visix in a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can be changed later, from vertical to horizontal or from horizontal to vertical. Please refer to the Images Window, Right Click On An Image section of this manual for instructions on how to rotate and flip individual images.

Reset Default Settings

Clicking the Reset Default Settings button will restore the original settings for this window.

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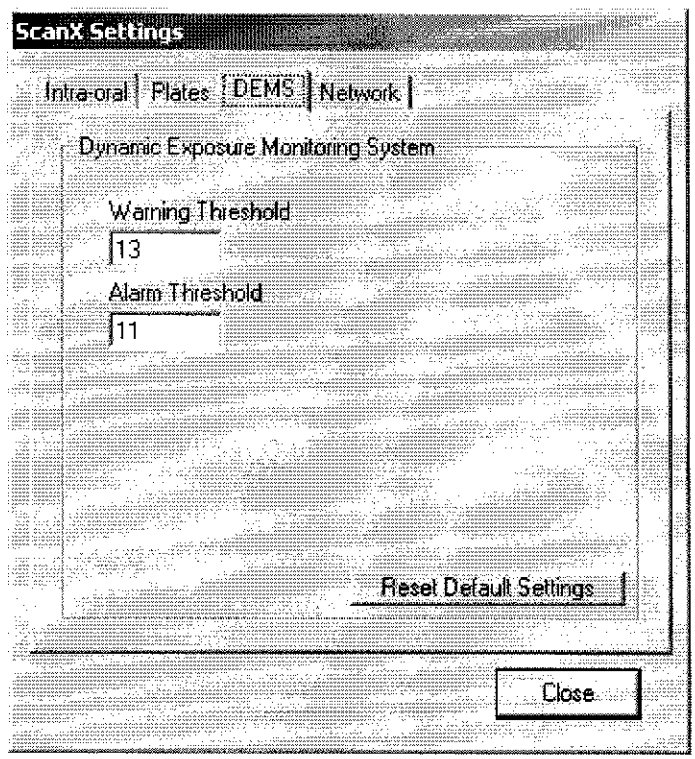
Settings Button – DEMS Window – ScanX scanner



DEMS

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset Default Settings button will restore the original settings.

The Dynamic Exposure Monitoring System lets the user know if the image being captured was shot with a less than optimum x-ray exposure setting.

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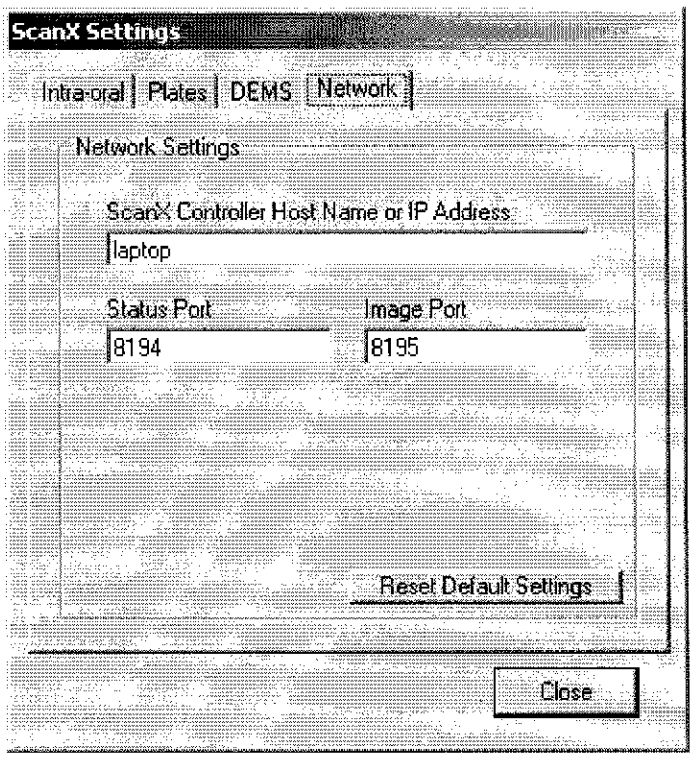
Settings Button – Network Window – ScanX scanner



ScanX Controller Host Name or IP Address

Enter the name or IP address of the computer the ScanX is physically connected to.

Status Port

Enter the number of the Status Port that will be used to send ScanX status information to this Visix workstation. Enter the same port that was entered in the ScanX Controller Configure window. The two entries must match.

Image Port

Enter the number of the Image Port that will be used to send images from the ScanX to this Visix workstation. Enter the same port that was entered in the ScanX Controller Configure window. The two entries must match.

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Scan Parameters

The Scan Parameters for the ScanX phosphor plate scanner specify the type of image being x-rayed and the resolution for the resulting digital image.

The Scan Parameter setting is selected from the list that displays by left clicking once on the ScanX icon in the System Tray.

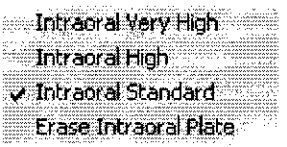

Image Type

Image types include:

- Intra-oral, where a phosphor plate is placed inside the patient's mouth and an x-ray is taken of a small group of teeth.
- Pan, where a panoramic x-ray machine takes a picture of the patient's entire jaw.
- Ceph, where a cephalometric x-ray machine takes an x-ray of the side of the patient's head.

Resolution

Selecting a high or very high resolution will result in an image with a greater amount of detail along with a larger file size that requires more hard drive space. For most x-rays, a Standard resolution scan setting is appropriate.

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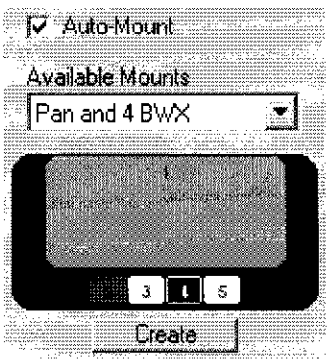
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

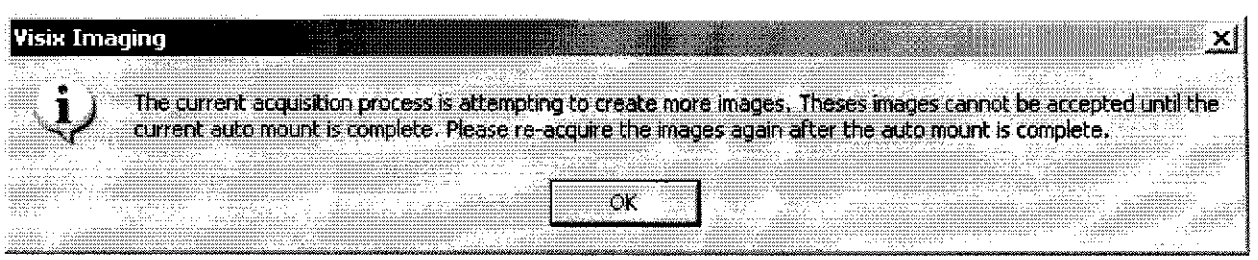
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

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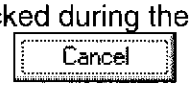
Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

At the ScanX Scanner

Load the phosphor plate or plates according to the manufacturer's directions into a ScanX track that displays a green light.

During the Scanning Process

Visix will automatically capture the image from the ScanX scanner. As the phosphor plate or plates advance through the ScanX scanner they will drop down the Visix Current Image box on the ScanX Acquisition window in a waterfall effect. As the plate is being scanned, the Status light on the ScanX and the corresponding light in Visix will turn red. A red light indicates that an image is being processed in that track. When a light turns green another phosphor plate can be inserted into that track to begin another scan. If the Cancel Button is clicked during the scanning process, the scan will be aborted. 

Please note that the Current Image box on the Acquisition Window is not a diagnostic quality image. The Current Image box is only used to show the image's progression through the scanner.

After the Scanning Process

Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the ScanX window. A DEMS light on each image will be green if Visix is satisfied with the x-ray machine settings used to acquire this image, yellow if Visix thinks the x-ray settings could be slightly better, and red if Visix thinks the x-ray settings are poor and the image should be checked.

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To check an image, double click on the image to open it into the Visix View window. If the image quality is acceptable, close the View window by clicking on the Close Window box ☒ in the upper right corner of the window. If the image quality is not acceptable, close the View window and consider either rescanning the plate, if it hasn't been erased, or retaking the x-ray.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are <u>not</u> recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

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Save an Image

To save images, click the Close and Save button at the bottom of the ScanX Acquisition window. [Close and Save] The images will save, no matter what color their DEMS lights are, to the currently selected patient.

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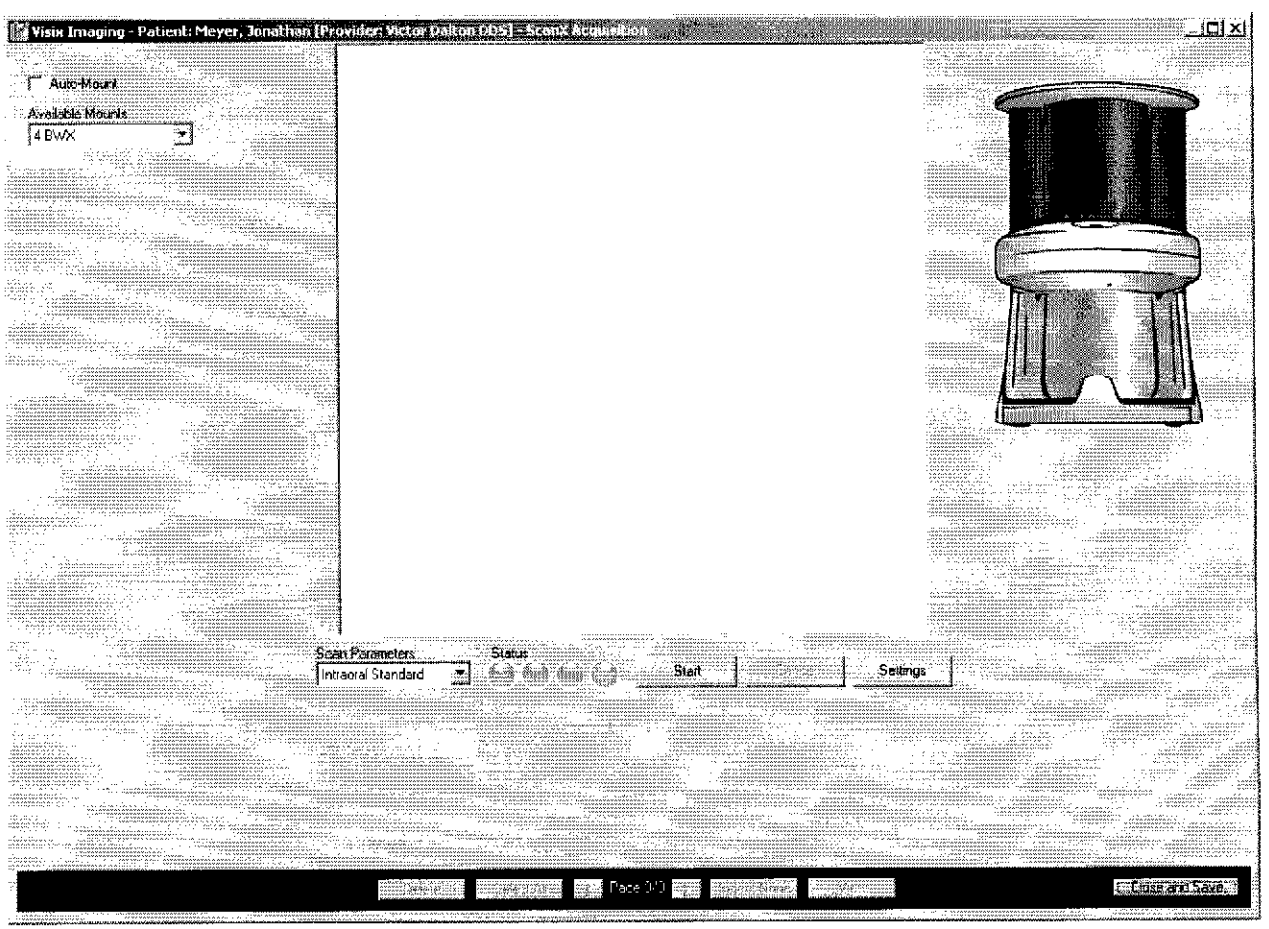
Intelligent Track Control – Setup Option 3

Although the ScanX is physically connected to this workstation, one or two other workstations will acquire images from it.

When the ScanX is physically connected to this workstation but controlled by other workstations, the ScanX Acquisition window looks the same as when Visix is setup in Direct Connect Mode. For instructions on how to use this window, please refer to the Direct Connect Mode section of this manual.

ScanX Acquisition window when Setup Option 3 of ITC Mode is selected:
The ScanX is connected to this workstation but one or two other workstations will acquire images from the ScanX



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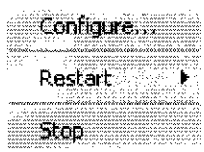
ScanX Controller

If the ScanX is configured for Client/Server mode the ScanX Controller will appear in the System Tray (the lower right corner on the computer screen). The background color of the ScanX Controller will be green if the ScanX is available for scanning, white if the ScanX and the ScanX Controller are not communicating with each other, and red if the ScanX is currently scanning plates.

ScanX Icon Right Click Menu

Right clicking once on the ScanX icon in the System Tray will display the following menu:



Configure

Information on the Configure windows should only be changed when:

- Visix is installed on this computer
- The Visix port numbers have changed
- The computer the ScanX scanner is connected to has had its name or IP address changed
- The Scan Mode needs to be changed.

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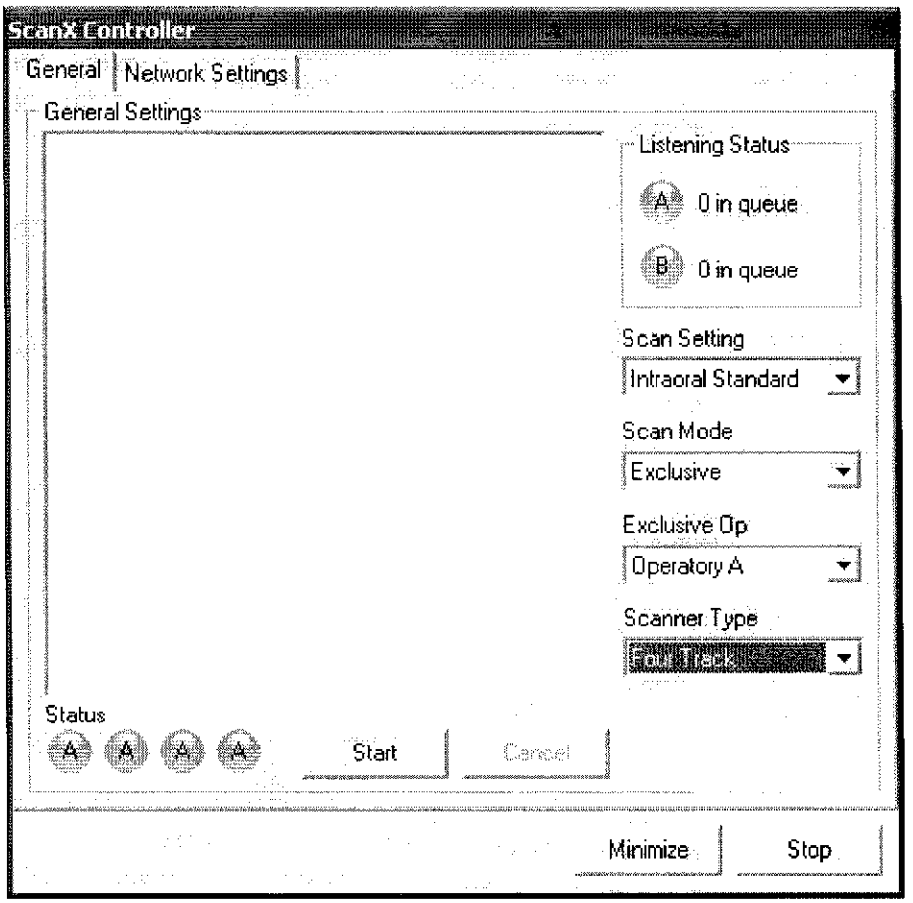
ScanX Controller - General Window



Queue

If plates were scanned by the ScanX Controller instead of from the Visix Op A workstation or Op B workstation, the images will sit in a queue until the client opens, at which time they will appear as thumbnails on the ScanX window and can be selected and saved.

Scan Setting

Select the ScanX Scan Parameter Setting that should be used when scanning images directly from the ScanX Controller instead of from the Visix Op A workstation or Op B workstation.

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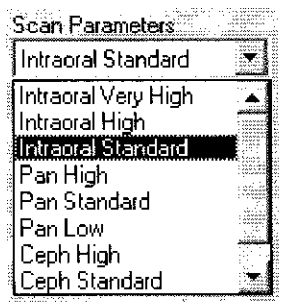

Scan Mode

Select Exclusive to allow just one workstation, either Op A or Op B, to acquire images from the ScanX. In Exclusive Mode, the workstation that is selected will be able to use all of the ScanX tracks.

Select Shared Mode to allow both workstations to acquire images from the ScanX. In Shared Mode each workstation is allowed to use only half of the ScanX tracks. In Shared Mode, Op A uses tracks 1 and 2, and Op B uses tracks 3 and 4. When using a ScanX Duo, Op A uses track 1 and Op B uses track 2.

Exclusive Op

If the Scan Mode is Exclusive, select the op that will acquire the images from the ScanX.

Scanner Type

Select Two Tracks if a ScanX Duo will be used to scan plates. Select Four Tracks if a ScanX will be used to scan plates.

Minimize and Stop Buttons

The Stop button at the bottom of both Configure windows will end the communication between Visix and the ScanX.

The Minimize button will close the Configure window.

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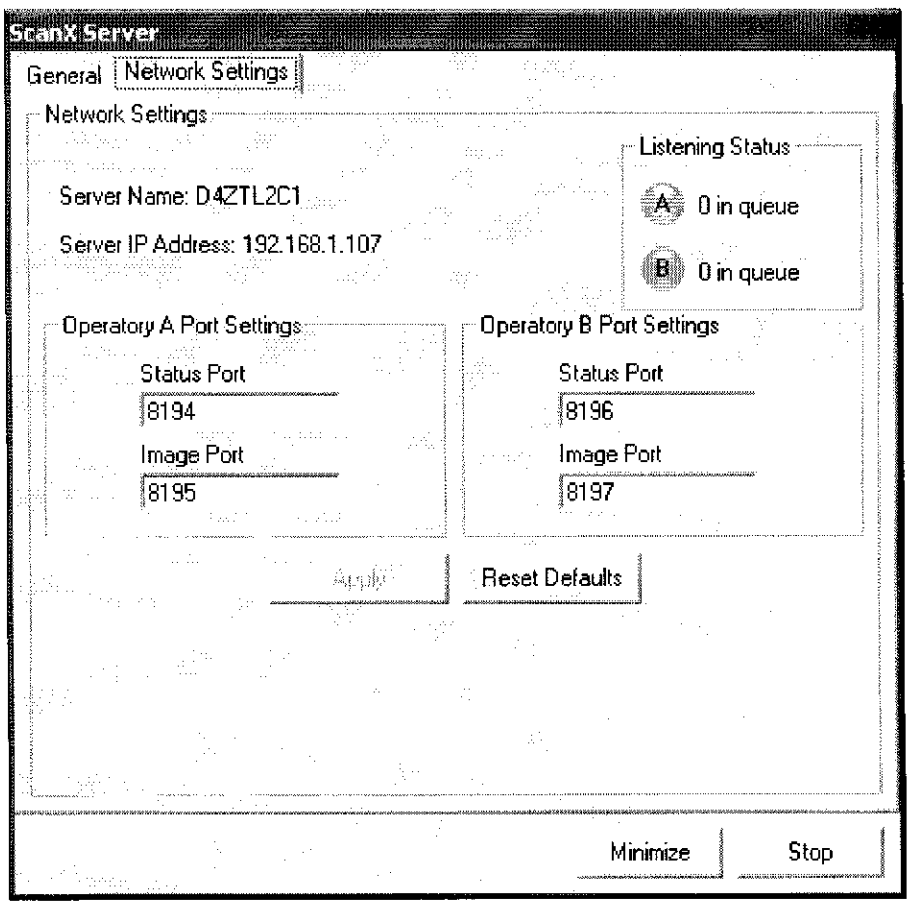
ScanX Controller - Network Window



Operatory A Port Settings

Enter two unused ports that the computer the ScanX is connected to will use to send ScanX status information and images to the workstation set up as the Visix Op A workstation. The Op A ports listed on the computer the ScanX is connected to must match the Op A ports listed on the Op A computer.

Operatory B Port Settings

Enter two unused ports that the computer the ScanX is connected to will use to send ScanX status information and images to the workstation set up as the Visix Op B workstation. The Op B ports listed on the computer the ScanX is

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connected to must match the Op B ports listed on the Op B computer.

Minimize and Stop Buttons

The Stop button at the bottom of both Configure windows will end the communication between Visix and the ScanX.

The Minimize button will close the Configure window.

Restart

Selecting Restart will display the following menu:

Rebooting this computer will have the same effect as selecting the ScanX and Communication options. Select ScanX to restart the ScanX controller on this computer. Select Communication to open the communication link between this computer and the ScanX scanner.

Stop

Select Stop to close the ScanX Controller.

ScanX Icon Left Click Menu

Left click on the ScanX icon in the System Tray to display the list of ScanX Parameter Settings along with the option to automatically erase the plate after it has been scanned.

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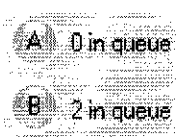
Scanning Images Without Visix Open

The ScanX Controller can be used to scan phosphor plates if the Visix Op A and Op B workstations are not available for use. To use the ScanX Controller in this manner, perform the following steps:

- Determine which Visix workstation, Op A or Op B, would normally have been used to acquire the images.
- Right click one time on the ScanX controller in the System Tray of the workstation the ScanX is directly connected to, and select Configure.
- On the General tab, select the Scan Setting that should be used to scan the phosphor plates.
- On the General tab, click on the Start button.
- Feed the plates into the ScanX tracks that are used by the Visix Op A or Op B workstation that would normally have been used to acquire the images.
- The images will be placed in the queue belonging to the Visix Op A or Op B workstation that would normally have been used to acquire the images.



- When the ScanX Acquisition window is opened on the Visix Op A workstation, the ScanX images acquired by the ScanX Controller using Op A tracks will appear at the bottom of the window as thumbnails.

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- When the ScanX Acquisition window is opened on the Visix Op B workstation, the ScanX images acquired by the ScanX Controller using Op B tracks will appear at the bottom of that window as thumbnails.
- To save the images, click on the Select All button at the bottom of the ScanX Acquisition window, then on the Close and Save button. The images will save to the currently selected patient.

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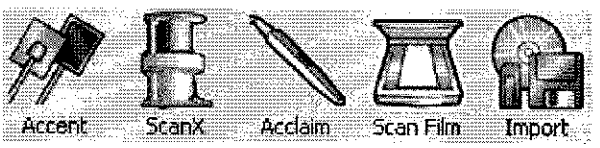
Acquisition Windows

Acclaim Camera

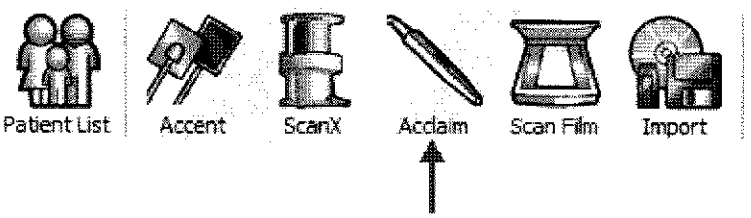
Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.



By default, Visix can only capture video images from the Acclaim USB camera and the SLC USB camera. For other intra-oral camera support, the Universal Video module must be used.

Acclaim Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Acclaim Acquisition window.



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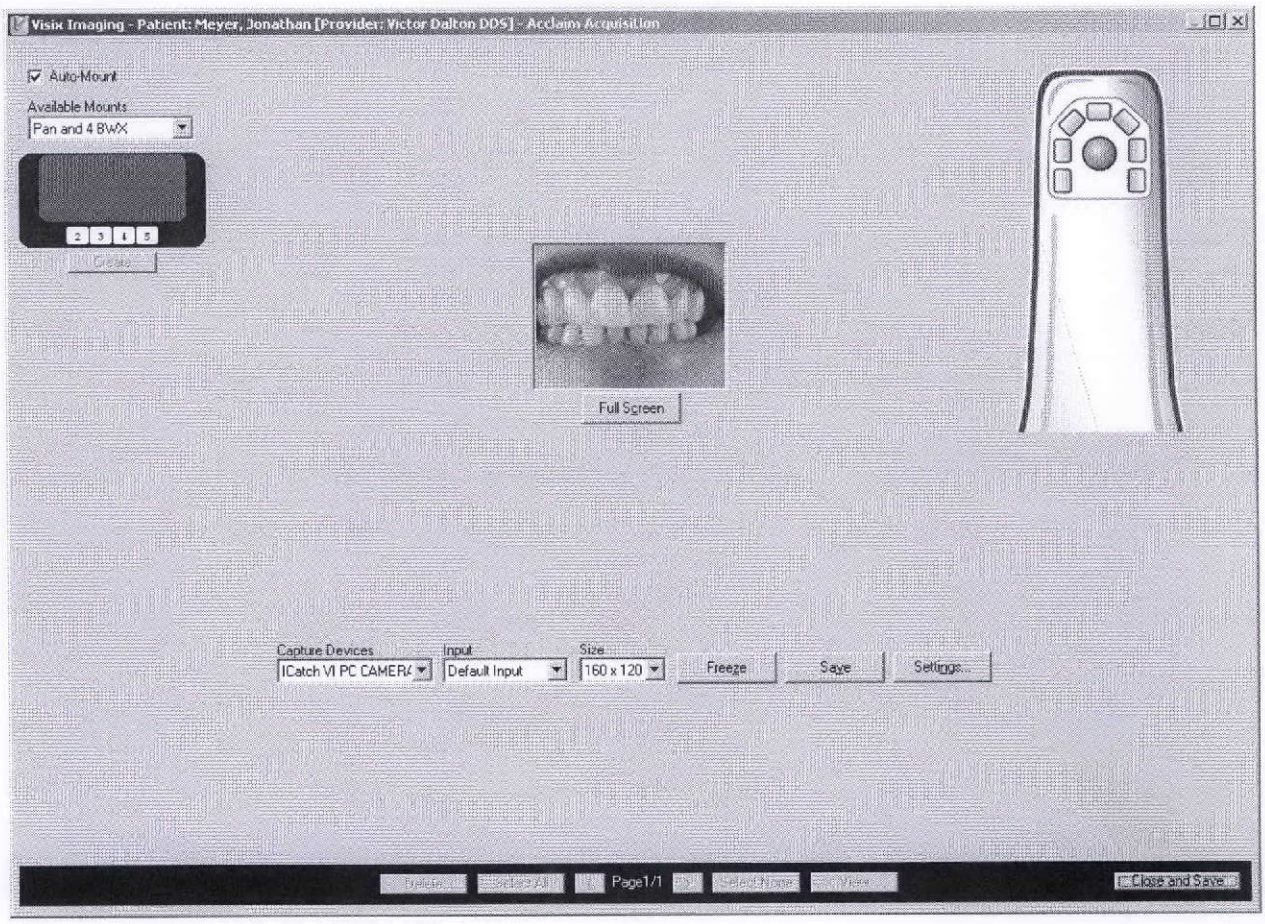

Capture Devices

Click on the down arrow of the Capture Devices drop down box to display the devices Visix can retrieve still images from. Select an intra-oral camera.

Input

Click on the down arrow of the Input drop down box to display different types of input such as S-Video or Composite. Select the correct type for the intra-oral camera that is connected to this workstation.

Size

Click on the down arrow of the Size drop down box to view the different sizes that the window used to display the

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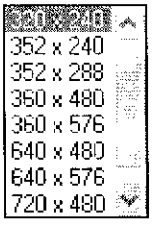
camera's live picture can be adjusted to. A few of the available dpi settings are pictured below.



Select a size. The recommended size for the Acclaim is 640 by 480.

Freeze / Live

Click on the Freeze button to cause the current image from the camera to freeze in the Current Image box. After Freeze is clicked on, either click on Save to put the image in the thumbnail row at the bottom of the window, or click on the Live button to restore the live feed from the camera to the Current Image box. The picture still needs to be saved to bring it into Visix.

Save

Click the Save button to capture an image. A thumbnail version of the image will appear at the bottom of the screen. The Current Image box will return to live feed. The image still needs to be saved to bring it into Visix.

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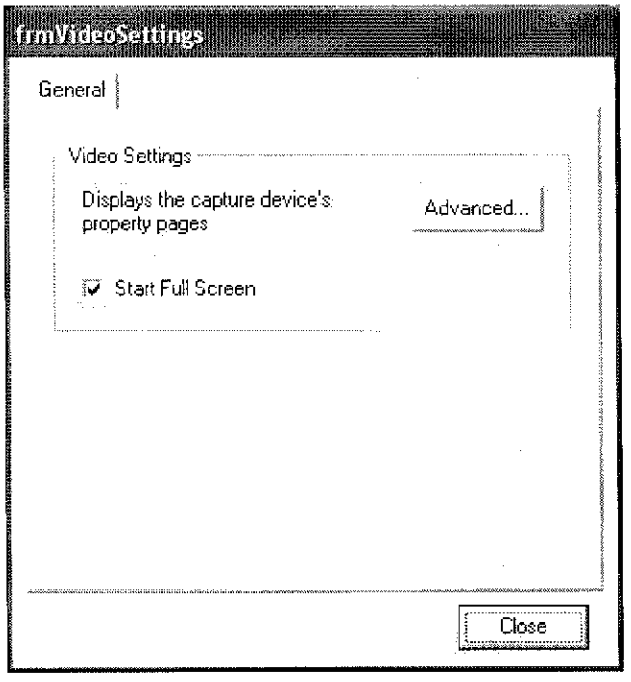
Settings Button

Settings Button – Acclaim Camera



Start Full Screen

Checking this box will automatically start the camera in full screen mode.

Advanced...

Clicking on the Advanced button will open the settings windows for the camera. Please refer to the camera manufacturer's instructions for an explanation of each setting. Please be aware that any changes made here will affect every future image taken by this camera.

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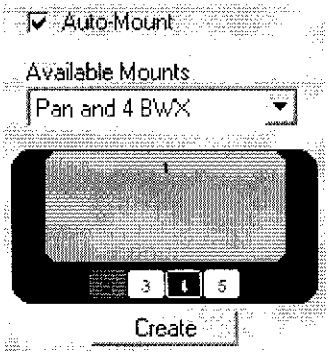
Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

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Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

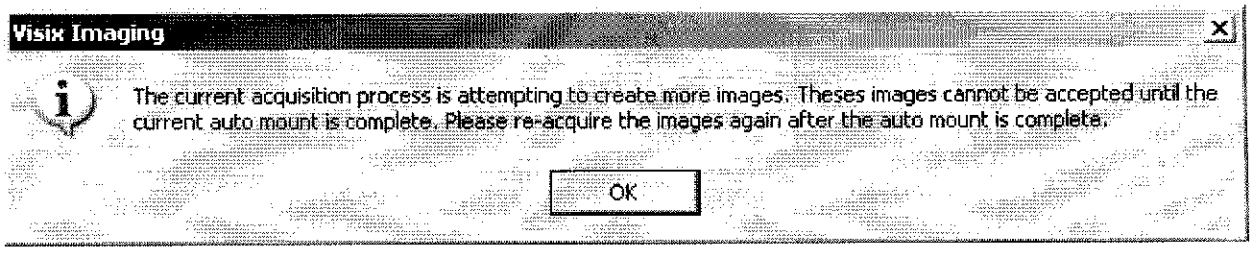
Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

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Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window. Select None

View an Image

To open an image into the View window, first select the image or images to be viewed and then click the View button at the bottom of the window. View

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Save an Image

To save an image or images, click the Close and Save button at the bottom of the window. Close and Save All of the images on the bottom of the window will be saved to the currently selected patient.

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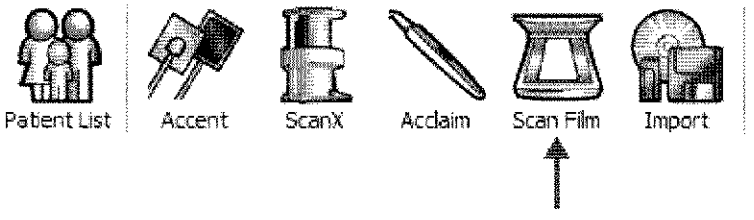
Acquisition Windows

Flatbed Scanner

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

Film Scanning Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Film Scanning Acquisition window.



Setting up Film on the Flatbed Scanner Bed

When scanning film, make sure the scanner's transparency cover – if it has one – is off. It will need to be replaced for scanning documents and photographs.

If the scanner's transparency area does not include the entire scanner bed, line up the negatives under the area of the scanner bed that the transparency area does cover. For example, the Epson Perfection 1600 transparency area includes just an oblong section of the center of the scanner bed. In this case, negatives would be placed in a straight row within the oblong area.

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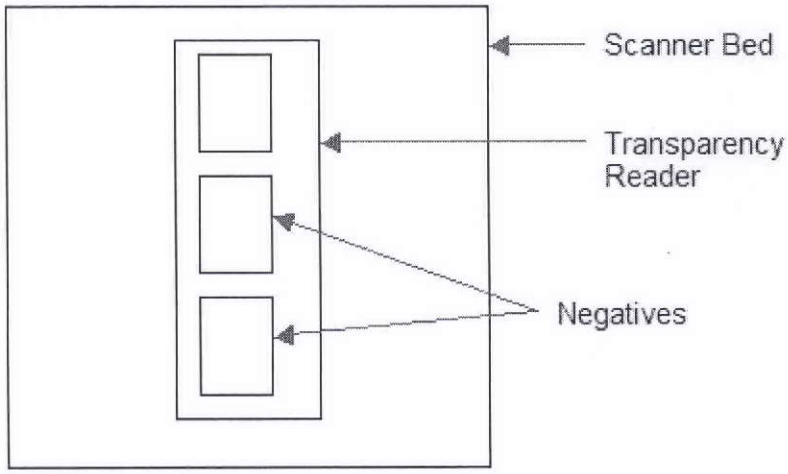
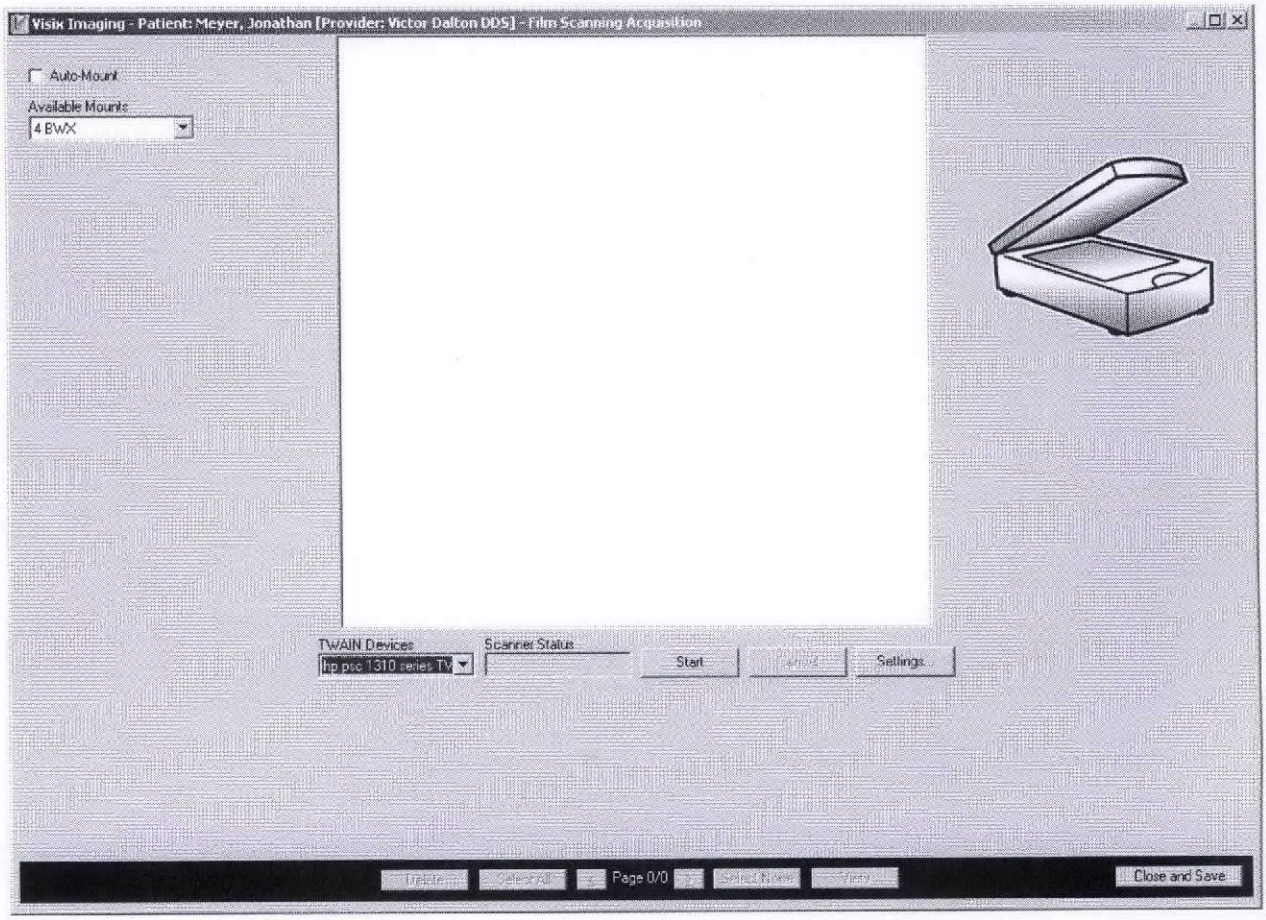


Film Scanning Acquisition Window



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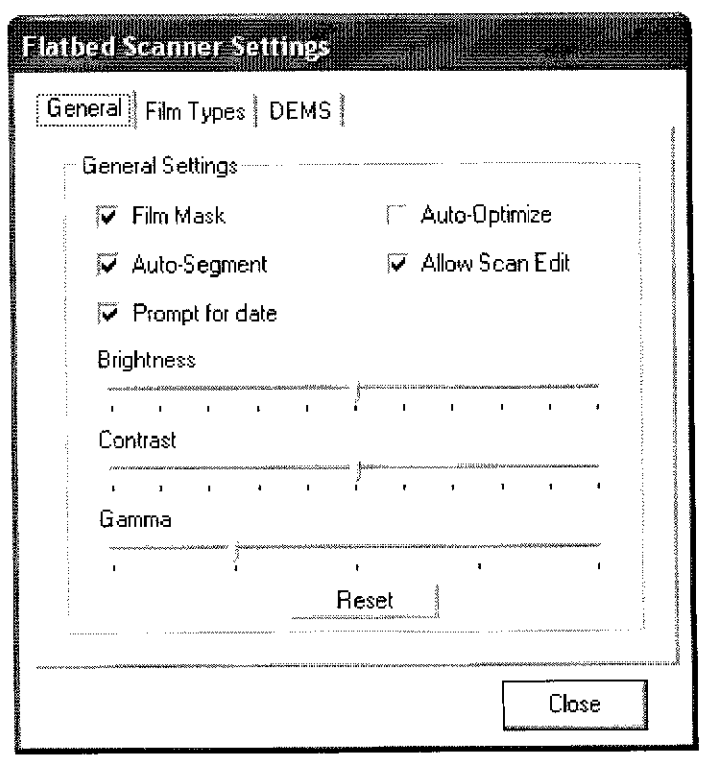
TWAIN Devices

Click on the down arrow of the TWAIN Devices drop down box to display the devices Visix can retrieve scanned images from. Select the appropriate flatbed scanner.

Settings Button for a Flatbed Scanner

The Settings button will display windows that hold optional scanning settings for the scanner that is connected to this computer. These settings are advanced and will apply to all of the future images acquired by this scanner. The Reset button on each window will change the settings for that window back to the original settings Visix came with.

Settings Button - Flatbed Scanner



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General Window

Film Mask

A Film Mask is a black border that is placed around an image in the same way a colored mat surrounds a painting. This border can make the edges of the image look sharper. A check mark indicates that a film mask will be placed on all future flatbed scanned images.

Auto Optimize

Auto Optimize will turn Visix processing routines on in an attempt to enhance the quality of the scanned image. When the film being scanned is over exposed turn Auto Optimize off. A check mark indicates that Auto Optimize is on.

Auto-Segment

Auto-Segment is the ability to automatically recognize separate items on the scanner face as separate images. If four standard size negatives are placed on the scanner face and Auto-Segment is on (the Auto-Segment box has a check mark in it), Visix should place a green selection box around each negative indicating that it recognizes four separate pieces of film to scan.

If Auto-Segment is off (the box is not checked), the user must draw a selection box around each image manually by clicking and dragging a box around the image. Allow Scan Edit must be on (checked) to manually draw selection boxes. Auto-Segment and Allow Scan Edit should never both be off.

Any image that does not have a selection box around it will not be scanned into Visix.

Allow Scan Edit

Allow Scan Edit will allow the user to be able to manually draw selection boxes around each image,

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or edit the selection boxes Visix automatically drew around the images using Auto-Segment.

Any image that does not have a selection box around it will not be scanned into Visix.

For instructions on how to add, edit and remove boxes please refer to the Add a Box Around an Item, Edit a Box Around an Item, and Remove a Box paragraphs coming up in this section of the manual.

Prompt for Date

If Prompt for Date is on (checked) Visix will prompt the user to enter the date the film was originally taken on. If Prompt for Date is off (unchecked), Visix will save each scan using the current date.

Brightness

Changing the Brightness setting can make up for an x-ray machine that shoots images with too much lightness or darkness. Brightness raises or lowers the lightness for every pixel in the image.

Contrast

Increasing the Contrast creates an image where the white areas are whiter and the black areas blacker. This causes the edges of a shape within the image to be more easily seen.

Gamma

A Gamma change leaves the whitest and blackest parts of an image alone as it makes the mid gray values lighter or darker. Changing the Gamma setting can make the image very dark.

Reset

Reset restores the default settings that came with Visix.

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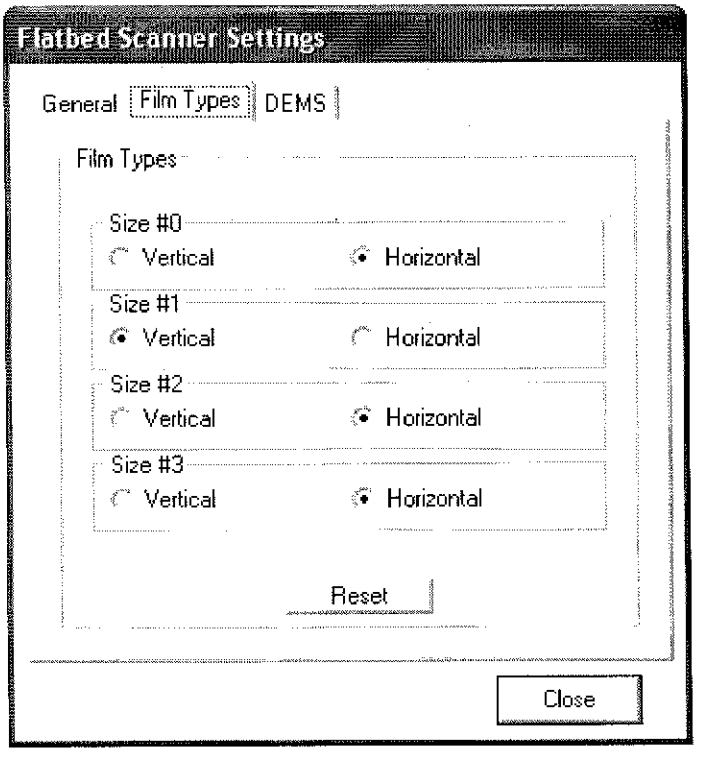
Settings Button – Flatbed Scanner



Film Types Window

The Film Types window lists four sizes of film and whether each is to be scanned into Visix in either a vertical or horizontal position. No matter how an image is brought into Visix, its orientation can always be changed later, from vertical to horizontal or from horizontal to vertical.

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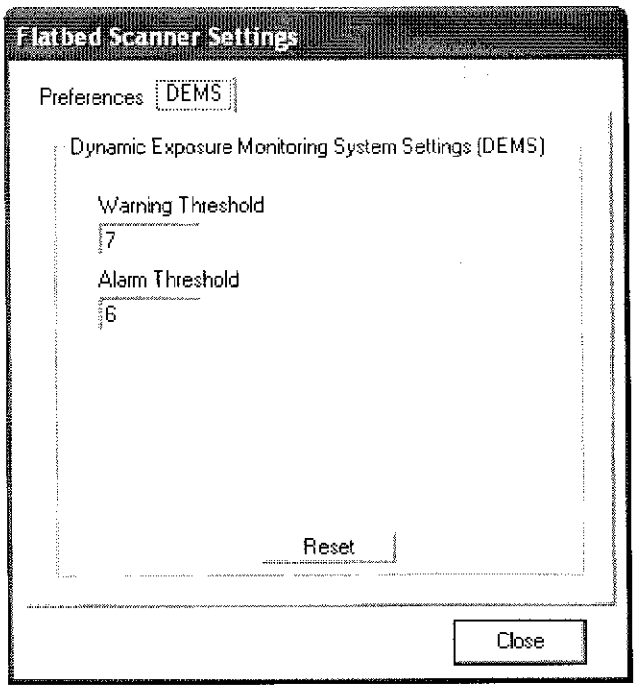
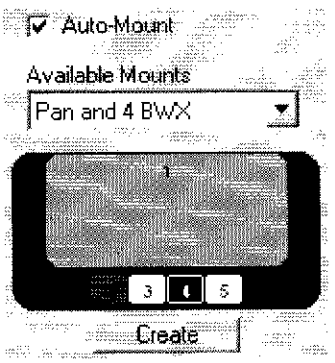
Settings Button - Flatbed Scanner



DEMS Window

DEMS stands for Dynamic Exposure Monitoring System. The DEMS thresholds are an advanced feature that should never be altered by the user without the permission of a Visix representative. If, for some reason, the DEMS settings are altered, clicking on the Reset button Reset will restore the original settings.

Auto-Mount



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Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is

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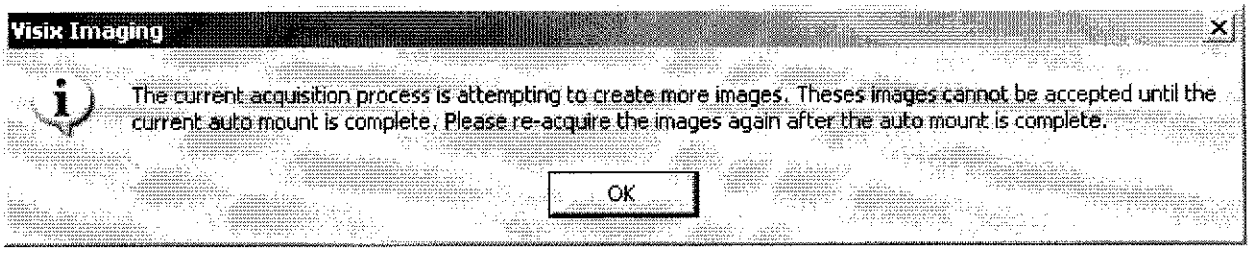
scanned will be placed in the open mount space that was created by removing the image.

Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

At the Flatbed Scanner

Load the film onto the flatbed scanner.

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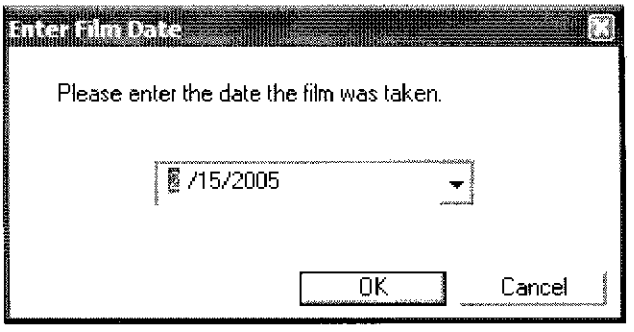
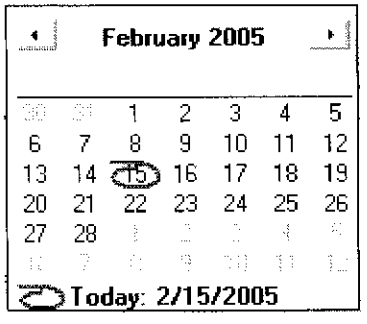
Start Button

Click on the Start button on the Film Scanning window to tell Visix a scan is ready to begin.

Enter Film Date



Enter the date that this film was taken then click on the OK button. If you are not sure of the date, click on the down arrow of the Enter Film Date drop down box to display a calendar.



Click on the left and right arrows that are on either side of the month and year to step backwards or forwards through the months. Click on a day to automatically insert that date into the Enter Film Date box and close the calendar.

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After the scan date has been entered, the scanner software will open.

Scanner Settings

For most flatbed scanners, the settings for the scanner driver window should resemble the following:

- Mode — Professional
- Document Type — Film
- Film Type — Positive Film
- Image Type — 8-bit Grayscale
- Resolution — 200dpi

Once the settings have been adjusted, click on the Scan button to begin the scan. Note that some scanners perform better if a Preview scan is performed before the actual scan.

During the Scanning Process

Visix will automatically capture the image from the flatbed scanner. If the Cancel button [Cancel] is clicked on during the scanning process, the scan will be aborted.

After the Initial Scanning Process if Allow Scan Edit is on

Once an image has been scanned, if Allow Scan Edit is on (the Allow Scan Edit box is checked on the Settings Button – General tab), Visix will pause to allow the user to add or edit selection boxes around each image. At this point, the scanner software will have closed, Visix will be open with the scan visible in the Current Image Box, and the Finish button will be present. An image must have a selection box around it for Visix to acquire it.

Add a Selection Box Around an Item

Adding a selection box around an item will cause Visix to scan that item. To add a selection box, left click on a corner of the item, hold the left mouse button down and drag the mouse to the opposite corner of the item to scan.

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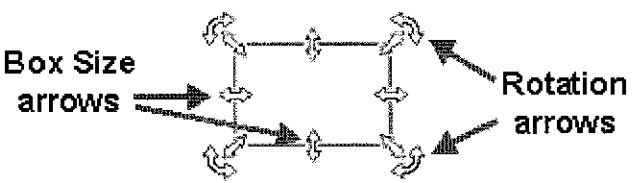
Each side of the box should touch its matching side on the image. If they don't, refer to the next paragraph.

Edit a Selection Box Around an Item

Editing a selection box involves using the resizing or rotating arrows on the box to change its size or orientation. The rotating arrows are curved arrows that are located at the corners of the box. The resizing arrows are straight arrows and are located in the middle of each side. Click and drag the appropriate arrow until each side of the box touches its matching side on the image.



Remove a Selection Box

Removing a green or blue selection box from around an item prevents that item from being scanned. To remove a selection box, right click on the box and select Delete Outline.

After the Boxes have been Adjusted

Once the user is done adjusting boxes the Finish button should be clicked to allow the final scanning processes to start. Once an image has been scanned, a small version of it, called a thumbnail, will appear in the lower left part of the Film Scanning window. The image still needs to be selected and saved into the Visix database.

After the Final Scanning Process

To check an image, double click on the image to open it into the Visix View window. When finished, close the View window by clicking on the Close Window box ☒ in the upper right corner of the window.

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Image Buttons

Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the window. Delete
Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. Select All
A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the window.
Select None

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window.
View

Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window.
Close and Save All of the images that appear as thumbnails at the bottom of the Acquisition window will save to the currently open patient.

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Acquisition Windows

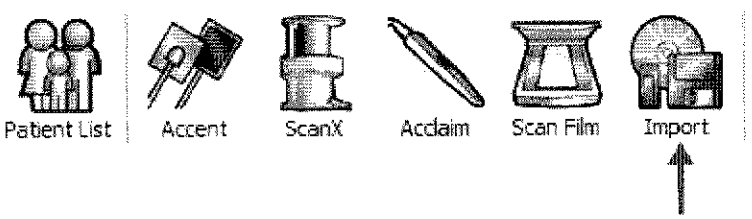
Import

Images are entered into Visix through the Acquisition buttons. The types of input include X-rays from an Accent sensor, a ScanX phosphor plate scanner, or a flatbed scanner, Video Stills from an Acclaim camera, and imported images.

Importing is the process by which a digital image, photo or document can be copied into Visix from a location that is outside of Visix.

Import Acquisition Window

Click on the Acclaim button on the Visix toolbar to open the Import Acquisition window.



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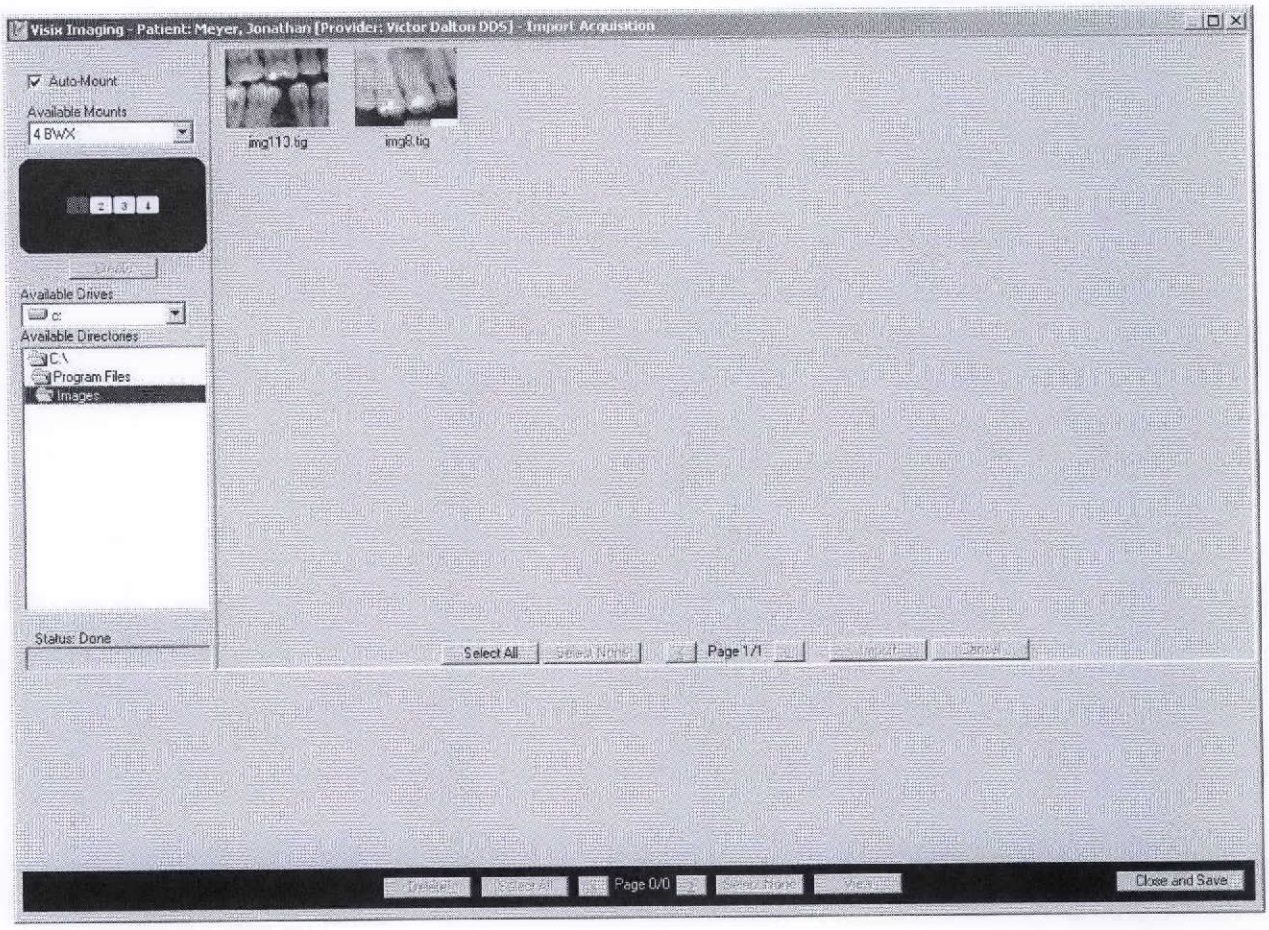
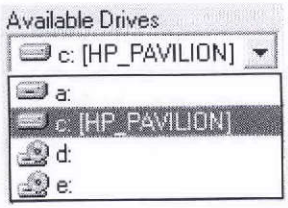


Available Drives

Click on the drop down box arrow to display the list of drives this computer can access. If this computer is on a network and has network drives mapped, the network drives will also display.



Select the drive where the imported images can be found. Note that the computer views many digital cameras as removable hard drives.

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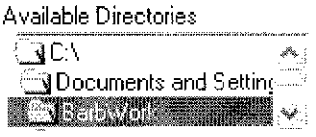
Available Directories

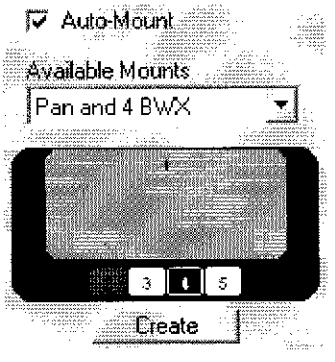
After the drive is selected, a list of the folders (also called Directories) on that drive will display.



Select the folder where the imported images can be found. Any images in the selected folder (directory) on the selected drive will display in the Current Image box on the Acquire window.

To import an image, select the image by left clicking on it once then click on the Import button. The image will appear at the bottom of the window, and, if Auto-Mounting is turned on, in the selected mount. Select the image at the bottom of the window and click on the Save button to save the image to the currently selected patient.

Auto-Mount



Check the Auto-Mount checkbox to automatically place each scanned image into a previously created and saved mount. Click on the down arrow of the Available Mounts drop down box to select a mount. The selected mount will display in the black mount box underneath the Available Mounts drop down box.

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Scanning Order

When using the Auto-Mount feature, images must be scanned in the order they are placed into the mount. For example, in the mount displayed above, the first scanned image would be placed in the image box with the number one on it, the second scanned image would be placed in the image box with the number two on it, etc. When mounting a large number of images, such as a full mouth series, taking the x-rays in the order specified by the mount can become a more complicated business.

Auto-Mount Colors

Different colors are used to represent different image holder situations in an auto-mount. An image holder that is green has an image loaded. An image holder that is red indicates the holder into which the next scanned image will be placed. An image holder that is white is empty. An image holder that is black will be skipped.

Skipping an Image in the Mount

There will be times when some of the image holders in a mount will need to be skipped because that particular x-ray was not taken. To skip an image holder, click on it before the scan begins. The image holder will turn black. Clicking on the image holder again will remove the black and allow the image holder to receive an image again.

Deleting an Image

If an image used in the mount is deleted before the mount is saved the image will automatically be removed from the mount. The next image that is scanned will be placed in the open mount space that was created by removing the image.

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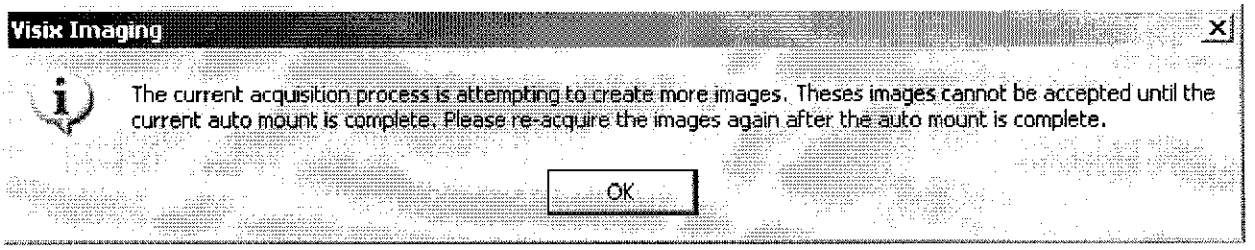
Creating the Mount

When a mount is full it will flash three times. Clicking on the Create button at this time will save the mount without disrupting any scanning that is still going on. This allows further scans to be placed in a new, empty mount automatically.

If the Create button is not clicked on time, the following warning message will appear and scanning will stop.



If the warning message appears, click on the OK button to close it, click on the Create button to save the mount, and then rescan any plates that did not have their image acquired.

Manually Mount Images

The alternative to Auto-Mount is to mount the images manually by dragging them onto a mount using the Mount window. For instructions on how to mount images manually, please refer to the Mount Window section of this manual.

Image Buttons Within the Current Image Box

Select an Image

To select an image to import, left click on it. To select multiple images, click on multiple images. To select all of the images click on the Select All button at the bottom of

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the Current Image box. Select All A selected image will have a green box around it.

Deselect an Image

To deselect an image, click on it a second time. To deselect all of the images click on the Select None button at the bottom of the Current Image box. Select None

Import an Image

To import an image, first select the image or images that require importing then click on the Import button at the bottom of the Current Image box. Import The image or images still need to be saved into the Visix database.

Stop the Import

If, during the import operation, the image is no longer desired, click on the Cancel button at the bottom of the Current Image box. Cancel The Cancel button will abort the import operation.

After the Import

Once an image has been selected and imported it will move to the area under the Available Directories box as a thumbnail image. The image still needs to be selected and saved into Visix.

To check an image, double click on the image to open it into the Visix View window.

Image Buttons below the Current Image Box

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Delete an Image

To delete an image, first select the image or images to be deleted, and then click on the Delete button at the bottom of the Acquisition window. [Delete] Deleted images are not recoverable.

Select an Image

To select an image, left click on it. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the Acquisition window. [Select All] A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on it again. To deselect all of the selected images, click on the Select None button at the bottom of the Acquisition window. [Select None]

View an Image

To open a single image into the View window, double click on the image. To open multiple images into the View window, first select the images to be viewed, and then click on the View button at the bottom of the Acquisition window. [View]

Save an Image

To save images, click the Close and Save button at the bottom of the Acquisition window. [Close and Save] All of the images that appear as thumbnails at the bottom of the Acquisition window will save to the currently open patient.

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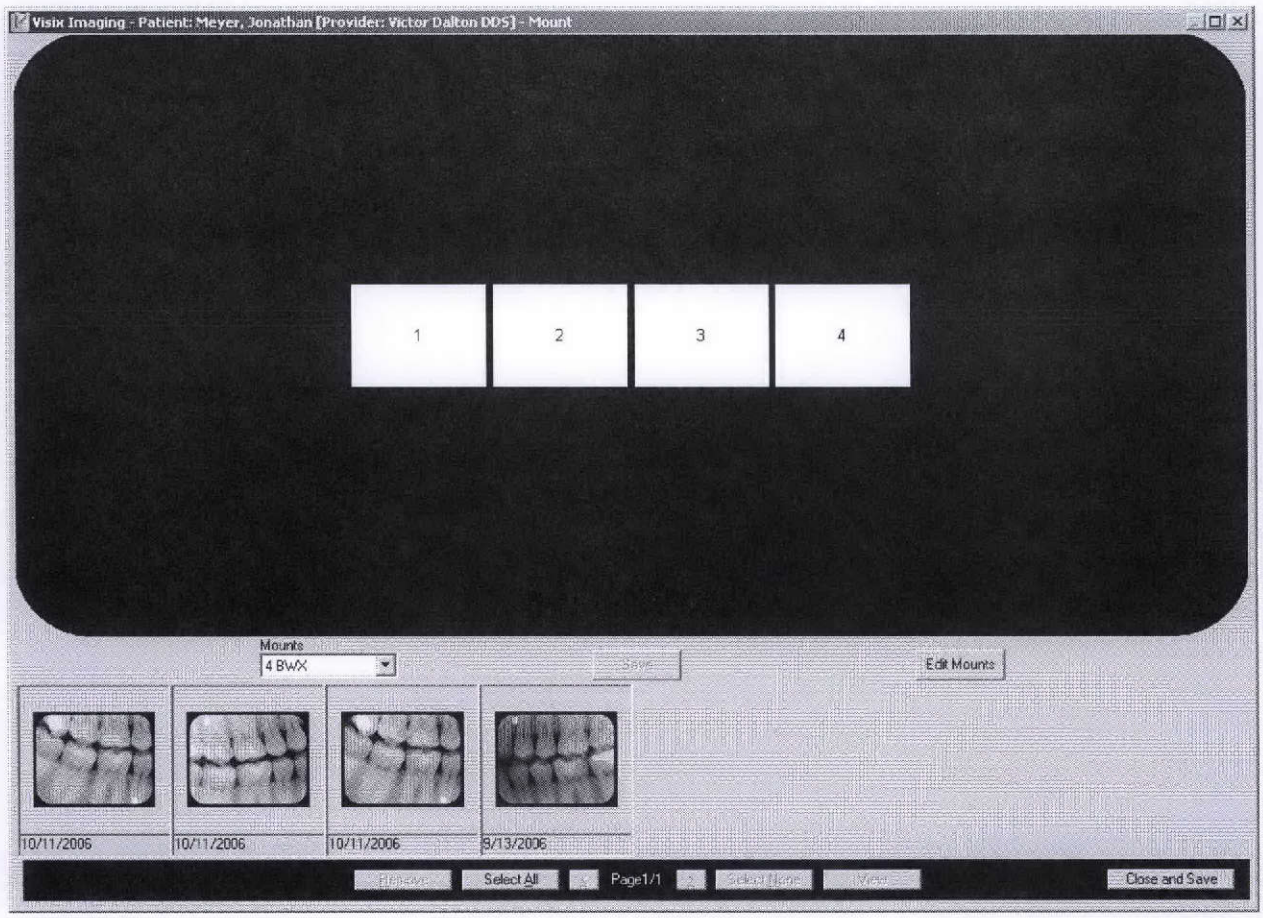
Mount Window



Any saved image can be brought to the Mount window to be viewed, and/or mounted.

Bring Images to the Mount Window

To bring images to the Mount window, select the images from the Images window, and then click on the Mount button at the top of the main Visix window. The images will appear on the Mount window below the black Digital Light Box.

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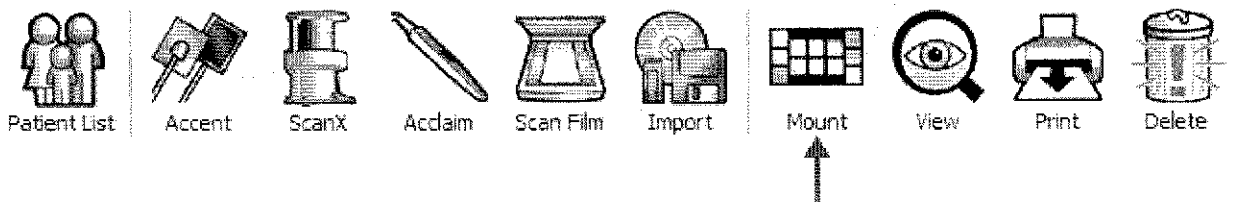


Using the Mount window to view existing mounts

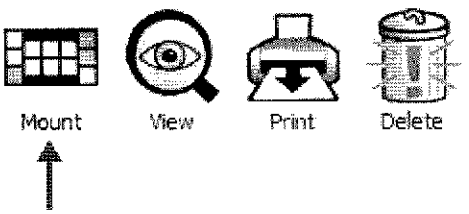
To use the Mount window to view an existing mount that has images in it, bring the mount to the Mount window then drag the mount onto a dark part of the Mount box. Double left click on each image in the mount to view that image in the View window.

Using the Mount Window to Mount Images

Mounting images is similar to placing photographs inside a mat that has multiple openings. The mounted photographs are now grouped together and can be viewed as one large picture. In the same way, images can be placed into the same mount then viewed, printed and exported as a single image.

Mount Images Using Existing Mount Templates

Move the images that need to be mounted to the Mount window by clicking on them and then clicking on the Mount button.



Click on the down arrow of the Mounts drop down box and select a mount.

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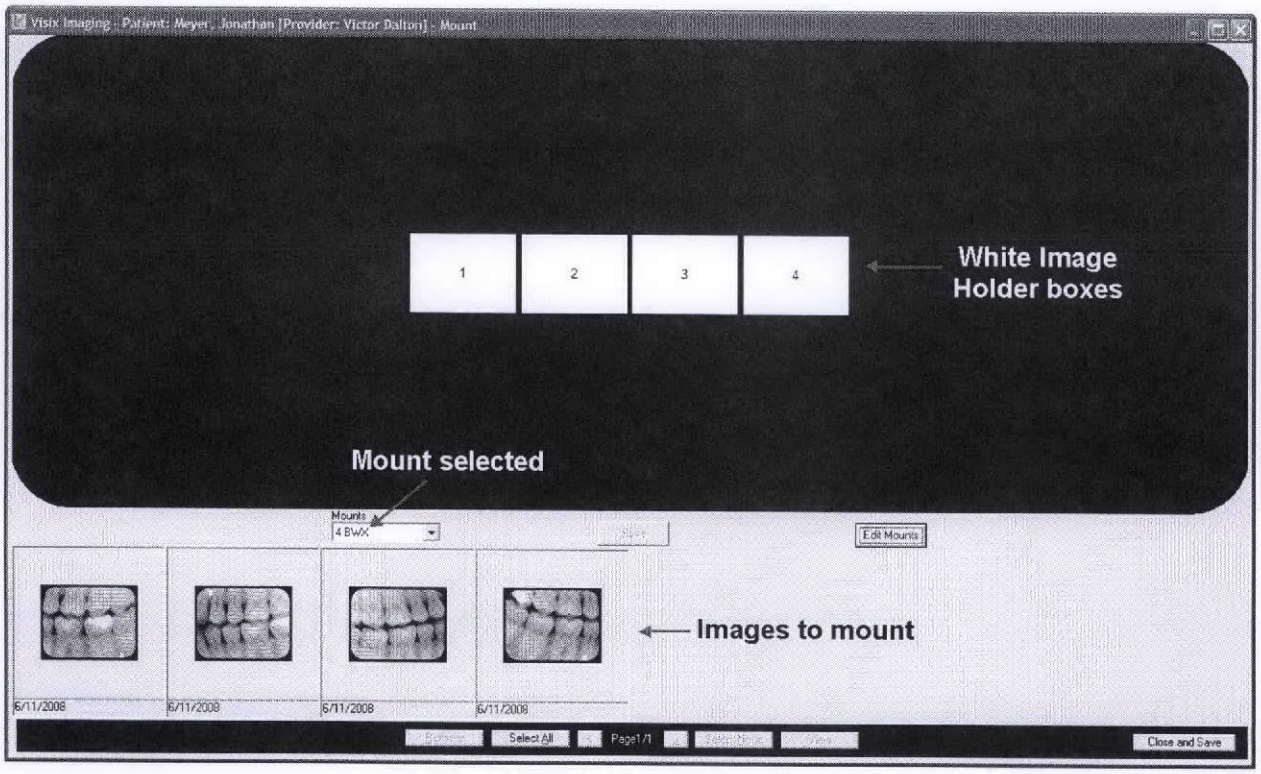
The white boxes that appear in the black Digital Light Box are meant to hold the images. Drag the images, one at a time, onto a white Image Holder box. The order that the images are dragged onto the white boxes does not matter.



- To move an image within the mount, drag the image from its current location in the mount to a different Image Holder Box.

- To remove an image from the mount, right click on the image in the mount and select Remove from the Right Click Menu that appears.

- To change the orientation of an image in the mount from vertical to horizontal or from horizontal to vertical, the orientation of the Image Holder Box must be changed. For instructions on how to change the orientation of an Image Holder Box on an existing mount please refer to the Edit An Existing Mount section below.

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When the images have been correctly placed in the mount, click on the Save button

to save them as a single mounted image

Making Changes after Images have been mounted and the Mount has been saved

Select a mount, plus any additional images that need to be placed in that mount, by clicking on them, and then click on the Mount button.

In the Mount window, drag the mount onto a black area of the Digital Light Box instead of onto a white Image Holder Box. The mount will open for editing. Images can be moved, removed, or added to the mount.

Move an Image in an Existing Mount

Once an existing mount has been opened for editing, an image can be moved by dragging it to a different Image Holder Box.

Remove an Image from an Existing Mount

Once an existing mount has been opened for editing, an image can be removed from it by right clicking on the image and selecting Remove from the Image Holder Right Click Menu that appears.

Add an Image to an Existing Mount

The mount plus the images to add to it must be moved to the Mount window at the same time. Once an existing mount has been opened for editing, images can be added by dragging them to Image Holder Boxes.

Save the Updated Mount

Click on the Save button to save the updated mount. The following window will open:

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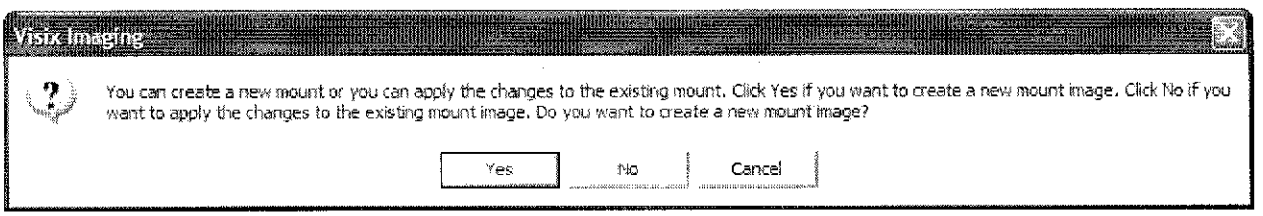


- Click on Yes to keep the original mount and save the updated mount as a separate image.
- Click on No to save the updated mount and delete the original mount image.
- Click on Cancel if the mount needs additional adjusting.

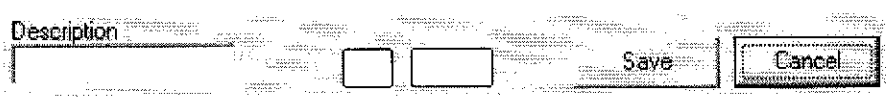
Create a New Mount Template

To create a new mount, in the Mount window click on the Edit Mounts button.

The area of the window underneath the Digital Light Box will change.

Click on the Add button to create a new mount.

The area of the window underneath the Digital Light Box will change again.



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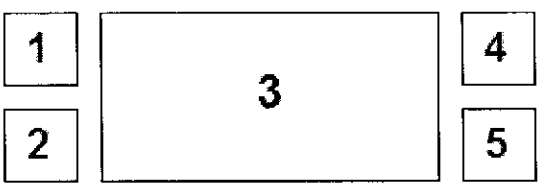
To create a new mount, drag one of the two boxes onto the Mount box to create an Image Holder. The boxes that are dragged onto the Mount box cannot touch each other. The larger oblong box, when dragged onto the Mount box, will hold a pan or ceph image. Notice that the Image Holder boxes are numbered. The numbers are important only if the mount is going to be used with the Visix Auto-Mount feature.

Creating a Mount that will be used with for Auto-Mounting

If the Auto-Mount feature is going to be used with this mount, the Image Holders must be placed on the mount in the same order that the images coming into Visix will be loaded into the mount. For example:



In the mount above, two bitewings are located on each side of a pan. Using a phosphor plate scanner for this example, the first plate that is scanned will be placed into the Image Holder with the number 1 on it, the second plate that is scanned will be placed into the Image Holder with the number 2 on it, the third plate that is scanned will be placed into the Image Holder with the number 3 on it (the pan), etc. If the plates are fed into the scanner in the wrong order the pan may end up in a bitewing sized Image Holder.

Image Holder Right Click Menu

To change one of the image holder boxes on the Digital Light box, right click on it. The Image Holder Right Click Menu will appear.

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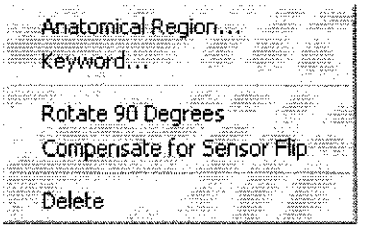
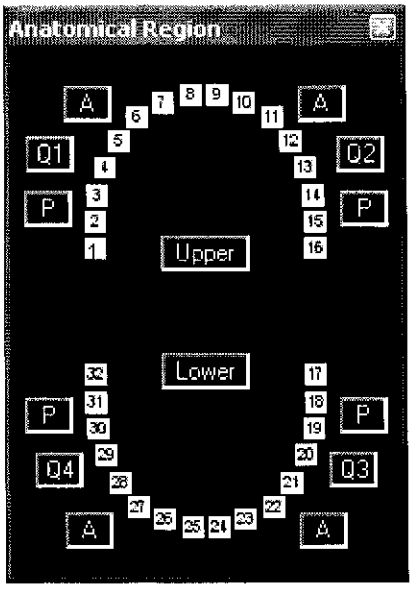


Anatomical Region



If the same type of image will always be placed in this image holder, the anatomical region represented can be preset. Select the teeth in the diagram that correspond with the teeth in the image by clicking on them. Clicking on "A", "P", "Q1", "Q2", "Q3", "Q4", "Upper" or "Lower" will highlight sets of teeth in green. Left clicking on a specific tooth number will highlight an individual tooth. Clicking highlighted teeth will un-highlight them. Changes to this window are saved when the window's close button ☒ is clicked.

Saving the anatomical region allows this image to appear (or not appear) in response to a search by anatomical region. The search is performed on the Patient Window.

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Keyword

If the same keyword will be assigned to every image placed in this image holder, the keyword associated with it can be preset. Assign Keywords by selecting them from the pull down menu. For instructions on how to use the Keywords window please refer to the Right Click On An Image section of this manual.

Rotate 90

Select Rotate 90 to rotate the Image Holder 90 degrees.

Compensate for Sensor Flip

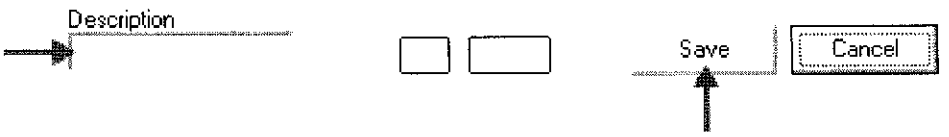
Select Compensate for Sensor Flip to automatically flip an image being placed in this image holder by a sensor. A check will appear next to this option on the Image Holder Right Click Menu to indicate that this function has been activated.

Delete

Select Delete to remove the Image Holder from the mount.

Complete the New Mount

When the Image Holders are adjusted correctly in the mount, click in the Description box and enter a descriptive title for this mount, then click on the Save button to save the new mount.



Edit an Existing Mount Template

To change an existing mount, in the Mount window click on the Edit Mounts button.

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The area of the window underneath the Digital Light Box will change.

Click on the down arrow of the Mounts drop down box to select the mount to edit, then click on the Edit button to edit the selected mount.

The area of the window underneath the Digital Light Box will again change.

Anything on the mount, including its description, can be changed. If the mount is being used with the Auto-Mount feature be cautious about adding and deleting Image Holders. You may affect the order that the digital images should come into Visix (see Creating A Mount That Will Be Used For Auto-Mounting above). When all of the changes have been made, click on the Save button Save to save the mount. Click on the Close Editor button to end this edit session.

Delete an Existing Mount Template

To delete an existing mount, in the Mount window click on the Edit Mounts button.

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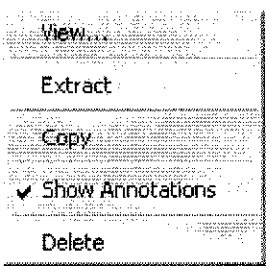
The area of the window underneath the Digital Light Box will change.

Click on the down arrow of the Mounts drop down box to select the mount to delete, then click on the Delete button. Click on the Close Editor button to end this edit session.

Right Click Menu for Images in the Mount Window

Placing the cursor on an image that has been dragged onto an Image Holder in the Mount box, then clicking the right mouse button once opens the Right Click Image Menu displayed below.



View

To view an image in the View window, right click on the image in the Mount and select View from the menu that appears. In the View window the image can be magnified, rotated, flipped, colorized, embossed, annotated, measured, inverted, etc.

Extract

To copy an image from the Digital Light Box to the area underneath the Digital Light Box, right click on the image in the Digital Light Box and select Extract from the menu that appears.

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Copy

To copy an image to the clipboard from the Digital Light Box, right click on the image in the Digital Light Box and select Copy from the menu that appears. The image will be copied to the clipboard and can then be pasted into any software product that can utilize the clipboard.

Show Annotations

Show Annotations will cause the annotations to display on the thumbnail version of the image. Selecting Show Annotations when the annotations already display will cause the annotations to be hidden.

Delete

To remove an image from a mount but leave it on the Mount window under the Digital Light Box where it can be used again, right click on the image in the Mount and select Delete from the menu that appears.

How to Drag and Drop an Image

To drag an image

Place the cursor (the arrow that moves on the screen when the mouse is rolled on a flat surface) on top of the desired image. Press down and hold the left mouse button. While holding the left mouse button move the cursor, by sliding the mouse on a flat surface.

To drop an image

To drop an image, release the left mouse button.

Image Buttons

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Remove an Image from the Mount Window

To remove an image from the Mount window, click on the image under the Digital Light Box then click on the Remove button at the bottom of the Mount window.

Select an Image

To select images, left click on them. To select multiple images, left click on multiple images. To select all of the images click on the Select All button at the bottom of the window. A selected image will have a green box around it.

Deselect an Image

To deselect an image, left click on the image again. To deselect all of the selected images, click on the Select None button at the bottom of the window.

If an image was mistakenly removed from the Mount window right click on the image in the mount and select Extract. A copy of the image will be placed under the Digital Light Box.

View an Image

To open an image in the View window, first select the image or images to be viewed, and then click on the View button at the bottom of the Images window. Another way of opening images in the View window is to first select the image or images to be viewed, then right click on one of the images and select View from the right click menu. For instructions on how to use the View window, please refer to the View Window section of this manual.

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View Window

The View window is used to examine and manipulate an image, through measurements of angles and lines, flipping, rotating, colorizing, zooming, changes in brightness and contrast, magnifying, annotations, etc.

Open an Image into the View window from the Images Window

To open a single image into the View window, double click on the image using the left mouse button or right click on the image and select View from the Right Click Menu.

To open multiple images into the View window do one of the following:

- Left click on the All button at the bottom of the Images window then right click on one of the selected images and select View from the Right Click Menu.
- Left click once on each image that needs to be viewed to select it, then left click once on the View icon at the top of the Visix window.
- Left click once on each image that needs to be viewed to select it, then right click on one of the selected images and select View from the Right Click Menu.

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Sections of the View Window

The box where the image appears is the Current Image box. To the left of the Current Image box are the tools available to examine and manipulate the image. At the top of the Current Image box are any settings and requirements needed for the currently selected tool. To the right of the Current Image box are the tools that adjust the brightness and contrast.

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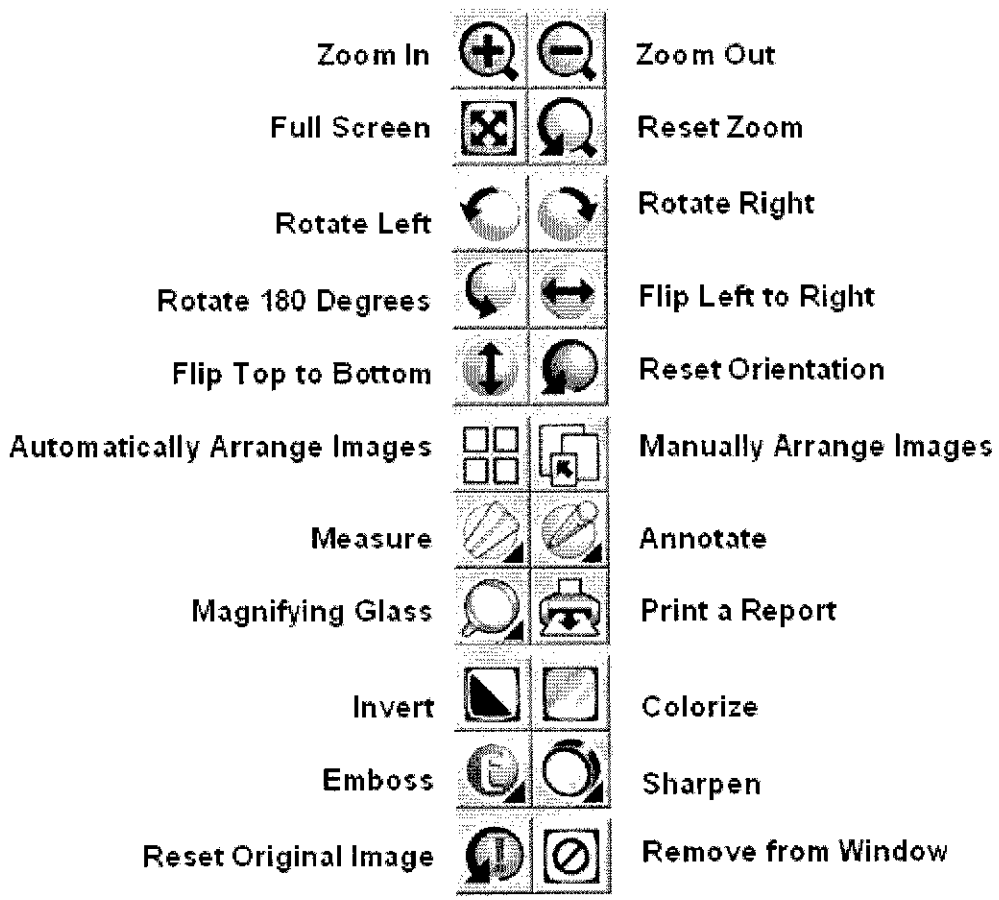
View Window Toolbar



View Window Tools

The tools will affect either the single image in the View Window, or, if there are multiple images in the window, the selected image. Left click once on an image to select it. The selected image on the View window will have a green box around it.

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Pan Tool

When viewing an image that has been zoomed in on, the Pan Tool can be used to move the area being displayed. Click and drag the red Pan Box to change the section of the zoomed in image that is currently displayed in the View window.

Zoom In

Each click on the Zoom In tool will make the image a little larger.

Zoom Out

Each click on the Zoom Out tool will make the image a little smaller until it's restored to its original size.

Full Screen

If more than one image is open in the View window, clicking on the Full Screen tool will make the selected image (the image with the green box around it) fill the View window. Click on Full Screen again to make the selected image fill the entire window. Click on Full Screen a third time to return the image to its original size.

Reset Zoom

Click on the Reset Zoom tool to return the image to its original size.

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Rotate 90 Degrees Counter Clockwise

Click on this tool to turn the image 90 degrees to the left.

Rotate the Image 90 Degrees Clockwise

Click on this tool to turn the image 90 degrees to the right.

Rotate the Image 180 Degrees

Click on this tool to turn the image 180 degrees so that what had been at the top of the image is now at the bottom of the image.

Flip the Image from Left to Right

Click on this tool to flip the image over from left to right.

Flip the Image from Top to Bottom

Click on this tool to flip the image over from top to bottom.

Reset the Image to its Original Orientation

Click on the Reset tool to return the image to the orientation it had when it was originally acquired.

Automatically Arrange Images

Click on the Auto Arrange Images tool to move the images in the View window to the position they were in when the View window was opened.

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Manually Arrange Images

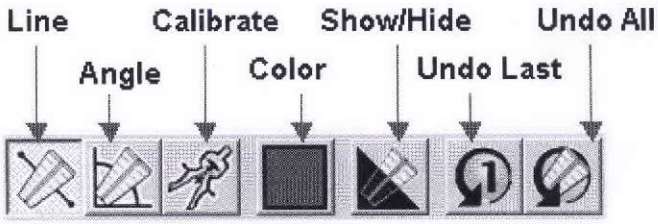
Click on the Manually Arrange Images tool to allow the images to be resized and moved anywhere on the View window. To move an image, click on the image and drag it to a new location. To resize an image, move the cursor on top of a corner box. When the cursor becomes a two headed arrow click and drag the corner box until the image becomes the desired size.

Measure

Click on the Measure tool to open the Measure Options window. The Measure tool might need to be calibrated before it can be used. After calibrating, if the color the lines will be drawn in needs to be changed, click on the Line Color button and select a new color. At this point, measurements may be taken.

Note: For accurate measurements, not only does the calibration need to be precise, but also the patient positioning and the acquisition device positioning needs to be precise to avoid images that are taken on an angle. Images taken on an angle will have measurements that are slightly different from reality.

To close the Measure options window, click on the Measure tool again.



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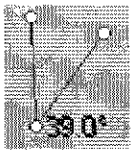
Line

Click on the Line option to measure a line. Left click on one end of the line then left click on the other end of the line. Right click to stop measuring lines.

Angle

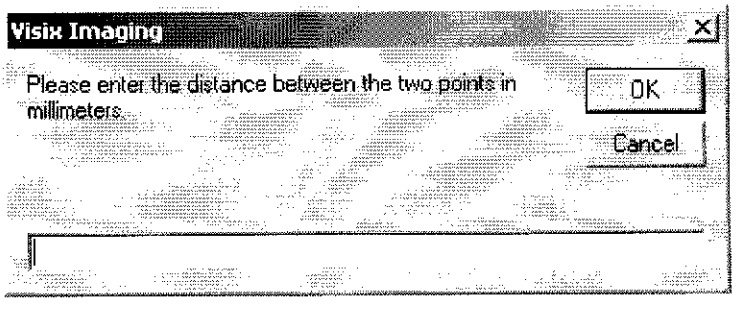
Click on the Angle option to measure an angle. Click on the end of one leg, then at the point of the angle, and finally on the end of the second leg. Right click to stop measuring angles.



Calibrate

To calibrate, something that has a known measurement in millimeters must be on the image. Click the Calibrate button, click on one end of the object to measure, then click on the opposite end of the object to measure. Do not click and drag.

The Calibrate window will appear.



Enter the length of the object in millimeters. For example, if the object is 20 millimeters long enter 20 then click on the OK button. Do not enter "mm" for millimeters. Once the system is calibrated, angles and lines can be measured.

Note: Be as precise as possible when drawing the calibration line. Try to start and end the calibration line exactly on the edges of the object that is being used for

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calibration. In addition, try to keep the calibration line as straight as possible, avoiding the tiny jogs in the line that the computer adds to create a line that angles across the screen.

Line Color

Select the color of the line from the pallet window that opens. The color must be selected before the line is drawn.

Show/Hide

The when the Measure tool is opened the default for Show/Hide is to Show the lines. Click on the Show/Hide option to allow the measurement lines to remain on the image but not display. Click on the Show/Hide option again to display the lines.

Undo Last

Delete the last measurement made on the currently selected image.

Undo All

Delete all of the measurements from the currently selected image.

Annotate

When the Annotate tool is clicked, the Annotation options window appears above the Current Image box. Note that annotations on an image cannot be moved or changed in any way. To move or change an annotation, the annotation must be deleted and then reentered.

To close the Annotation options window click on the Annotate tool again.

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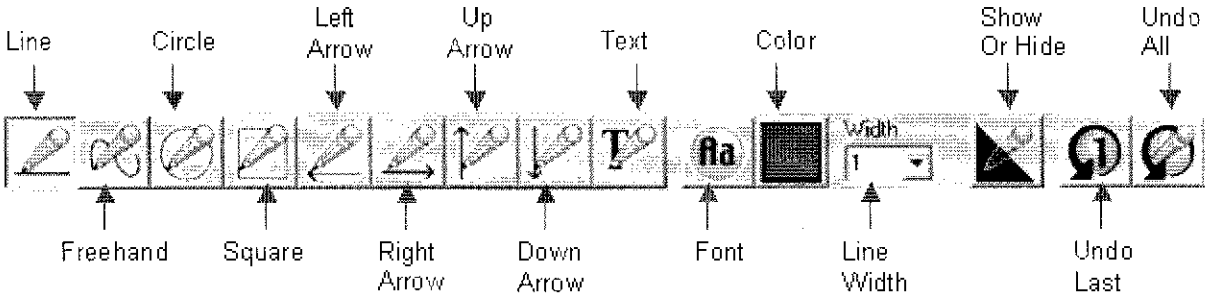

Line

Select the line width and color first, then left click on the image on one end of the line, left click on the other end of the line, and right click to stop the line drawing. A series of connected lines (for example, to draw a triangle) can be drawn by left clicking at each corner and right clicking only when all of the lines have been drawn.

Freehand

Select the line width and color first, then hold down the left mouse button and draw.

Circle

Select the line width and color, then click and drag a circle on the image.

Square

Select the line width and color first, then click and drag the square on the image.

Arrows

Select the left, right, up or down arrow option then left click where the tip of the arrowhead should be. Arrows and text are not affected by line width.

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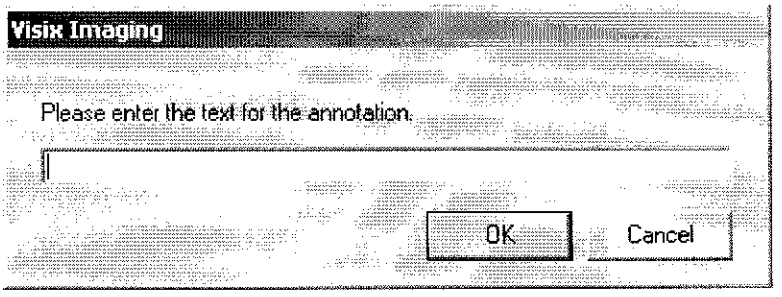
Text

Select the text color and font first then click on the point at which the first letter of the text should be placed. The Text Entry window will display allowing the text to be entered. Arrows and text are not affected by line width.



Font

Select the font, font style and font size for the text before entering the text.

Color

Select the color the annotation will display in before creating the annotation.

Width

Select the width of the line for a line, freehand, circle or square before it is drawn.

Show/Hide

The when the Annotation tool is opened the default for Show/Hide is to Show the annotations. Click on the Show/Hide option to allow the annotations to remain on the image but not display. Click on the Show/Hide option again to display the annotations.

Undo Last

Delete the last annotation placed on the currently selected image.

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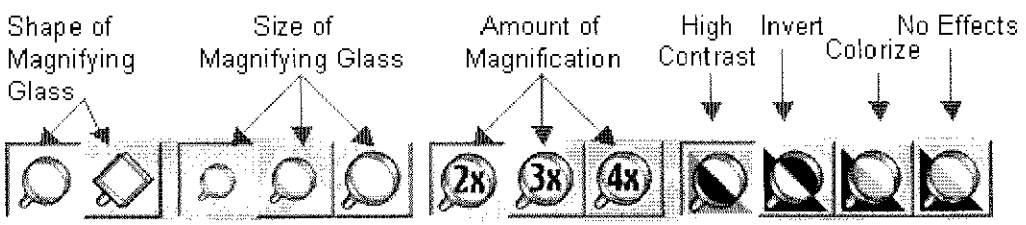
Undo All

Delete all of the annotations from the currently selected image.

Magnifying Glass

Click on the Magnifying Glass tool to open the Magnifying Glass Options window.



Click on the desired shape, size, magnification amount and special effect then hold the left mouse button down as the mouse is moved over the image. The area under the mouse will be affected.

Click on the Magnifying Glass tool again to close the Magnifying Glass Options window.

Print Selected Image

When the Print tool is clicked, the Microsoft Print window is opened to select the device to print to, the number of copies to print, etc. The selected image will print along with the patient's name, ID, date of birth, and gender, plus the provider's name and phone number, and the date the image was taken. The practice's name, address and phone number will display above the image.

Negate Image

When the Negate Image tool is clicked, the image areas that were black become white, and the image areas that

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were white become black. Click the Negate Image tool again to return the image to its previous appearance.

Colorize Image

When the Colorize Tool is clicked, a different color will be substituted for each grayscale value in an image. To return an image to its original grayscale appearance, click on the Colorize Image tool again.

Pseudo 3D

When the Pseudo 3D tool is clicked, the image will appear to be more three-dimensional, helping to emphasize the edges of the teeth. To return the image to its original 2D view, click on the Pseudo 3D tool again.

Sharpen Image Edges

Sharpness looks for the boundaries between the light and dark areas of an image. When a boundary is found, sharpening it will make the first few pixels on the dark side darker and the first few pixels on the white side whiter. This causes more contrast at the edges. Making an image too sharp can cause the image to appear grainy.

Click on the Sharpen Image Edges tool again to return the image to normal.

Reset Original Image

When clicked, the Reset Original Image button will return the image to its original appearance at the time the image was acquired. Measurements and annotations that were previously saved on the image will still be there.

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Remove From Viewer

Removing an image from the View window does not delete the image from Visix; it simply takes the image off the View window. Left click once on the image that needs to be removed to select the image. A green box displays around a selected image. Click on the Remove From Viewer button to take the image off the View window.

Brightness/Contrast Control

Left click and drag the small red circle on the Bright/Cont Tool. Moving the circle causes changes in the brightness (overall lightness) and contrast (the whites become whiter and the blacks become blacker) of the image.

Gray Shift (Gamma)

Gamma will not change the whitest and blackest grayscale values in the image. It will, however, change the in-between colors – the different shades of gray. When the Gamma Slide Bar is slid down, the grays are lightened. When the Gamma Slide Bar is slid up, the grays are darkened.

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A Few Recommendations from the maker of Visix . . .

Equipment

Make sure that the equipment used to run Visix at the very least meets the minimum requirements for Visix as well as for each acquisition device used. Remember that better computer equipment (including the monitor and the printer) and acquisition devices result in better images. Image printouts should be made on high quality color ink jet printers such as those made by HP and Epson.

Backups

Make a backup of your database and image files daily. We also strongly recommend that you use multiple backup media. For example, if you are backing up your files to disks, use a different disk for each day of the week plus a set of disks for each month end. By using multiple media in this way you reduce the risk of copying a damaged file over your only good backup.

Training

There is no substitute for investing in good hands-on training. As staff is added, make a practice of having the employee with the strongest knowledge of Visix completely train the new employee. In addition, make sure the Visix manual is easily accessible by all employees, and strongly consider purchasing a yearly support contract, which provides you with Visix support over the telephone.

Internet Access

Image files are large. If you intend to transfer them using the Internet (using, for example, email with the images sent as attachments) high speed Internet access is preferred.

Office Phones

Please have at least one cordless phone or cell phone available for use by the office staff for making support calls

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to Visix. Solving problems frequently involves multiple computers so mobility is important.

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Visix

What Folders to Backup – Short Guide

The maker of Visix recommends that the Visix database and images be stored on the network server and backed up nightly. There are many different backup schemes and software. Which is employed is up to the user.

To locate the folder(s) to backup:

- Close Visix
- Open Visix Administration
- Login to the Administration program
- Click on Program Configuration and then click the Next button
- Click in the top box labeled "Database Connect String" and use the right arrow on the computer keyboard to move to the right, down the string. The location of the database is listed immediately after "Data Source = ". Tvdata.mdb is the database.
- The middle box displays the location of the images folder, where the images are kept.
- By default, the Images folder is located in the same folder that holds the database.

If you have questions, call Visix Technical Support at 1-866-908-4749.

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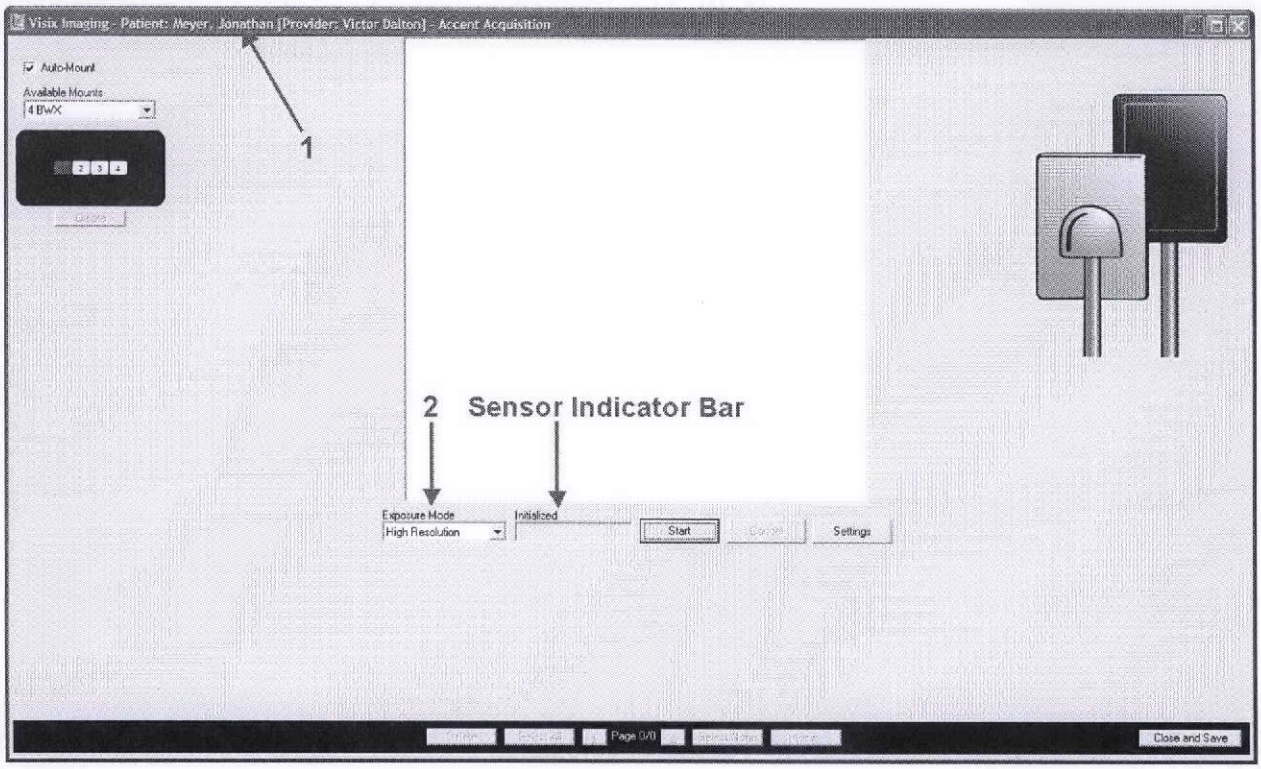
Accent Sensor Short Guide

Visix



Check 2 things:

1. Is this the correct patient?
2. Is this the correct Exposure Mode?

Sensor Indicator Bar:
During the time that the Accent Sensor is initializing, the Sensor Indicator Bar to the left of the Start button will display the word "Initializing". Once the Accent Sensor is ready to be used, the bar will display the word "Initialized", and then will flash green and the text "Waiting for Exposure" will display. After the x-ray button has been pressed to take the x-ray, the bar will flash red, the text "Processing Image" will display, then the thumbnail image will appear at the bottom.

If the Accent sensor has been set to automatically re-arm, the Sensor Indicator Bar will return to the "Waiting for Exposure" message. If the Accent sensor has not been set to automatically re-arm, click on the Start button to activate the sensor for the next shot

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, and then click on the Close and Save button at the bottom of the screen.

For more information, refer to page 42 in the Visix manual

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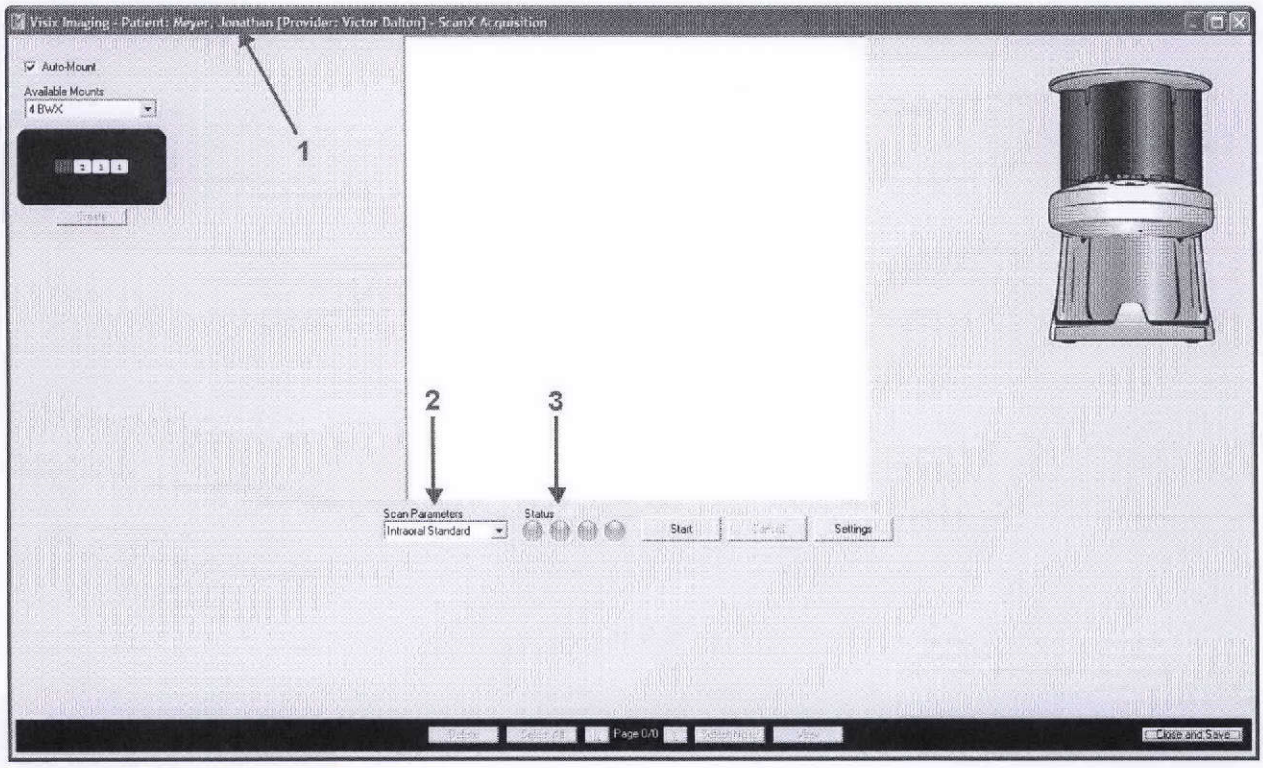
ScanX Scanner Direct Connect Short Guide

Visix



Check 3 things:

1. Is this the correct patient?
2. Is the Scan Parameters setting correct?
3. Are the Slot Status lights green?

If the three things listed above are all correct, the plate can be scanned.

Feed the plate into a slot with a green light. The white side of the plate should be against the ScanX. Press the plate down until you feel the ScanX rollers grab it.

A crude version of the image will float down the waterfall window, showing the progress through the ScanX. The actual image will appear in thumbnail size on the lower part of the window.

Check the DEMS light on each image. Images with a red DEMS light should be opened into the Viewer and checked there.

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.

For more detailed information, refer to page 55 in the Visix manual

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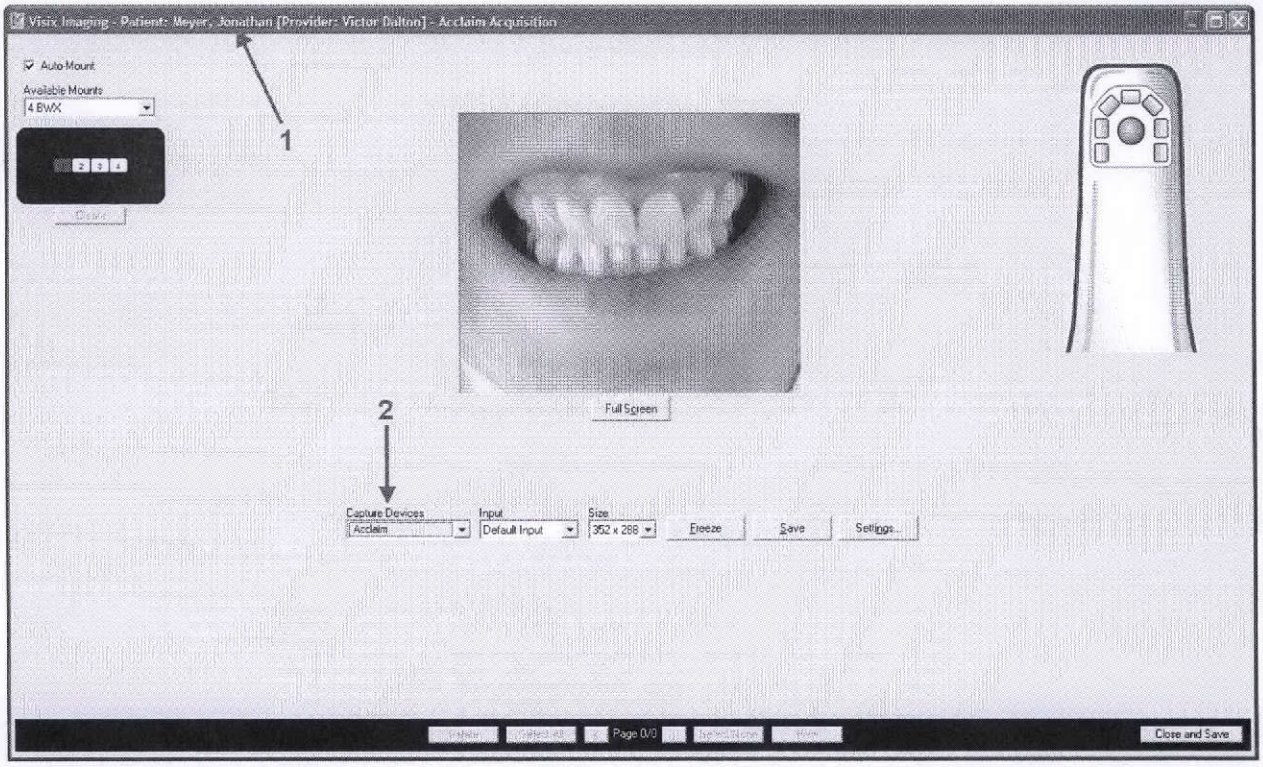
Acclaim Camera Short Guide

Visix



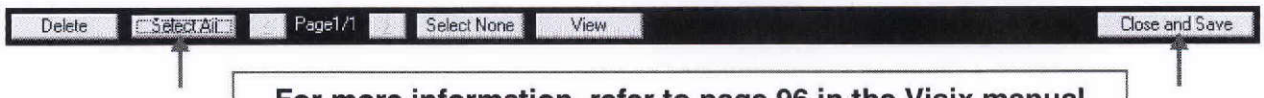
Check 2 things:

1. Is this the correct patient?
2. Is this the correct camera?

Prepare the Acclaim camera by placing a sheath over it and then removing the extra section from the lens side of the camera. Pull the sheath down snuggly over the lens so the picture is clear.

Point the camera at the area to take a picture of. When the correct teeth display on the screen, either click on the Freeze button on the screen or press the forward button on the camera to freeze the picture. If the picture is good enough to save, either click on the Save button on the screen or press the rear button on the camera. An image called a "thumbnail" will appear at the bottom of the window.

To Save:
Click on the individual images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.



For more information, refer to page 96 in the Visix manual

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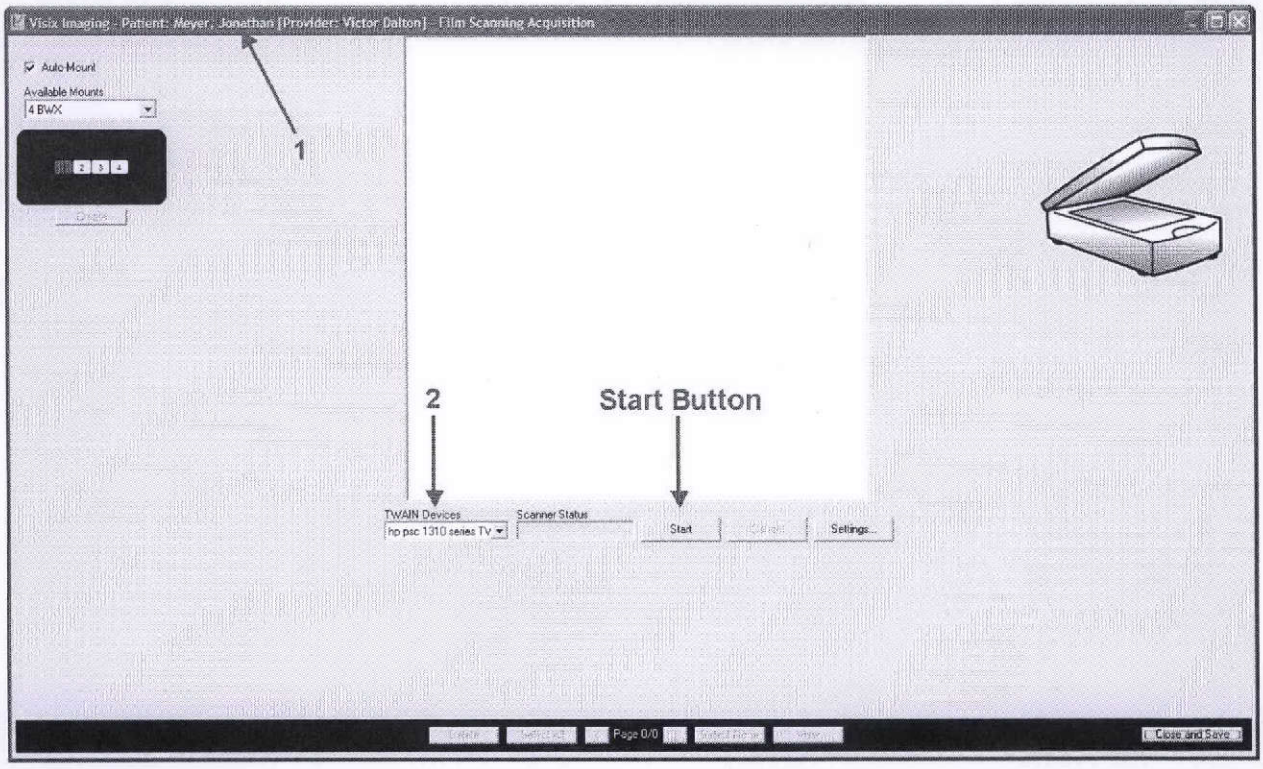
Flatbed Scanner Short Guide

Visix



Check 2 things:

1. Is this the correct patient?
2. Is this the correct Flatbed Scanner?

Place the film to scan on the scanner bed, close the lid and click on the Start button.

If the scanner was setup to ask for a date, a window will open that asks for the date the x-rays were taken. Click on the down arrow and then click on the date.

The software that runs the scanner will open.

For most flatbed scanners, the settings for the scanner driver window should resemble the following:

- Mode — Professional
- Document Type — Film. Film refers to something that light can shine through, such as film or transparencies.
- Film Type — Positive Film
- Image Type — 8-bit Grayscale
- Resolution — 200dpi

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Once the settings have been adjusted, click on the Scan button to begin the scan. When the scanner is finished scanning the image will appear in the Visix window.

If the scanner was setup with Allow Scan Edit on, the program will stop to allow you to add, delete or adjust image boxes. Whatever is inside an image box is what Visix will capture as an image. Once the boxes are adjusted, click on the Finish button.

If the scanner was not setup with Allow Scan Edit on, thumbnail images will appear in Visix according to what the scanner thinks is a separate image to scan. With Allow Scan Edit off, you are not allowed to adjust what is being acquired.

To Save:
Click on the individual thumbnail images to save or click on the Select All button at the bottom of the screen, then click on the Save button at the bottom of the screen.

For more detailed information, refer to page 104 in the Visix manual

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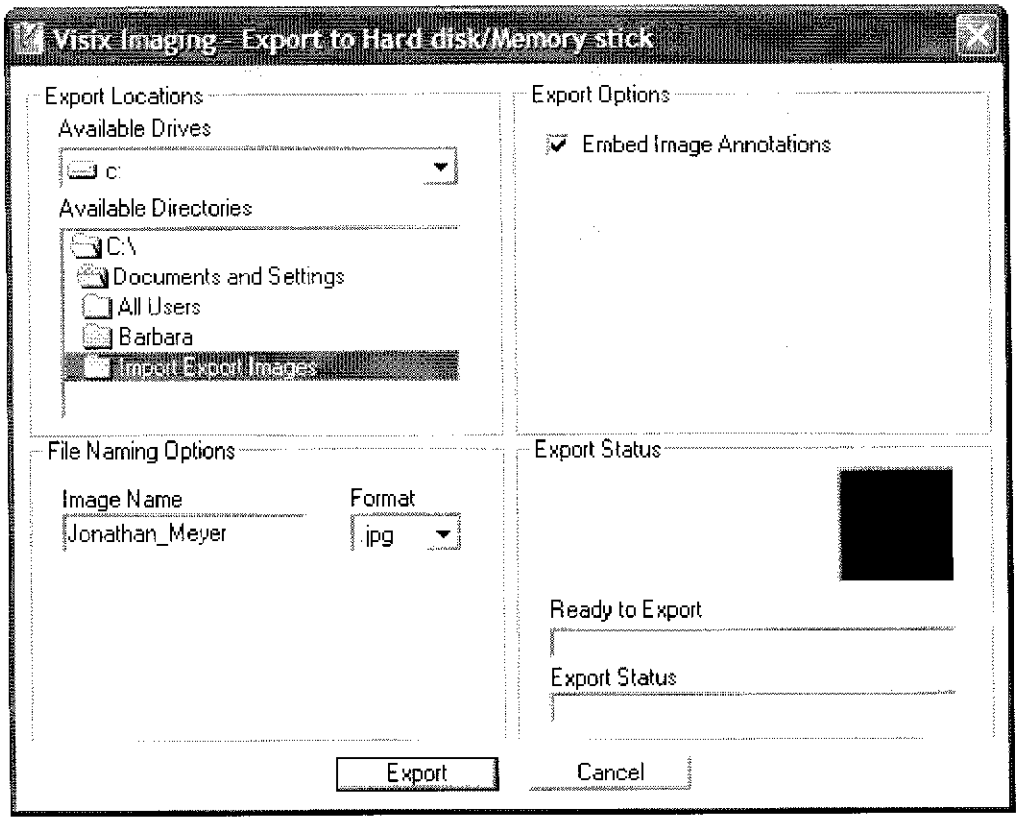
Export Images Short Guide

Visix



1. Left click one time on each image that needs to be exported.
2. Right click once on any of the images that were just left clicked on
3. Select Export
4. The Export window will open
5. The makers of Visix recommend creating a folder called "Import Export" directly under the Documents and Settings folder on Local Disk C: and using it to Export to and Import from.
6. Left click on the folder to export to. Locate it using Available Drives and Available Directories.
7. Click on the Format down arrow to select the type of export file to create. JPG is the safest file type to send because most programs will read it.
8. If you want all of the annotations that are on the images to go with the images, click on the Embed image annotations checkbox to put a check in it.
9. Click on the Export button

For more information, refer to page 32 in the Visix manual

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For questions about Visix that are not answered in this manual, please call the Visix support line at 1-866-90-VISIX from 8:15 AM EST to 5:00 PM PST.

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

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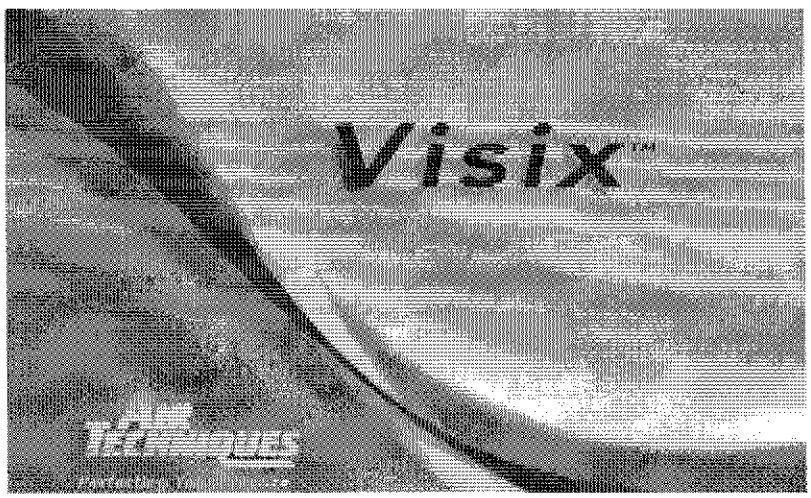
Perfecting Your Practice...



Visix Imaging Administration Manual

Dental Imaging Software

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Indications for Use

Visix is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, Visix enables the storage of clinical exam data and measurements.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Caution: Federal law restricts this device to sale by or on the order of a dentist or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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

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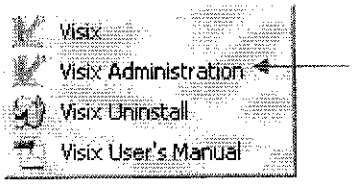
To Open Visix Administration

On your desktop, click on the Start button

Go to All Programs

Go to Visix Imaging

Then click on Visix Administration. 

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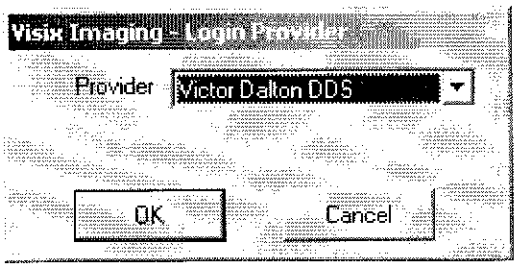
Select a Provider

The first Visix window that opens is the Login Provider Window.



A provider is a doctor. If the name that displays is the correct provider click on the OK button. Otherwise, click on the Provider name down arrow to display a drop down box of other providers that may be selected from. If the necessary provider does not appear in the drop down box, select a different one and use the Administration program to enter the missing provider.

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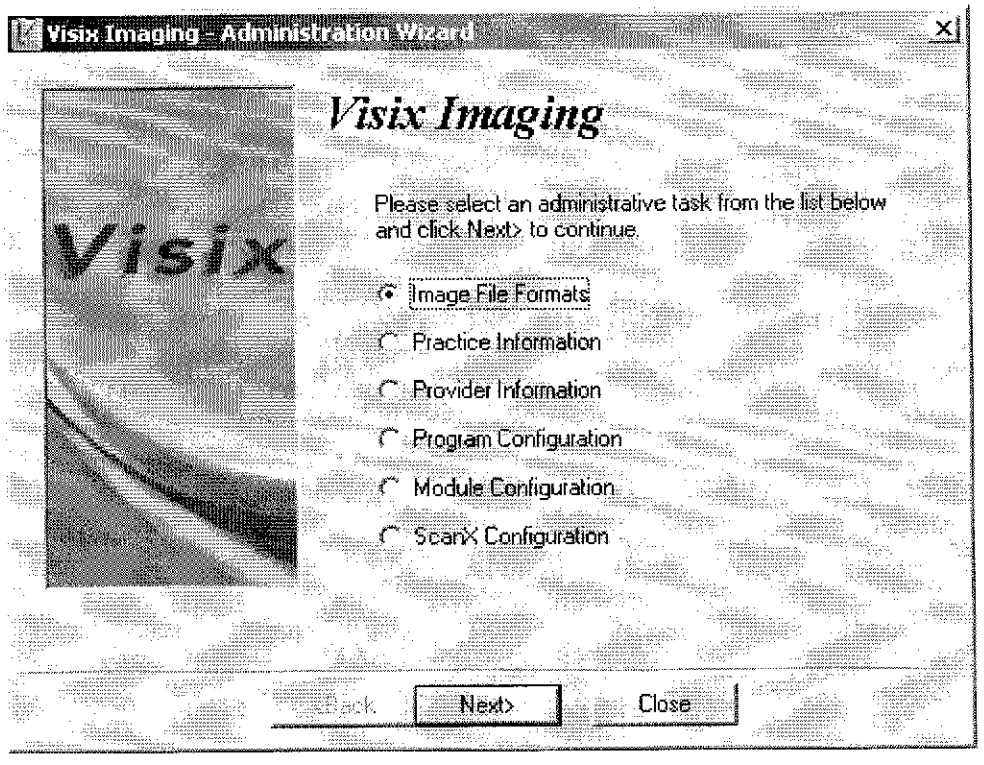
Visix Imaging Administration Main Menu



To update administration information click on the radio button next to the information that requires updating then click on the Next button at the bottom of the window.

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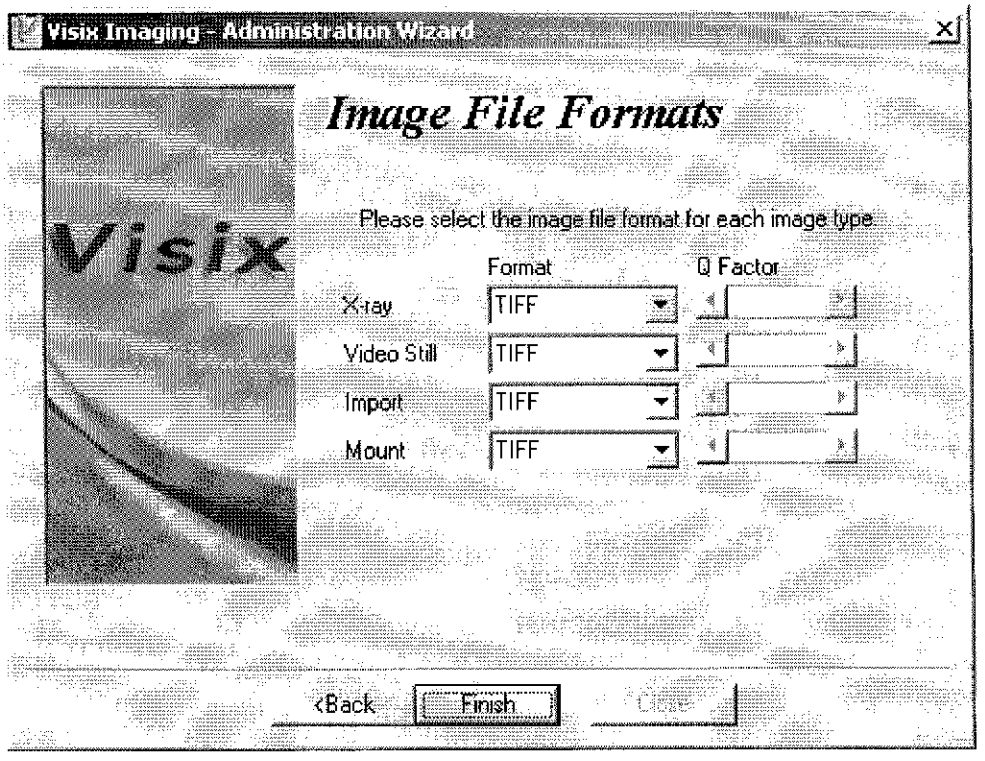
Image File Formats



To access the Image File Formats window click on the radio button next to Image File Formats on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Format

Select the type of image file for each type of image Visix saves. Image file formats include TIFF, JPEG (lossy) and JPEG (lossless). If JPEG (lossy) is selected the Q Factor slider will become accessible.

Q Factor

Q Factor stands for "Quality Factor" and is available only for JPEG (lossy) files. The Q Factor determines the amount of compression that will be applied when the image file is saved. Some images can be compressed more than others. Images with a lot of detail cannot be compressed as much as images without a lot of detail and still maintain the same image quality. The lower the Q

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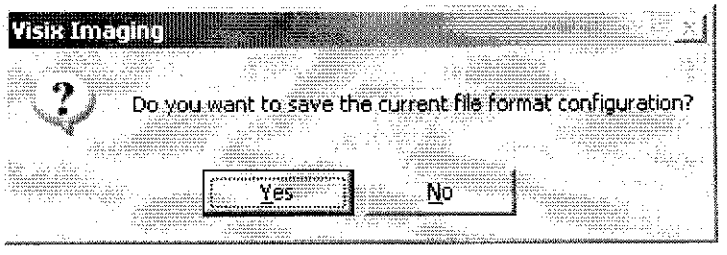
factor the higher the degree of image quality and the smaller the amount of compression applied. Entries from 2 through 50 are allowed.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the image format information that was entered. Click on No if any changes that were made should be edited.

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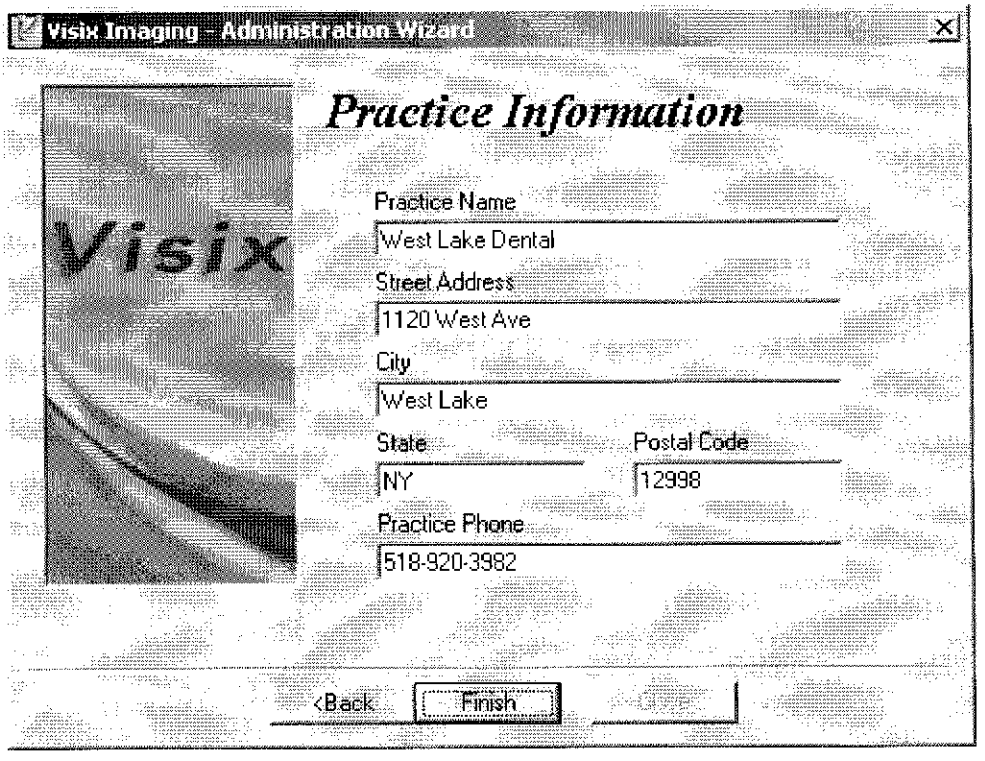
Practice Information



To access the Practice Information window click on the radio button next to Practice Information on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Practice Name

Enter the business name of the practice.

Street Address

Enter the street address of the practice.

City

Enter the name of the city that the practice is located in.

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State

Enter the state that the practice is located in.

Postal Code

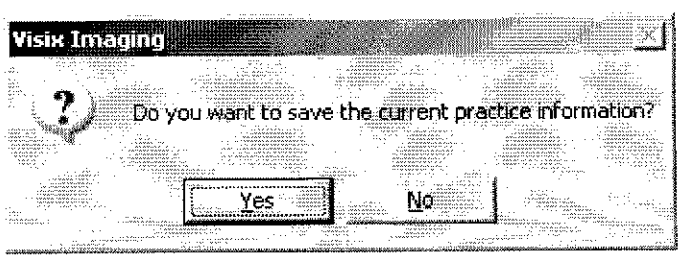
Enter the postal or zip code that the practice is located in.

Practice Phone

Enter the main phone number for the practice. A dash (minus sign), period, or parenthesis can be used as a separator character between sections of the phone number for ease of viewing.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the practice information that was entered. Click on No if any changes that were made should be edited.

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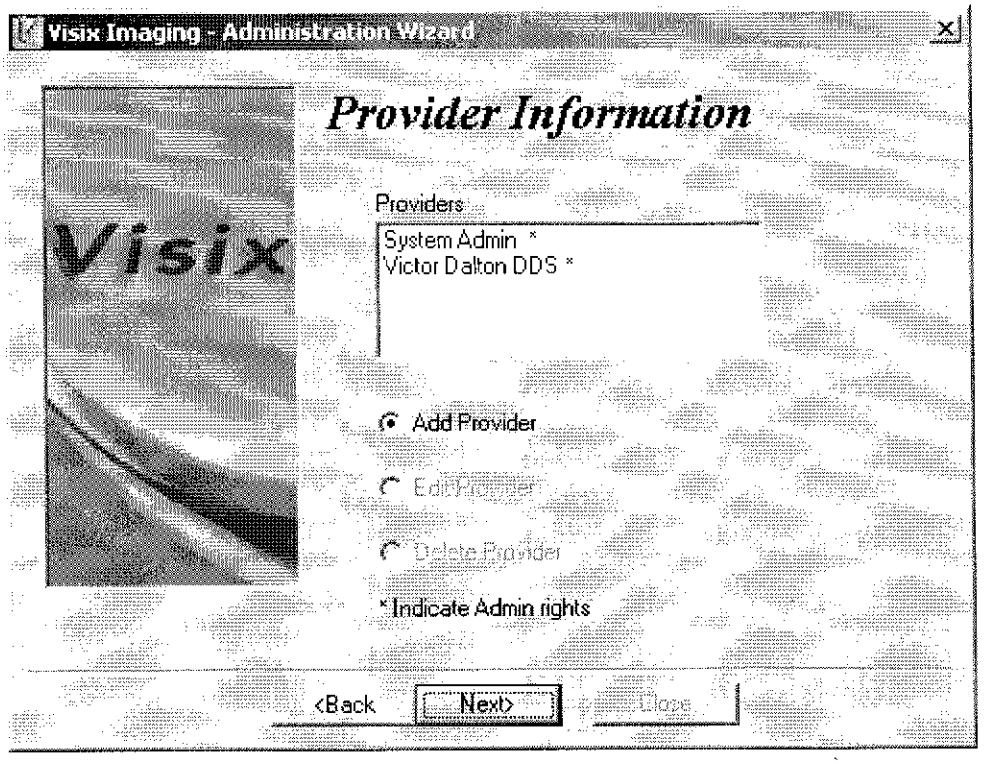
Provider Information



To access the Provider Information window click on the radio button next to Provider Information on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Add a Provider

To add a provider (a doctor) click on the radio button next to Add Provider then click on the Next button at the bottom of the Provider Information window. An empty Provider Information window will display.

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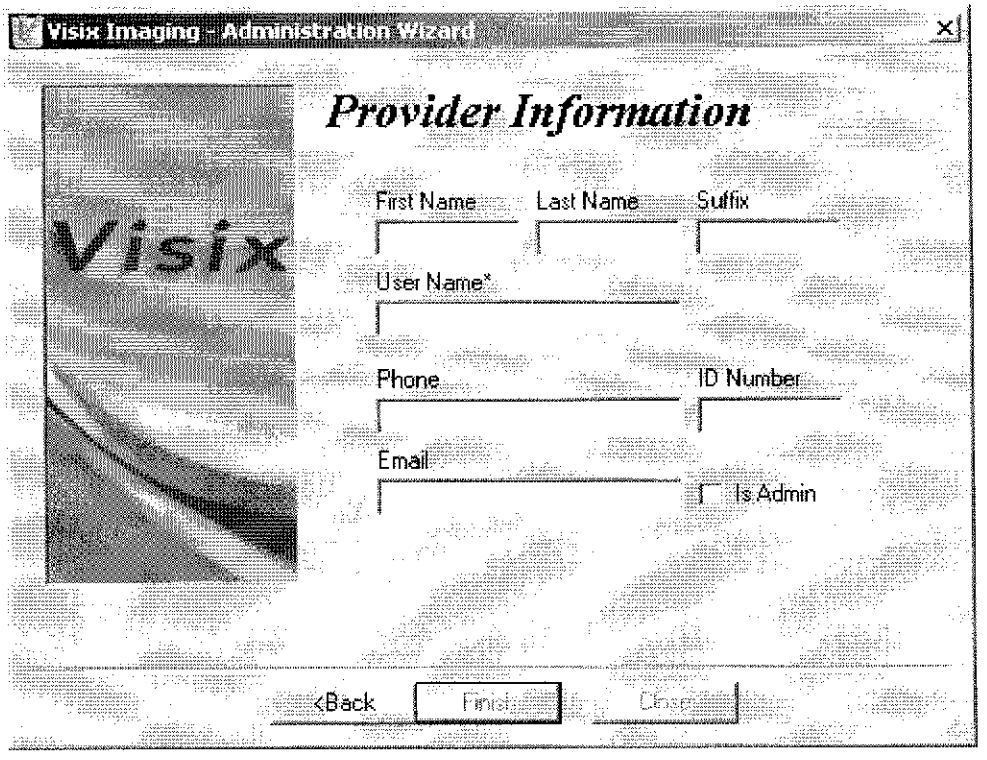

First Name

Enter the first name of the doctor. This information is required before the doctor's record can be saved.

Last Name

Enter the last name of the doctor. This information is required before the doctor's record can be saved.

Suffix

Enter any initials that should be placed at the end of the doctor's name. A maximum of 10 characters may be entered. The characters that can be used in the Suffix include letters, a period, and a dash (minus sign).

User Name

Enter a name of at least five characters that will represent this provider. The characters that can be used in the User

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Name include letters and numbers. This information is required before the doctor's record can be saved.

Phone

Enter the provider's office phone number. The characters that can be used as a separator character in the phone number include a period, parenthesis, or dash (minus sign).

ID Number

Enter the ID number assigned to this provider for use inside Visix. The characters that can be used in the ID Number include a period, letters and numbers.

Email

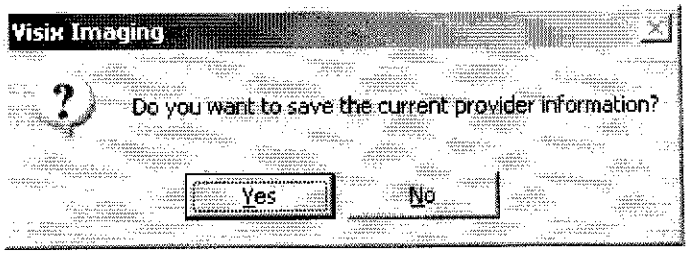
Enter the email address for this provider.

Is Admin

Put a check mark in the box by clicking on the box if this provider should have administrator rights in Visix. To remove a check, click on it.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



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

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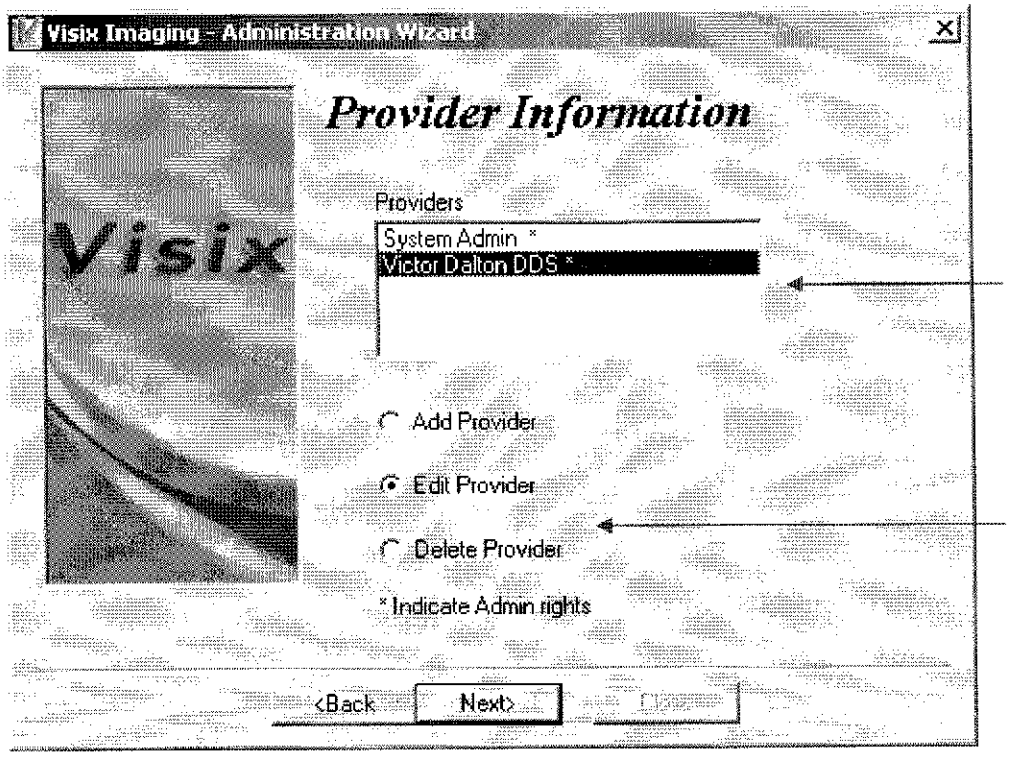
Click on Yes to save the practice information that was entered. Click on No if any changes that were made should be edited.

Edit Provider

To edit provider information click on the provider's name in the first Provider Information window then click on the radio button next to Edit Provider and finally click on the Next button at the bottom of the window.



The same Provider Information window will display that displayed for Add Provider. Edit information as needed then click on the Finish button at the bottom of the window.

Delete Provider

To delete a provider click on the provider's name in the first Provider Information window then click on the radio button next to Delete Provider and finally click on the Next button at the bottom of the window.

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

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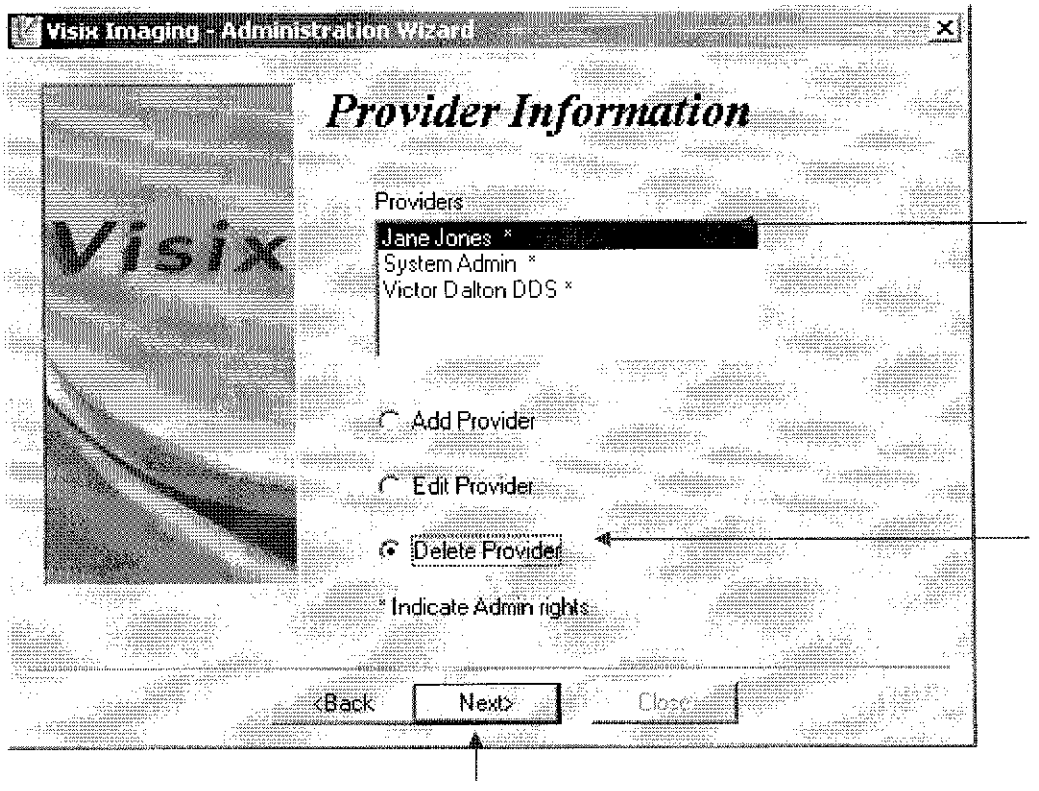

If the provider being deleted has patients, a window will open that asks which single provider to transfer the patients to.

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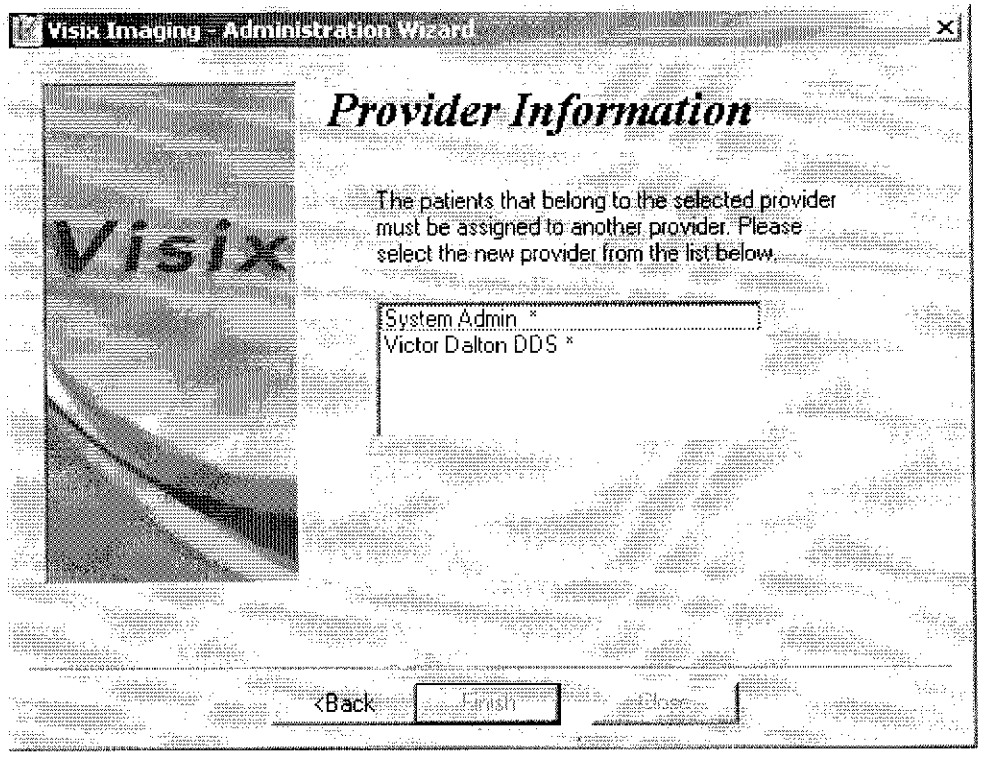
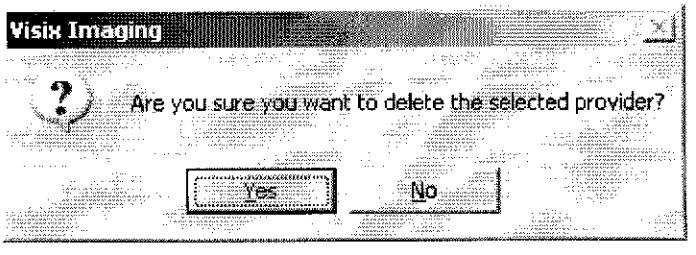


Click on the provider who will receive the patients then click on the Finish button.

Once the patients have been transferred the following screen will display:



Click on the Yes button to delete the provider.

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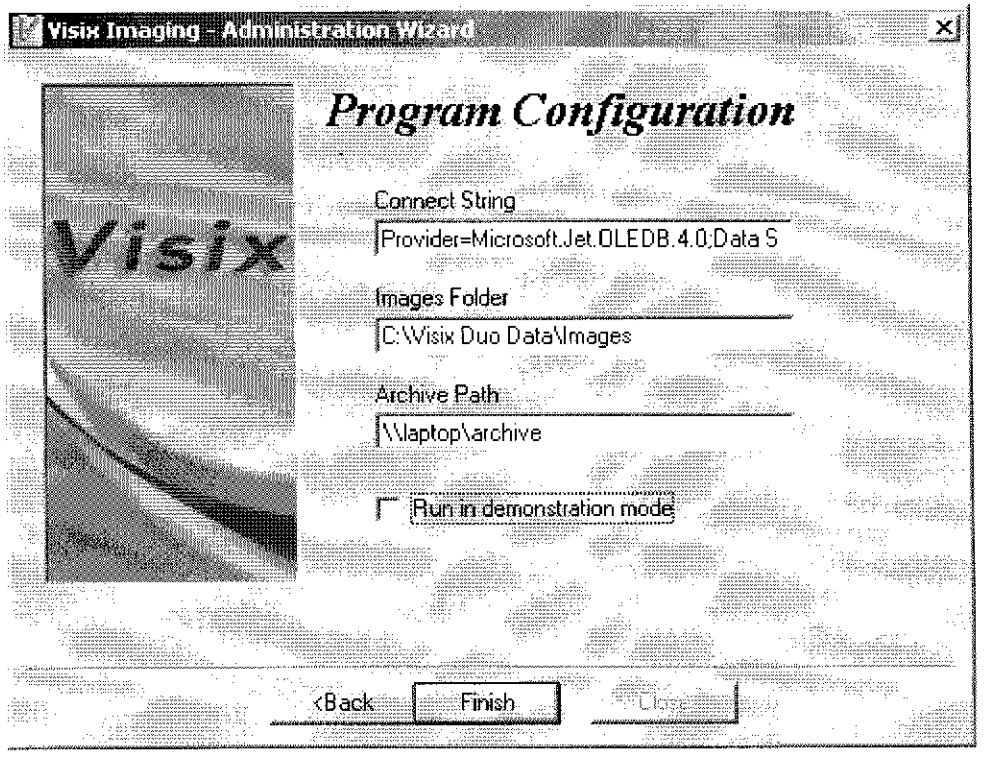
Program Configuration



To access the Program Configuration window click on the radio button next to Program Configuration on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Database connect string

The Database Connect String specifies which version of the Microsoft Jet engine is used and the name and location of the Visix data file. Do not change this.

Images Folder

The Images Folder specifies the name and location of the folder where Visix stores the image files. Do not change this.

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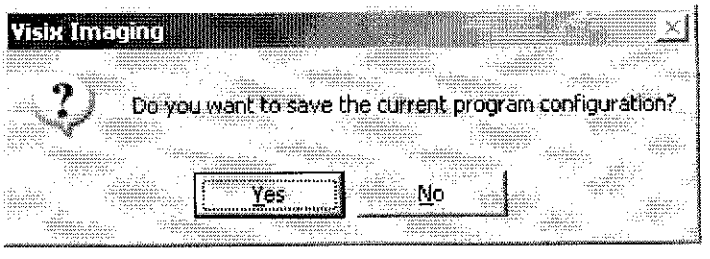
Archive Folder

The Archive Folder specifies the name and location of the folder where Visix will store its archived images. The folder must be shared and entered with its UNC path (\\computername\shared folder name).

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window. If the Finish button is clicked, the following window will open:



Click on Yes to save the program configuration information that was entered. Click on No if any changes that were made should be edited.

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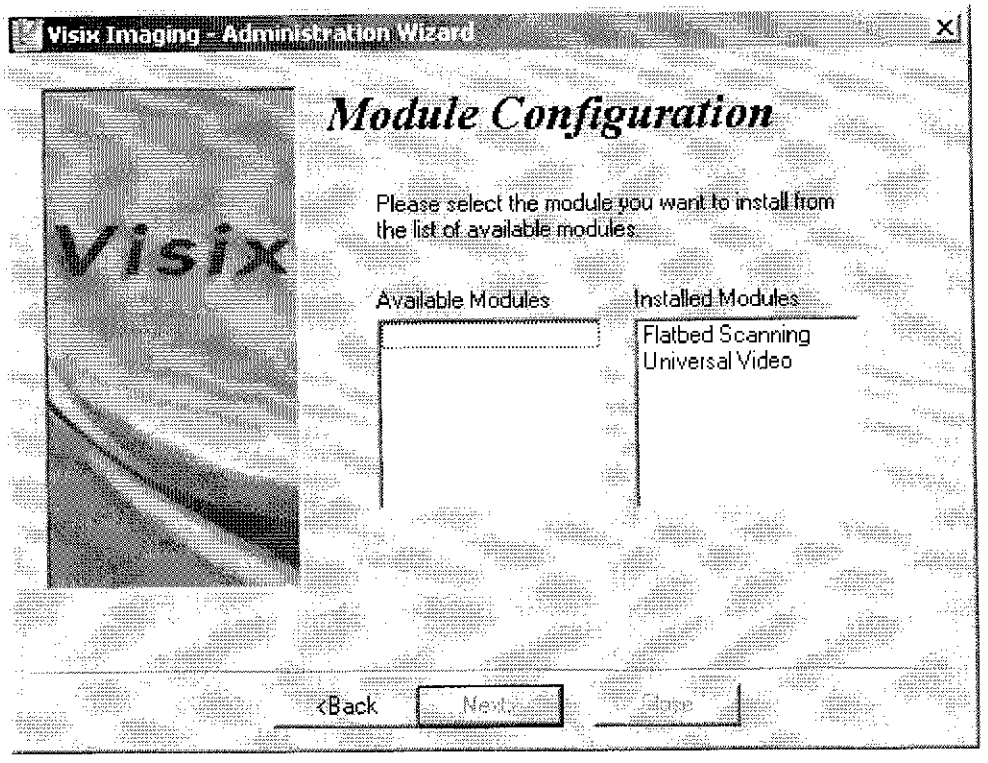
Module Configuration



To access the Module Configuration window click on the radio button next to Module Configuration on the Visix Administration Main Menu then click on the Next button at the bottom of the window.

Available Modules

All of the modules available for use with Visix are listed in the Available Modules window. A module must be purchased, by either calling Visix and providing credit card information or by sending Visix a written order with a check attached, before it can be installed.

To install a module after it has been purchased click on the module in the Available Modules window then click on the Next button. A small window will open that asks for an activation code. Call the Visix 800 number and ask a support technician for an activation code. The support technician will ask you to tell him the code that is displayed on your computer screen and will then give you a code to type in. This code will allow Visix to install the requested module.

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Installed Modules

All of the modules that have had their activation codes entered into Visix are listed in this window.

Back and Finish Buttons

Click on the Back button to return to the Visix Administration Main Menu. Click on Finish to save the information in this window.

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

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ScanX Configuration

The ScanX can be setup in either Direct Connect Mode or Client/Server Mode.

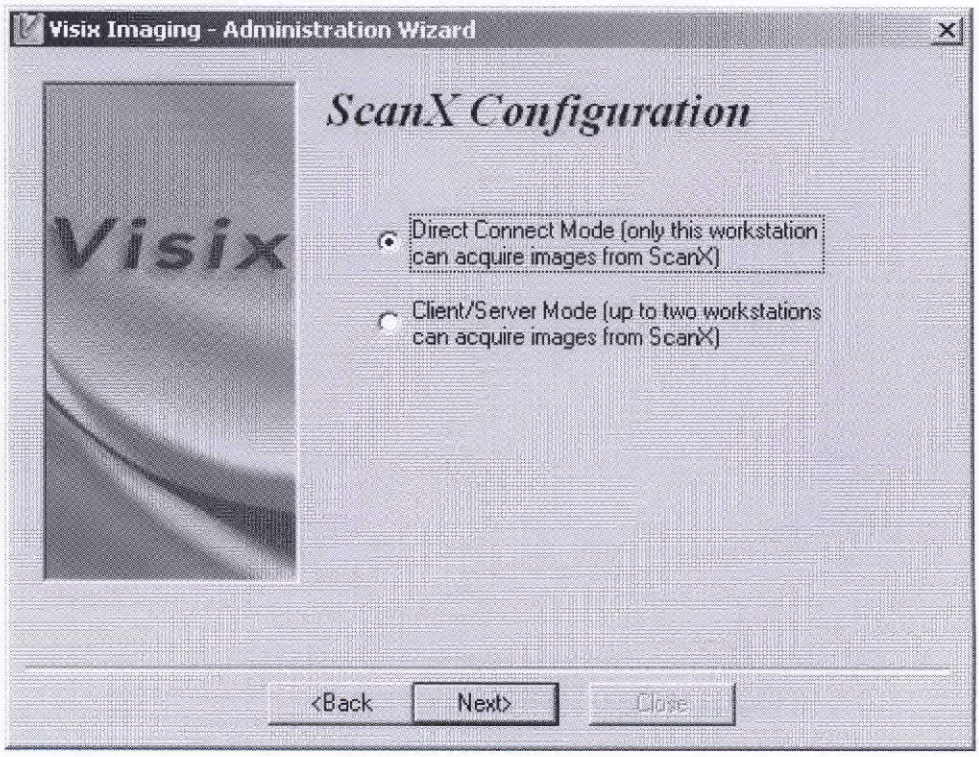
If the ScanX is setup in Direct Connect Mode, it will be directly connected to this computer and only the copy of Visix that runs on this computer will acquire images from it.

If the ScanX is setup in Client/Server Mode, also known as Intelligent Track Control Mode, it has the option of operating in three different ways:

- The ScanX will be directly connected to this computer and the copy of Visix that runs on this computer will acquire images from it. This is similar to the Direct Connect Mode except that a second workstation can also be setup to acquire images from the ScanX.
- The ScanX will be directly connected to this computer but Visix on two different workstations will acquire images from it.
- The ScanX will be directly connected to a different computer but Visix on this workstation will acquire images from it.

Note that in Client/Server Mode, all of the Visix workstations on the network will be able to access ScanX images after they have been acquired and saved, but no more than two of those Visix workstations may actually acquire the images from the ScanX.

Direct Connect Mode



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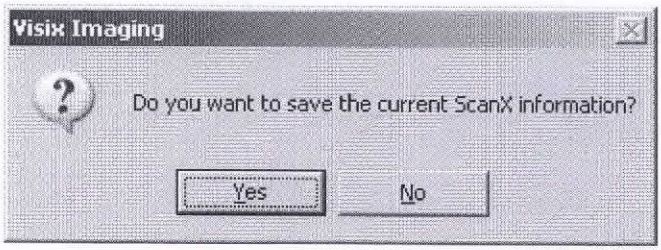
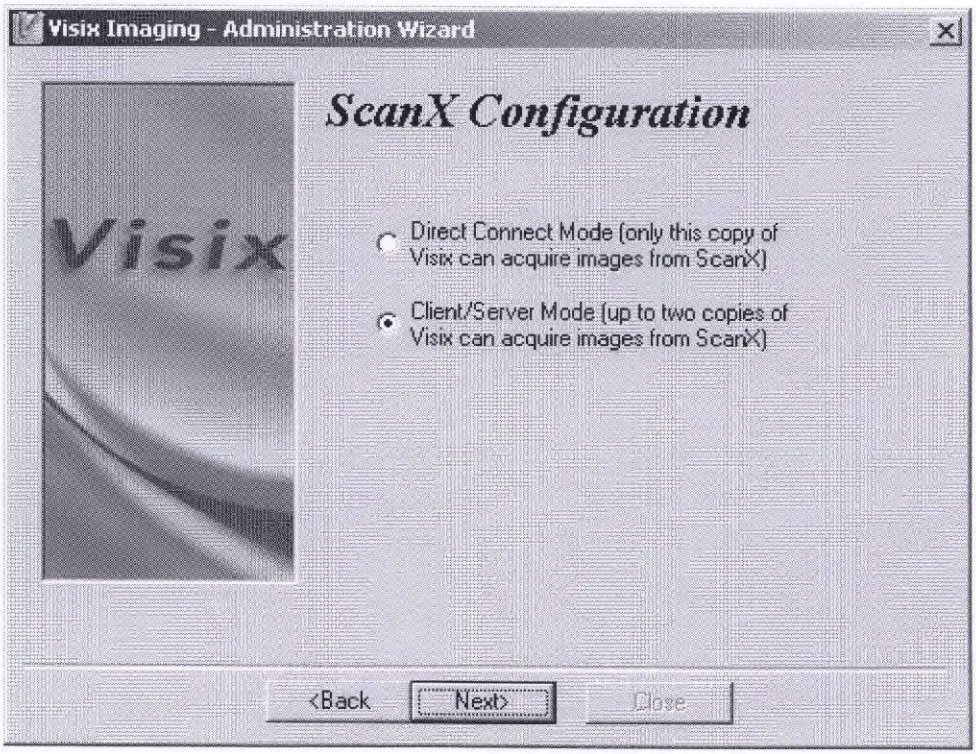
Click on the Direct Connect Mode radio button then click the Next button to display the Save window.



Click on the Yes button to save the ScanX setup information.

Client/Server Mode



Click on the Client/Server Mode radio button then click the Next button to display the second ScanX Configuration window.

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

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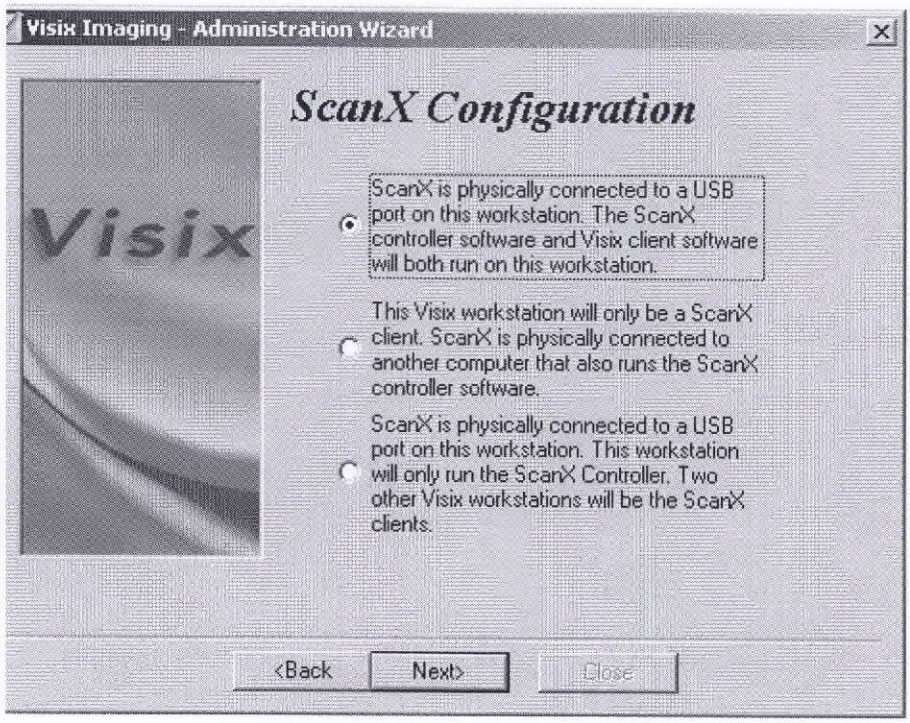
The ScanX is directly connected to this workstation with a cable and the copy of Visix on this workstation will be used to acquire images from it



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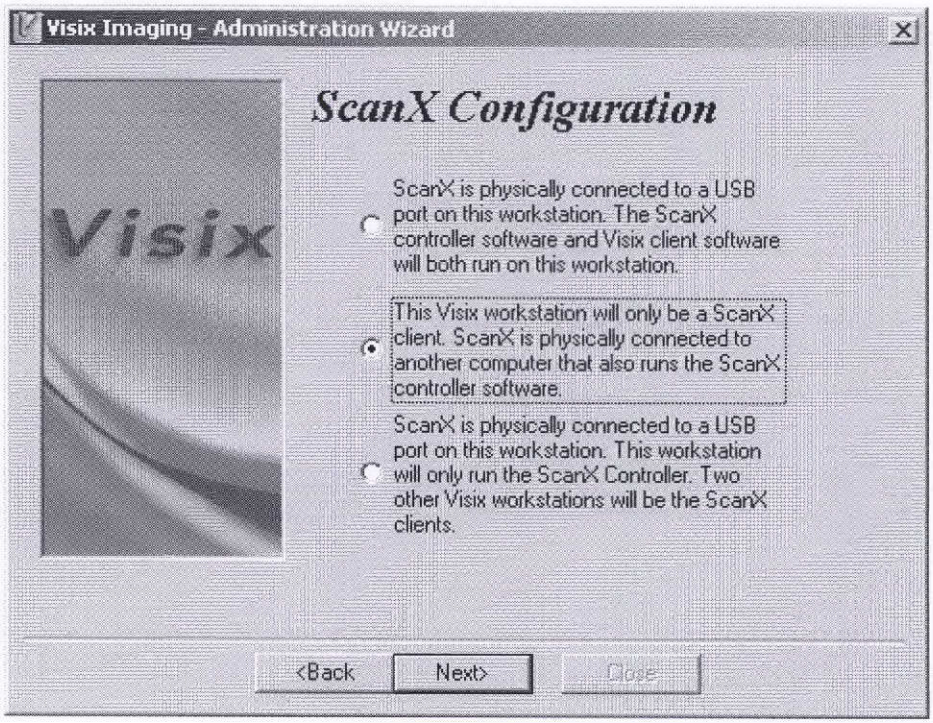
The ScanX is not connected to this workstation with a cable but the copy of Visix on this workstation will still be used to acquire images from it



If the ScanX will be directly connected to this computer and the copy of Visix that runs on this computer will acquire images from it, OR if the ScanX will be directly connected to a different computer but the Visix on this workstation will still acquire images from it (the top two options in the ScanX Configuration screen above), clicking the Next button will display the following window:

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

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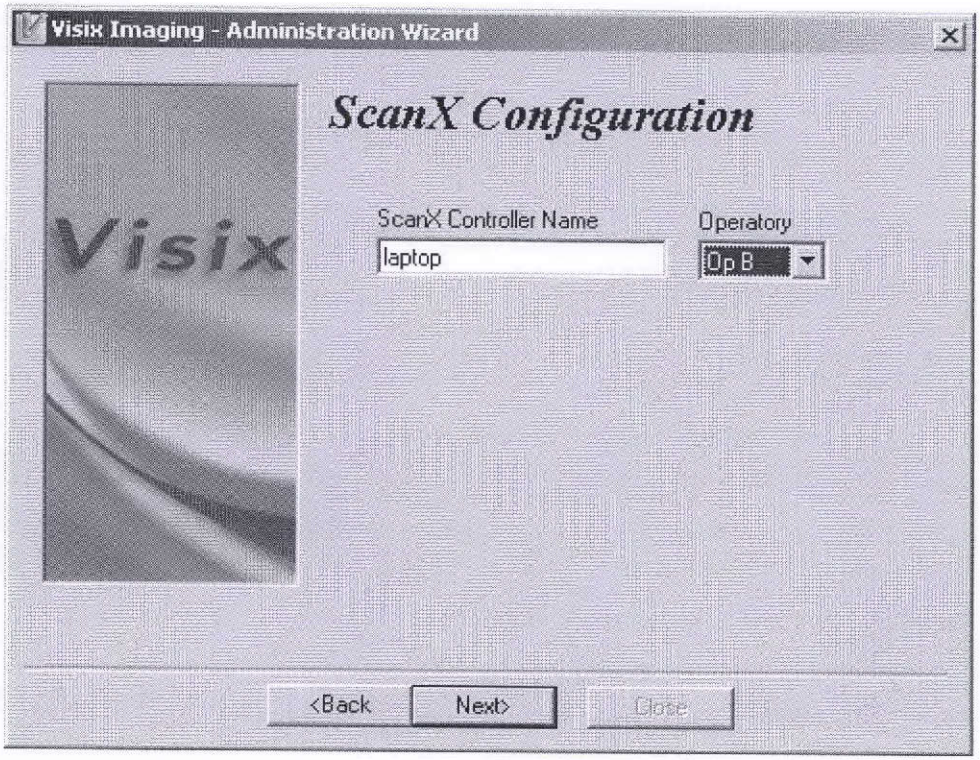


ScanX Controller Name

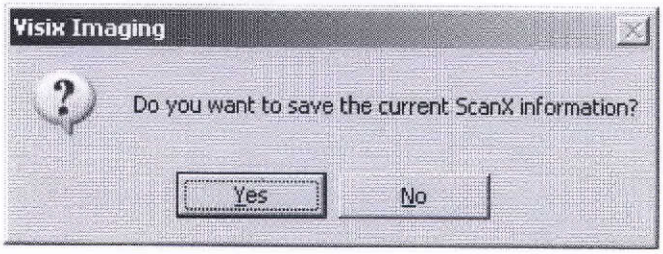
Enter the name of the computer that has the ScanX directly connected to it with a cable.

Operatory

Click on the Operatory down arrow and select either Op A or Op B. If two copies of Visix will be acquiring images from the ScanX make sure that one is set to Op A and the other is set to Op B.

Next and Back Buttons

Click on the Back button to return to the previous window. Click on the Next button to display the Save window.



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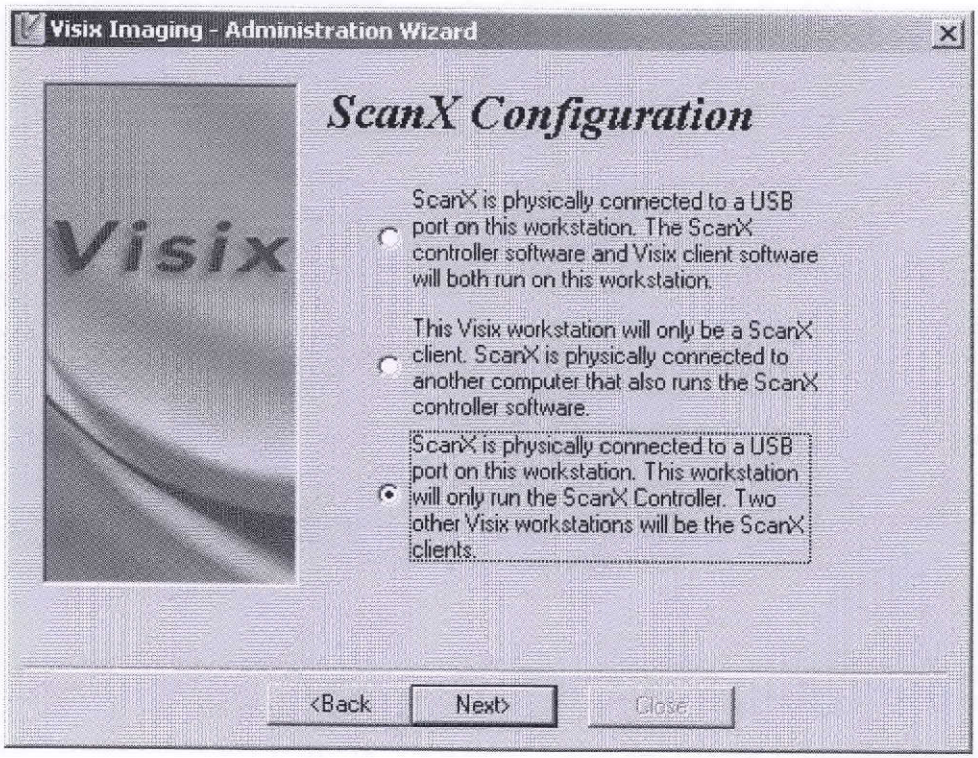
Click on the Yes button to save the ScanX setup information.

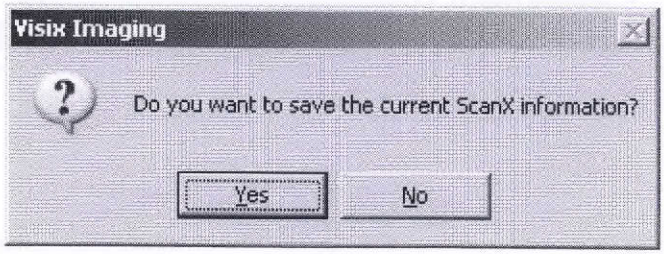
Third ScanX Configuration Option:

The ScanX is connected to this workstation with a cable but the copies of Visix that will be used to acquire images from it are on two different workstations.



Next and Back Buttons

Click on the Back button to return to the previous window.
Click on the Next button to display the Save window.



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

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Click on the Yes button to save the ScanX setup information.

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

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For questions about Visix Imaging
that are not answered in this manual, please call
the Visix support line at 1-866-908-4749 from
8:00AM EST to 5:00PM PST.

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

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PRODUCT LABELING

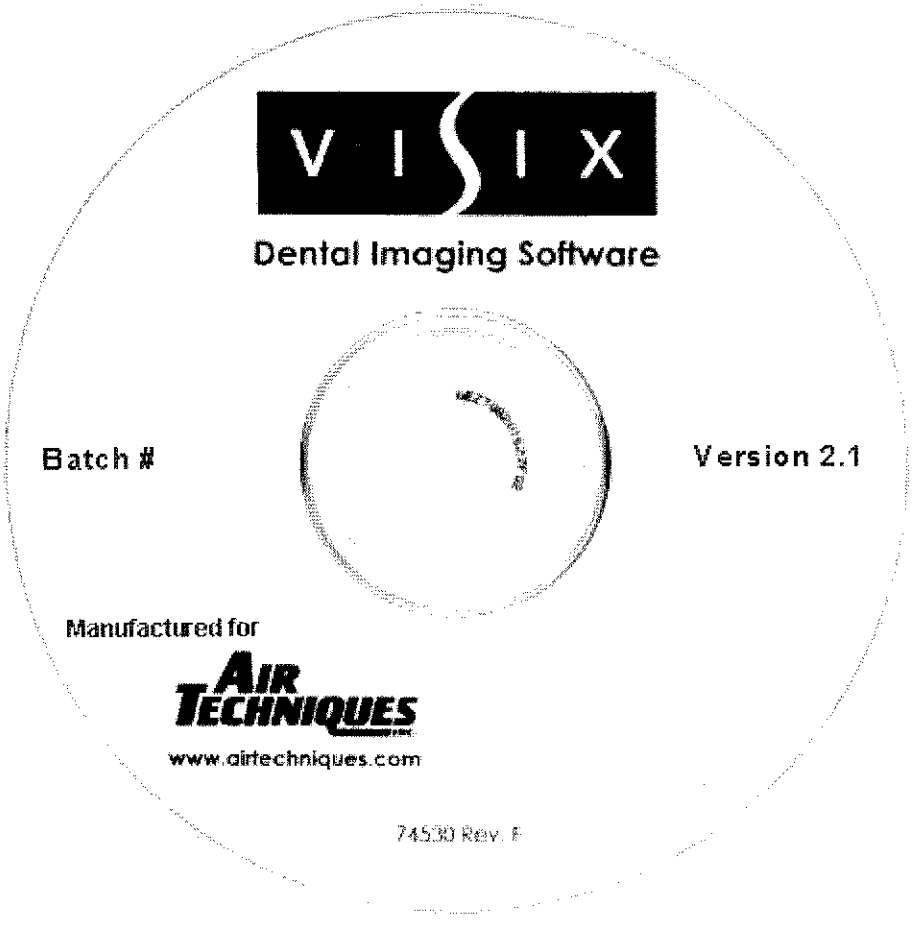
CD Label for Visix Imaging disk

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

Records processed under FOIA Request # 2015-8521; Released by CDRH on 05-10-2016

PRODUCT LABELING

CD Label for Visix Imaging disk



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

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Web Site Main Page:

VISIX Imaging Software

...the superb software complement for Accent, ScanX and Acclaim.

Air Techniques is pleased to introduce Visix, our new comprehensive digital imaging software program. Visix seamlessly integrates with our digital imaging suite; the Accent CCD Intraoral Sensor, ScanX PSP System and Acclaim Intraoral Camera.

Key Features

- Easy to learn
- Simple to use
- Acquire, mount, view and store images with just a few mouse clicks
- Customize images to your personal preference with our simple Set-Up 1-2-3 tool
- Exposure: Our Stop Light Exposure System is a unique indicator to ensure optimum data capture. It helps you acquire great images by monitoring X-ray exposure.
- Viewing. Visix provides automatic image mounting that is completely customizable.
- Visix includes a built-in bridging solution to over 35 Practice Mangement Software titles.

Product Specifications

PN 74500 Visix Dental Imaging Software (includes 5 licenses)

Computer Requirements

Minimum Computer Requirements

CPU Speed: 2 GHz Pentium IV Class.
Operating System: Windows 2000 Professional with Service Pack 4 or later, or Windows XP Professional Service Pack 1a or later.
RAM: 256 MB.
CD ROM Drive: 48X speed
Hard Drive: 60GB (2GB free for image acquisition, the rest for program files and image storage.)
Monitor (1024 x 786 resolution or higher): SVGA 17", contrast ratio 450:1, .22 dot pitch capability.
Video Display Adaptor: 128 MB RAM.
Keyboard/Mouse: Standard keyboard and mouse.
USB Port: USB 1.1.

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

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Web Site Main Page (con't):

Preferred Configuration

CPU Speed: 2.8 GHz Pentium IV or higher.
Operating System: Windows 2000 Professional with Service Pack 4 or later, or Windows XP Professional with Service Pack 2.
RAM: 2 GB.
CD ROM Drive: 48X speed.
Hard Drive: 120 GB (2GB free for image acquisition, the rest for program files and image storage).
Monitor (1024 x 786 resolution or higher): SVGA 17" or larger, contrast ratio 1000:1, .22 dot pitch capability.
Video Display Adapter: 256 MB RAM.
Keyboard/Mouse: Standard keyboard and mouse.
USB Port: USB 2.0.
Backup Device: Recommended.

Warranty Information

Visix support is available to every new owner for a 30 day period. Please call 1-866-90-Visix/84749.
Yearly support agreements and on-site training are available. Please download ordering information below for more details.

For software registration, please visit www.visixsoftware.com

Suggested Products

You may also want to look at:
ACCENT™ CCD Direct Digital Sensor
Acclaim® Intraoral Camera
ScanX®

DOWNLOADS

Visix Ordering Information
Visix Quick Start Guide
List of compatible Practice Mangement Systems
Visix Supported Cameras
Visix Supported Scanners

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

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Visix Web Site Downloads section (bottom of page 2 above):

Visix Ordering Information

VISIX

VISIX™ Imaging Software

Visix is the superb software complement to Air Techniques' Accent, ScanX and Acclaim. You will appreciate the simplicity of Set-Up 1-2-3. This utility enables a quick start using a one-time routine that allows you to customize images to your personal radiography preferences.

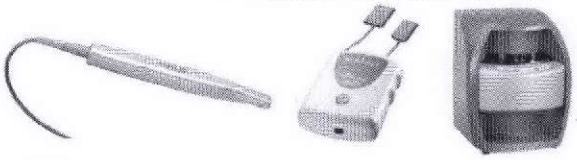
The Visix Stop Light Exposure System® is a unique indicator that ensures optimum data capture. Incorrect exposure reduces image quality. The Stop Light system helps you acquire great images by monitoring X-Ray exposure.

Visix accommodates a limitless range of image mounting and display preferences by providing automatic image mounting that is completely customizable. Create mounts to match the sequence in which you take images; for example left to right or top to bottom. Perhaps you want to see different image formats mounted and presented together, like panoramic and bitewings. Fully customizable mounting will make your edition of Visix feel like it was created just for you.

What's more, Visix includes a built-in bridging solution to over 35 practice management software titles. The bridge, Visix Link®, allows you to access a patient's images with a single click from the patient record in the management software.

Ordering Information

PN 74500	Visix Dental Imaging Software (includes 5 licenses)	$1,995.00
PN 74505	Visix Dental Imaging Software License Pack (5 licenses/pack)	$ 995.00
PN 74510	Visix Dental Imaging In-Office Training (on-site, 3 hours)	$ 995.00
PN 74509	Visix License Add-on	$ 250.00
PN 74525	Visix Software 1 year support contract	$ 795.00
PN 74540	Visix Film Scanning/Intraoral Camera Module	$1,495.00



Visix Imaging Software integrates seamlessly with all of Air Techniques' digital imaging products.

AIR TECHNIQUES INC.
1295 Walt Whitman Road, Melville, NY 11747-3062
516-433-7676 • Fax 516-433-3831 • www.airtechniques.com

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

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Visix Web Site Downloads section (bottom of page 2 above):

Visix Quick Start Guide

VISIX Imaging Software

Version 2

Quick Start Guide

AIR TECHNIQUES INC.

ALLPRO IMAGING

August 29, 2008

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FOREWORD

Air Techniques and its ALLPRO Imaging division have prepared this guide to provide brief instructions to install, configure, setup and use the VISIX Imaging Software provided with the digital imaging system (Scan*X*, Accent or Acclaim). References in this manual to Air Techniques include its division ALLPRO Imaging. This document is arranged as follows:

- Computer Requirements - Provides the minimum computer system requirements necessary to operate the digital imaging system (Scan*X*, Accent or Acclaim) with the VISIX Imaging Software.
- VISIX Installation - Provides the necessary instructions for the proper installation of the VISIX Imaging Software.
- Configuring VISIX Admin - Provides instructions to configure the VISIX administration settings. This allows the user to personalize their VISIX application and specify operating preferences as desired.
- Scan*X*Configuration Options - Provides instructions to configure the a Scan*X*I/O or Scan*X*Duo with VISIX. This allows the user to have two computer workstations acquire images from a single Scan*X*.
- VISIX Operation - Provides brief instructions to get the user started using the VISIX Imaging Software with either Scan*X*, Accent or Acclaim digital imaging system.
- 1. 2. 3 Setup - Provides instructions on using the 1. 2. 3 Setup tool of the VISIX Imaging Software. This tool adjusts the amount of edge enhancement filters, smoothing and amount of brightness, contrast and gray shift (or gamma) for the best image quality possible.

Since this guide provides basic information meant to quickly get the user started using VISIX, it is recommended that the user refer to the VISIX documentation included on the supplied CD for detailed information.

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COMPUTER REQUIREMENTS

Computer System Requirements.
The Computer System (laptop or computer, monitor, etc.) and any related peripheral or equipment must comply with the requirements for accessory Equipment as specified in the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard. The minimum computer system requirements necessary to operate the digital imaging system (Scan*X*, Accent or Acclaim) with the VISIX Imaging Software are listed below:

Important: The Bluetooth Accent Camera requires Windows® XP Professional with Service Pack 2.

Operating System:

Windows® 2000 Professional for an Intel 32-bit processor with Service Pack 4 and the KB 820759 update, or later; or
Windows® XP Professional for an Intel 32-bit processor with Service Pack 1 and the KB 822603 update, or later.

USB Port:

Must be USB 1.1 or later

RAM Memory:

1 GB minimum

Processor Speed:

Pentium 4, 2 GHz or faster

Hard Drive:

120 GB

Peripherals:

CD-RW Drive

SIS Driver Note.
There are known issues with the device drivers provided by SIS. If you have a SIS USB controller and experience problems operating the digital imaging system (Scan*X*, Accent or Acclaim) , it is recommended that you disable the SIS device drivers and use drivers provided by Microsoft. Microsoft and SIS are working to resolve these problems.

Display Setting Setup.
The color quality of the computer display must be set to True Color (32 bit) for proper operation using VISIX Imaging Software. Change the display settings in Windows® by performing the following:

1. Open the Control Panel window by pressing the ***Start*** button and selecting ***Settings*** and ***Control Panel***.
2. From the Control Panel window, open the Display Properties window by double-clicking the display Icon.
3. Click the ***Settings*** tab the Display Properties window and select True Color (32

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bit) from the Color drop down list.
4. Set the Screen Area for 1024 by 768 pixels or higher.
5. Click ***Apply*** and ***OK*** and return to the Desktop.

VISIX INSTALLATION

The installation of the VISIX Imaging Software is a multi-step process. To simplify the process, an installation script is provided on the VISIX CD that should start automatically when inserted into the the CD-ROM drive. If not, go to **My Computer,** open the CD-ROM drive letter (typically located at drive ***D:***) containing the VISIX CD and Run the ***setup.exe*** program.

Important: If in a network situation, install the **Database** on the designated server computer. Make sure that all network connections or mapped drives to the server are set with **full** read and write access to the Data folder and its contents.

Database Installation.
This starts the installation script that provides the steps necessary to install VISIX. When given the option on whether to install the **Database** or **Workstation**, choose to install the **Database** first.

Important: The VISIX **Workstation** portion must be installed separately on each workstation computer on a network.

Workstation Installation. After finishing the **Database** installation, run the CD again and choose to install the **Workstation** this time. If installing VISIX across a network, take the VISIX CD to each workstation computer and install **only** the workstation portion.

Important: It is strongly recommended that the VISIX data folder be backed-up daily.

Database Connection. During the **Workstation** install, the installation script will ask to connect to the database. So prior to installing the workstation component, make sure that all network connections or mapped drives to the server are set with full read and write access to the Data folder and its contents.

VISIX Activation. Once the **Workstation** installation is completed on all computers, a one-time activation code must be obtained for the VISIX software. There is a 10-day grace period to activate the VISIX software. If this code is not obtain within 10 days, the user will be locked out of the VISIX Application.

Activation is done in a two-step procedure. First a reference code is given when double-clicking the VISIX icon on your desktop. This reference code is needed by the VISIX staff to generate an activation code.

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Second, obtain your activation code by calling the VISIX Technical Support at 1-866-90-VISIX or by visiting www.visixsoftware.com. Mention you are activating VISIX and have the following available to complete activation:

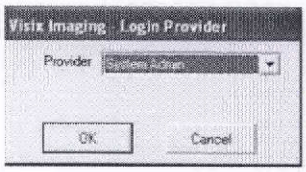
1. Doctor's name
2. VISIX reference code(s)
3. VISIX part number
4. VISIX serial number

CONFIGURING VISIX ADMIN

Configuration of VISIX administration settings allows the user to personalize their VISIX copy and specify operating preferences. Configure VISIX as follows:

1. Go to the **Start** button and select ***Programs***.
2. Select the ***VISIX Imaging*** program option and click on **VISIX Administration**.
3. Observe that the The ***VISIX Imaging - Login Provider*** window opens as shown below.

The ***VISIX Imaging - Login Provider*** window starts allowing the selection of a provider. Make sure that ***System Admin*** is selected in the **Provider** field and click the **OK** button to open the ***VISIX Administration Main*** window.



VISIX Administration Main Window

This window allows the editing of VISIX configuration categories:

1. Image File Formats
2. Practice Information
3. Provider Information
4. Program Configuration
5. Module Configuration
6. ScanX Configuration

Select a radio button to edit the configuration category desired.

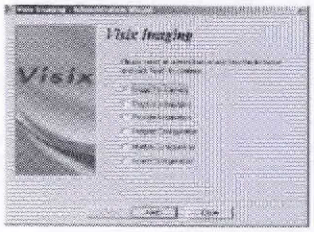
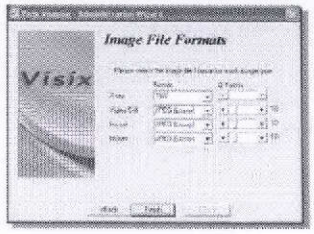
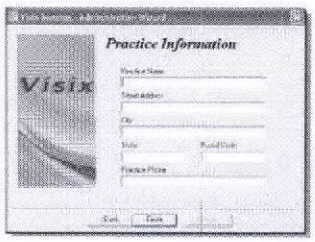


Image File Formats Window

This selection opens a window to allow the setup of the **save** file format for each type of image that can be acquired in VISIX.

The default settings are shown in the screen to the right. If using JPEG (lossy) setting, the compression factor applied to the image can also be specified.





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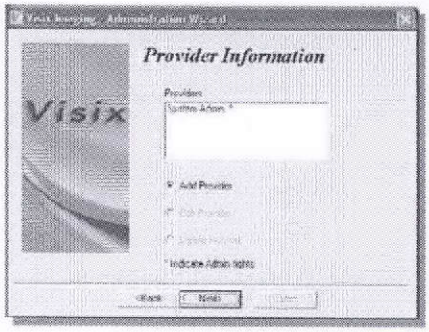
Practice Information Window
This selection opens a window to allow the input of your professional practice information including the practice name, address and phone number if applicable and/or desired.

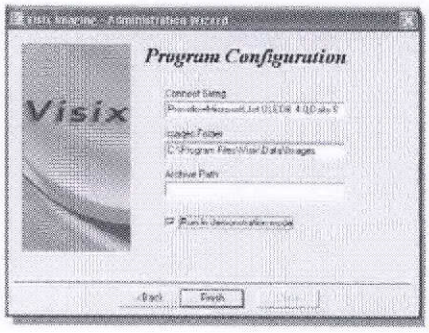
CONFIGURING VISIX ADMIN

Provider Information Window
This selection opens a window to allow the addition and editing of provider information for the practice as necessary. A Provider is any individual you wish to have access to VISIX.
Each new provider must select a user name. There is also the option to allow each provider Administrative rights by checking the ***Is Admin*** box.



Program Configuration Window
This selection opens a window where you will find the location of your database (Connect String) and images (Images folder) folder in Program Configuration.

You also have the opportunity to specify an Archive directory. This must be entered as a UNC path (i.e. //server name/share name)

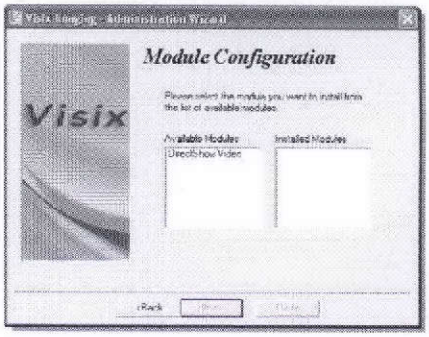


The ***Run in demonstration mode*** check box, when checked, will run both ScanXand Accent in demo mode with sample images. Un-checking this box returns VISIX to powering the hardware in Live mode.

Module Configuration Window

If purchased, you can activate support for another Direct show compatible video device here. Obtain a one time activation code by calling 1-866-90-VISIX and providing the module serial number.

If you are interested in purchasing this module, please contact your dealer.



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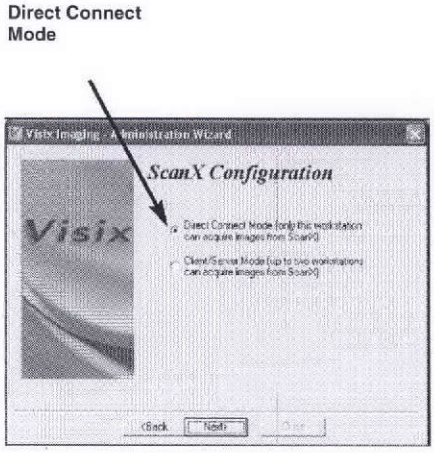
CONFIGURING VISIX ADMIN

Important: The ScanXConfiguration window is only necessary for use with either a ScanXI/O or ScanXDuo image scanner manufactured by Air Techniques, Inc.

ScanX cConfiguration Window
This selection opens a window that allows setting up a ScanXI/O or ScanXDuo with VISIX. There are 2 modes available:

1. Direct Connect Mode
2. Client/Server Mode

Refer to the configuration options below to determine which mode is best for your office setup



SCANX CONFIGURATION OPTIONS

Direct Connect Mode
The Direct Connect Mode is the default setup for VISIX as shown above with the Direct Connect Mode Radio Button selected. The Direct Connect Mode option allows only the ScanX connected directly to a single computer to acquire images.

- Direct Connect requires only one computer.
- The computer is normally located in a centralized location such as a hallway and not located in an operatory.
- The ScanX must be physically connected to the computer via USB.
- This computer only needs the VISIX workstation software running.
- All ScanX tracks are operated via the installed computer.

If you plan to position your ScanX in a hallway or room connected to a dedicated computer that all x-ray technicians will access via a computer network, then Direct Connect Mode is the best option for that office setup.

The Direct Connect mode enables VISIX to receive images from all ScanX tracks at the dedicated computer connected to ScanX via USB. Once the images are saved at this computer they will be accessible from all network computers running the VISIX software. Change to the Direct Connect Mode from the Client/Server Mode by selecting the Direct Connect Mode Radio Button and pressing the Next button. Save the new configuration. This ends the configuration setup and the computer must be rebooted in order for the changes to take effect.

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SCANX CONFIGURATION OPTIONS

Client/Server Mode

The Client/Server Mode uses Intelligent Track Control to enable up to two computer workstations to acquire images from one Scan*X*. Intelligent Track Control allows for half of the available tracks to be assigned to one operatory and the other half to a second operatory. This enables a single Scan*X* I/O or Scan*X* Duo to be shared between two operatories.

- ITC requires at least two computers connected together by a network.
- One of the computers must run a piece of VISIX software known as the Scan*X* Controller (Server). The ScanX device must be physically connected to this computer
- Both computers must run VISIX workstation (Client) software.

Note: For most installations operating in Client/Server mode, the Scan*X* Controller must be installed on the computer directly connected via USB to the Scan*X*.
The second computer with access to the Scan*X* will only have the Client software installed on it.

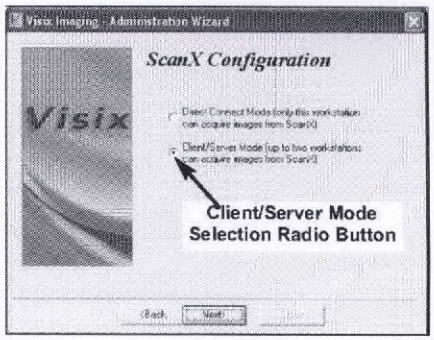
If you plan to position your Scan*X* in a pass-through between operatories or in location that can be easily accessed by technicians from two different operatories, then the Client/Server mode is an option for you.
There are two main approaches when operating in Client/Server mode:

1. There are total of two computers.
2. One computer is the "Server" running Scan*X* Controller software, and both computers run the "Client" software.
   a. The "Server" must be the computer that is directly connected via USB to the Scan*X* machine. The Scan*X* Controller will be installed on this computer.
   b. The "Client" is one of two computers that can receive the images from the Scan*X* Controller.

Client/Server Mode Selection

The Client/Server Mode is selected from the Scan*X* Configuration Window shown to the right. This is accomplished by selecting the Client/Server Mode Radio Button and pressing the Next button. A new window as shown on the top of page 9.

Scan*X* Configuration must be done on at least 2 computers when operating in Client/Server Mode.



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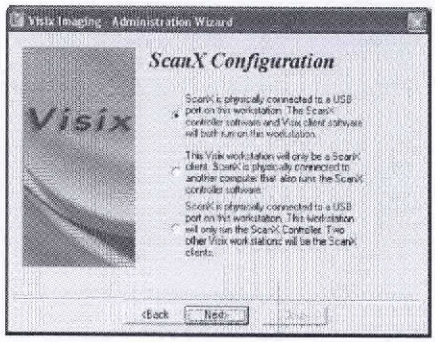
SCANX CONFIGURATION OPTIONS

Important: Separate Scan*X* Configurations must be run on each computer used to receive images from Scan*X*. Reboot all computers in order for the configuration changes to take effect.

Client/Server Mode Window

The Client/Server Mode Window (shown to the right) provides 3 separate configuration options.

Read all three descriptions first and use the one that applies to the office setup.



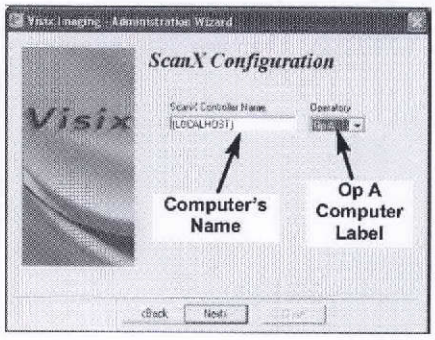
Controller and Client Software

This option activates both the Scan*X* Controller and the Scan*X* Client software on the subject computer that is physically connected via USB to the Scan*X*.

Choose the first option (top radio button) and press the Next button to run this Scan*X* Configuration on the subject computer.

As shown to the right, a new window opens showing that VISIX has input your computer's name as the Scan*X* Controller Name. By default this computer will be labeled Op A and will communicate via ports 8194 and 8195.

Press the Next button and save the changes to Scan*X* Configuration. Reboot the computer once completed.



Note: Editing of the Scan*X* Controller name or port numbers can be done in the Scan*X* Controller configuration and/or the Network tab in the VISIX Client.

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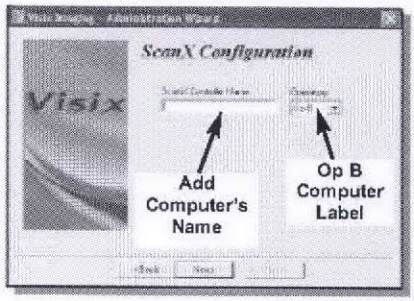
SCANX CONFIGURATION OPTIONS

Client Software Only
This option activates **only** the Scan*X* Client software on the subject computer that is **not** physically connected to the Scan*X* but will receive images. Choose the second option (middle radio button) from Client/Server Mode Window and press the Next button to run this ScanX Configuration on the subject computer

Note: Editing of the Scan*X* Controller name or port numbers can be done in the Scan*X* Controller configuration and/or the Network tab in the VISIX Client.

Observe that a new window opens (shown right) with a blank field seeking the computer name. Enter the computer name from the first option configuration of the computer that is directly connected via USB to the Scan*X* as the Scan*X* Controller Name.

By default this computer will be labeled Op B and communicate via ports 8196 and 8197. Press the Next button and save the changes to Scan*X* Configuration. Reboot the computer once completed.



Important: Choosing the third option requires you to run Scan*X* Configurations on **3 total** computers. This configuration is for a 3-computer network and is rarely used.

Controller Software Only
Choose the third option if your office setup uses a 3-computer network where the computer that is directly connected to the Scan*X* acts as the network server and the two other computers will receive images from the Scan*X*.
This option activates **only** the Scan*X* Controller software on the subject computer that is physically connected via USB to the Scan*X* and acts as the network server.
Choose the third option (bottom radio button) from Client/Server Mode Window and press the Next button to run this Scan*X* Configuration on the subject computer. Save the changes to Scan*X* Configuration. Reboot the computer once completed.
The two other computers of the network must be configured to receive the images from Scan*X*, using the second option (Client Software Only) described above. The Scan*X* Controller name given during the option three configuration must be entered on both computers configured under the second option.

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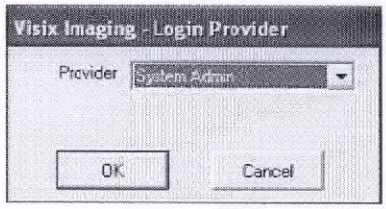
VISIX OPERATION

Open VISIX.

Launch VISIX simply by double clicking the VISIX icon on the desktop. or via the ***Start*** button as follows:

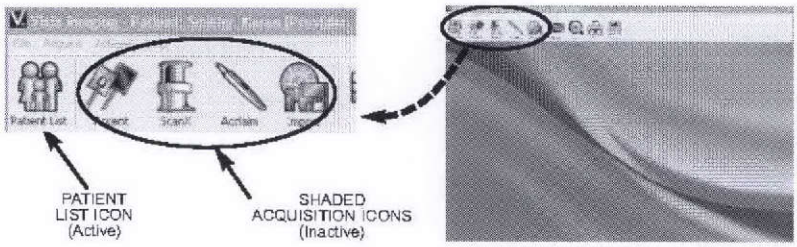
1. Click on the ***Start*** button and select ***All Programs.***
2. Select the ***VISIX Imaging*** program option.
3. Then select the VISIX icon.

Upon startup, the first VISIX window that opens is the Login Provider Window shown below. If the name that displays is the correct provider, click on the ***OK*** button to Login to VISIX. Otherwise, click on the Provider down arrow to display a drop down box of other active providers. Select the correct provider and click the ***OK*** button to Login.



Main VISIX Window.

The Main VISIX window opens upon the correct provider Login as shown below. Note that the Patient List Icon is brightly colored denoting that it is active while the next four acquisition icons are gray or inactive.



Patients Window.

In order to acquire images, the **Patients Window**, shown below, must be opened to define or select a patient. VISIX initially opens **without** a patient selected. Notice that the Main VISIX window title bar displays the message ***Patient: No Current Patient, [Provider: System Admin].***

The **Patients Window** is divided in two sections:

1. The left side is the patient's area where a patient is selected or information is added, deleted, edited.
2. The right side provides a Search Criteria area used to locate specific images previously acquired for the selected patient.

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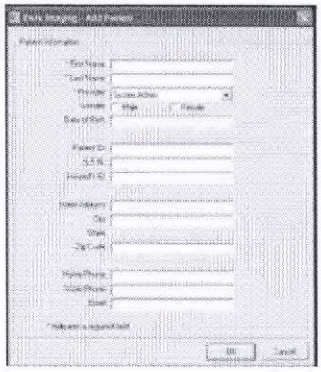
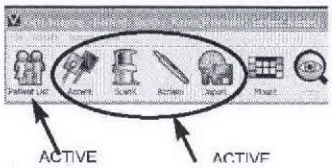
VISIX OPERATION



Adding a New Patient.
Add a patient by clicking the ***Add*** button on the top left side of the **Patients Window**. Observe that the **Add New Patient Window**, shown on the right, opens containing the patient information form.
Enter the patient's information in the form as desired and click the ***OK*** button to to save the patient record.
Once saved, the patient record will appear on the **Patients Window** in alphabetical order by last name.



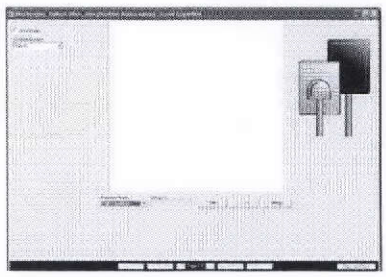
Acquiring Images.
Refer to page 7 above if needed and open VISIX and Login.
Select a patient by clicking the **Patient List** icon and double-clicking the patient's name from the list on left side of the **Patients Window**.
Observe that the Main VISIX window opens with active Acquisition Icons.

Important: Make sure that after a patient is selected the patient's name appears in the title bar of the Main VISIX window.

After selecting a patient, images can be acquired by VISIX through the Acquisition icons located on the Main VISIX window tool bar. The input methods consist of X-rays (Accent and Scan*X*), Video (Acclaim), and imported images from other media. Acquire an image by left clicking on the Acquisition Icon corresponding to the desired image input as follows.

Acquiring Images with the Accent Sensor

Selecting the Accent icon opens the Accent acquisition window. If the device is installed per manufacturer instructions, the initialized bar flashes and then turns solid green. This indicates that the sensor has been initialized and is ready to acquire images. Click the **Start** button to open the sub-acquisition window of the accent sensor. VISIX automatically captures X-ray images from the sensor. Select the **Settings** and **1. 2. 3 Setup** buttons to check and adjust the current settings as necessary. If the **Cancel** button is clicked during acquisition, the process is aborted.



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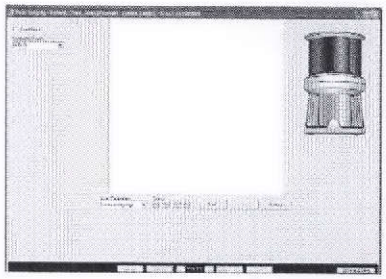
VISIX OPERATION

Acquiring Images with the ScanX

Selecting the Scan*X*icon opens the Scan*X* acquisition window. If the device is installed per manufacturer instructions, the status bar is a solid green. This shows that the scanner has been initialized and is ready to acquire images.

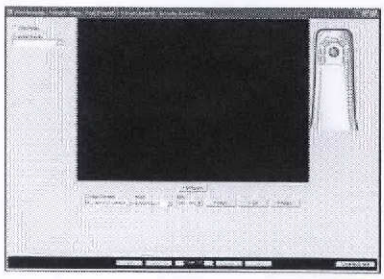


Select an appropriate scan setting from the Scan Setting list in the lower left hand corner. Intraoral Standard, Pan Standard, or Ceph Standard is suggested. Select the **Settings** and **1. 2. 3 Setup** buttons to check and adjust the current settings as needed.

Load the phosphor plate or plates into the Scan*X*in accordance with the manufacturer's directions. VISIX automatically captures the image from the Scan*X*. If the **Cancel** button is clicked during the process, the scan is aborted.

Acquiring Images with the Acclaim Camera

Selecting the Acclaim icon opens the Acclaim acquisition window if the device is installed per manufacturer instructions.



Observe that the live feed video input is displayed in the Preview Image box. If the video is not displayed check the following:

1. Make sure that the Acclaim USB Camera is selected on the **Capture Devices** drop down box.
2. Make sure that the **Input** drop down box should read ***Default Input*** indicating that the Acclaim drivers have been loaded successfully.
3. Set the image resolution by clicking the down arrow of the **Size** drop down box and selecting 640 by 480 dpi (recommended).

Freeze/Live Button

Click **Freeze** of the **Freeze/Live** button to freeze the video display to show a still frame image on the Preview Image box.Notice that clicking **Freeze**, changes the button's name to **Live**. Clicking the **Live** of the **Freeze/Live** button again brings the live feed back to the Preview Image box.

Saving an Image

After clicking **Freeze**, while a still frame image is in the Preview Image box, the **Save** button is enabled. Click the **Save** button to capture the existing still frame image. A thumbnail will appear at the bottom of the screen. The main image will return to live feed.

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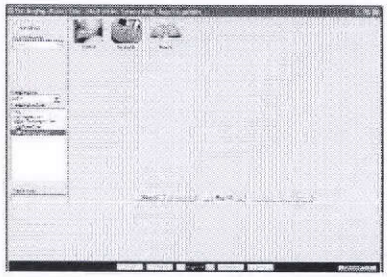
VISIX OPERATION

Imported Images from Other Media

Selecting the Import icon opens the Import acquisition window.

Click on the drop down box arrow to display the list of available disk drives the computer can access. If this computer is on a network and has network drives mapped, the network drives will also display.



Note: The computer views many digital cameras as removable hard drives.

Select the drive where the imported images can be found. After the drive is selected, a list of the folders (also called Directories) on that drive will display.

Select the folder where the imported images can be found. Any images in the selected folder (directory) on the selected drive will display in the **Current Image** box on the Acquire window.

To import an image, the image must be selected then imported, then selected and saved.

Note: A selected image will have a green box around it.

Selecting and Importing Images

1. Select an image or images as follows:.
   a. Select one image by left clicking on it.
   b. Select multiple images by left clicking on the rest of the desired images.
   c. Select all of the images by clicking on the **Select All** button at the bottom of the window.

2. Import the selected image or images by clicking on the **Import** button at the bottom of the Current Image box.

Saving Images

Once an image has been selected and imported it will move to the area under the **Available Directories** box as a thumbnail image. The image still needs to be selected and saved into VISIX by clicking the **Save and Close** button at the bottom of the window. All images will be automatically saved.

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1.2.3 Setup

1. 2. 3 Setup is a tool that adjusts the amount of edge enhancement, smoothing, contrast and gray shift (or gamma) for the best image quality possible when using the Accent sensor or Scan*X*unit. The 1. 2. 3 Setup tool is accessed from the **Settings** button on the Accent or Scan*X*Acquisition window. One image must be processed before using the 1. 2. 3 Setup tool. Changes made in 1. 2. 3. Setup under the Intra-oral tab will only be applied to future Intra-oral images. Click the **1. 2. 3. Setup** button to start the process.

Step 1.
Step 1 allows the user to set the amount of edge enhancement filtering that is applied to all future images. Edge enhancement filters increase the sharpness of the edges and structure of the teeth. There are four setting selections; None, Low Med and High. While selecting different levels of edge enhancement, observe the result on the last processed image to better determine which setting gives the best image quality. The selected enhancements will affect all future images.
The ***Advanced*** button should only be accessed by trained service personnel! Changing its values may adversely affect image quality. Clicking the ***Back*** button will exit out of the 1. 2. 3. Setup tool without saving any of the changes made. Click the ***Next*** button to precede to Step 2. Observe that the Step 2 window opens.

Step 2. Step 2 allows the user to set the amount of smoothing that is applied to all future images, and ranges from None to High. Smoothing filters attempt to remove any extra "noise" or graininess from the image caused by the edge sharpening applied.
While selecting different levels of smoothing, observe the result on the last processed image to better determine which setting gives the best image quality.

The Advanced button should only be accessed by trained service personnel! Changing its values may adversely affect image quality. Clicking the ***Back*** button will return you to Step 1, Edge Enhancement and undo any selected smoothing setting. Click the ***Next*** button and observe that the Step 3 window opens.

Step 3.
Step 3 allows the user to set the amount of brightness, contrast and gray shift (or gamma) that is applied to all future images. The default values can be set by clicking the Center Controls button below the sliders. As the different levels of brightness, contrast or gray shift are adjusted, you will see live feedback on the last processed image to determine which setting gives the best image quality.

Clicking the ***Back*** button will return you to the Step 2 window, Smoothing. will undo any selected brightness, contrast or gray shift settings .

Click the ***Finish*** button to end the 1. 2. 3...Setup tool. You will see a summary of your new settings that will be applied to every image processed.

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Air Techniques and ALLPRO Imaging are leading manufacturers of fine dental, medical and veterinary equipment from air and vacuum systems and X-ray film processors, to an impressive line of new products incorporating the most recent technological advances. These new products, vital components of the innovative professional practice, include intraoral cameras, digital imaging systems, which utilizes phosphor plate technology and, most recently, an intraoral digital X-ray system using sensor technology.

Air Techniques and ALLPRO Imaging have been manufacturing quality products for the dental, medical and veterinary professional since 1962.

Air Techniques and ALLPRO Imaging products are distributed only through authorized dealers. Refer to www.airtechniques.com or www.allproimaging.com to find a dealer in your area.

- ❑ Accent™ Intraoral Digital X-ray Image System
- ❑ Acclaim® Intraoral Digital Video Camera System
- ❑ Acclaim® USB Only Intraoral Digital Video Camera System
- ❑ AirStar®
- ❑ A/T 2000® XR
- ❑ Guardian™ Amalgam Collector
- ❑ Peri-Pro®
- ❑ Provacta 70™
- ❑ Rinsendo Root Canal Disinfection System
- ❑ ScanX®
- ❑ STS™
- ❑ VacStar™

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- ❑ 2010
- ❑ Medscope
- ❑ Provacta V
- ❑ ScanX® 12
- ❑ ScanX® DVM
- ❑ ScanX® 12 DVM
- ❑ ScanX® NDT
- ❑ ScanX® 12 Portable
- ❑ ScanX® 14 Portable
- ❑ ScanX® NDT Portable
- ❑ ScanX® 14 In-Counter

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Visix Web Site Downloads section (bottom of page 2 above):

List of Compatible Practice Management Systems

Compatible Practice Management Systems & Supported Hardware

Can I access the images from my practice management software? Yes, nearly all practice management software companies have "bridged" to Visix. The following companies have bridged to Visix:

Ablesoft
AbelDent
Ace Dental
Alphadent
BRS Computing
Ciraden
ComputerAge
The Complete Exam
Daisy
Datacon
Dental Exec
Dental Office Express (DOX)
Dental PRO
Dental Vision/Discus
Dental.com
Dentech
DentiMax
Dentisoft
Dentrix **
Desco
Direct Vision
DOM for Windows
Eaglesoft**
Easy Dental
Exact Dental
EZ Dent
First Pacific Corporation
FoxdentOffice
Genesis
Human Touch
Innova
Intellident
Kcomp
Medident
Mogo
NDC
Oasys
OCS
Open Dental
Oral Surgery Exec
Partner
PatientBase
Practice-Web
Practice works **
PBS Endo
PEB for Windows
PEB's XLDent **
Perio Apprentice
Perio Exec
Perio Vision
Primadent
Power Practice
Practice Outlook
Practice Web
QSI
Scandent
Softdent **
Softech
Suzy
Three Star
Time for Perio
Tri-Star
Vantage-Med
Windent

** In some cases these companies may charge a fee for their bridge. Under these circumstances Visix offers a free alternative called VisixLink, that allows Visix to access the patient name from the PMS and retrieve the image file corresponding to that specific patients' name.

Please call Visix for the most up-to-date list of compatible bridges. It is also prudent to contact your practice management software vendor to discuss the details of the bridge and or a proposed bridge.

Visix Imaging – 1-866-90-VISIX

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Visix Web Site Downloads section (bottom of page 2 above):

Visix Supported Cameras

Compatible Cameras and Video Capture Cards

By default Visix Imaging supports only the Air Techniques' Acclaim intraoral video camera. With the addition of the Visix Imaging DirectShow Video Capture module, Visix Imaging supports virtually all intraoral video cameras.

Intraoral cameras fall into roughly two main categories, digital cameras and analog cameras. Digital cameras usually output video through a USB 2.0 or an IEEE 1394 interface (FireWire). Virtually all digital cameras include a CD that contains Microsoft DirectShow drivers that allow the camera to interface with Visix Imaging.

Analog cameras usually output video through S-Video or Composite Video connectors. Analog cameras require the addition of a Video Capture Device to convert the analog signal to a DirectShow compatible digital signal. There are many video capture devices available at your favorite computer/office supply store, many of them are priced less than $100. We have listed a small selection of devices that we have tested and know are compatible with Visix below. There are many other makes and models that our customers use with equal success.

Some intraoral cameras have buttons on the handpiece or footpedals for freezing live video and/or saving images. In order for Visix Imaging to respond to button or footpedal operations, the camera or footpedal must have DirectInput drivers. You can tell if your camera's buttons or footpedal will work with Visix Imaging by opening Control Panel and checking the Game Controllers Applet. If you see your device listed as a one button or two button game pad, it will work with Visix Imaging. Please contact your camera company to obtain these drivers if necessary.

Recommended Video Capture Cards

Make	Model	Price	Comments
ATI	All-in-Wonder Radeon 9000	~$180	Single card large capture size DirectShow Compatible
Dazzle	Digital Video Creator 90	~$79	USB 2.0 solution with full size video capture (640x480)
Hauppauge	WinTv-Go Video TV Tuner	~$50	Needs separate video card Video for Windows

Compatible Intraoral Cameras

Camera Manufacturer	Model	Special Instructions
A-Dec	A-Dec Intraoral Camera	
Acteon, Inc.	Sopro	Capture "button" not supported at this time
Air Techniques	Acclaim	
Dentrix Dental Systems	ImageCAM	
Digital Doc	Evolution Series	
Gendex	AcuCam	The firewire version requires connection by S-Video for proper function
Henry Schein	ViperCam	
Imagin Systems Corporation	HotRod Dental Imager	
Kavo Dental Corporation	ERGOcam	
Kodak Dental Systems	Kodak 1000	
Lightyear Direct	Lightyear Digital Camera	
Planmeca, Inc.	Intracam	
Progeny Dental	Progeny Micro	
RF Systems	Einstein	
Scican, Inc.	Intra Oral Ultimate	Requires configuration – call Visix support
Sota Precision Optics	Claris Series	Displays "mirrored" image only

Visix Support Office – 1611 Center Ave. – Janesville, WI 53545
1-866- 90- VISIX

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Visix Web Site Downloads section (bottom of page 2 above):

Visix Supported Scanners

Visix

Compatible Flatbed Scanners

Scanners Compatible for use with Visix is listed below in size order from smallest to largest.

In addition to these listed below, Visix will accommodate all Twain based flatbed scanners that have a transparency adapter. A transparency adapter is nothing more than a "light-lid" that fits on top of the scanner so light can pass through x-rays when they are being scanned. The adapter just adds the capability to scan x-rays and other transparent material such as 35mm slides. These scanners can scan in color as well as black and white.

All of the scanners listed below deliver excellent image quality, even the inexpensive ones. The major distinction between an inexpensive scanner and an expensive one is the size of the transparency adapter, time of the scan, and the durability of its components. The size of this adapter determines the maximum size of film that can be scanned. If you are interested in scanning pans and FMXs, you should consider the larger scanners listed below. If you will be scanning only individual x-rays or slides, then the smaller ones will be adequate.

Make	Model	Adapter Size	Price	Comments
Epson	Perfection 4870 Photo	6" X 9"	~$430	Scans 35mm slides, film strips
Microtek	i900	8" X 10"	~$600	Scans pans and some FMXs
Epson	Expression 1680 Pro	8.5" X 11.7"	~$1100	Scans pans and most FMXs.
Microtek	ScanMaker 9800XL	12"X 16"	~$1400	Scan pans and larger FMXs.

1-866- 90- VISIX

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Visix Imaging Marketing Document:

Visix

IMAGING SOFTWARE SPECIFICATIONS

VISIX Imaging Network Computer Requirements/Recommendations

CPU Speed:	2 GHz Pentium Class, or higher.
Operating System:	Windows 2000 Service Pack 4, or later. Windows XP Professional Service Pack 1a, or later.
RAM:	512 MB, or higher.
CD ROM Drive:	48x speed, or higher.
Hard Drive:	100 MB of free disk space on each work station for program files. 80 GB, or higher, on server for image storage.
Monitor:	1024x768 resolution minimum. 1280 x 1024, or higher, recommended.
Keyboard/Mouse:	Standard keyboard and mouse required.
Backup Device:	Tape backup or external hard drive recommended. (Tape or drive capacity should be greater than the space designated for image storage on server.)
External Surge Protector:	Recommended.
Printer:	720 DPI of higher inkjet or photo printer. LaserJet's are NOT recommended.
USB Port:	USB 1.1 minimum. USB 2.0 is recommended.
Network:	100 mbps network speed, or higher. Client/Server network topology recommended. Microsoft 2000 or 2003 Server recommended for server OS.

AIR TECHNIQUES INC.
1295 Walt Whitman Road, Melville, NY 11747 / www.airtechniques.com
516-433-7676 / Fax 516-433-7684 / Toll free in the U.S. and Canada: 800-Air-Tech
Western Facility 951-898-8555 / Fax 951-898-7646

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STERILIZATION AND SHELF LIFE

This section does not apply as the proposed device contains software only and does not require sterilization or have a shelf life identified.

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BIOCOMPATIBILITY

This section does not apply, as the proposed device does not contain components that come into direct or indirect contact with patients.

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SOFTWARE

Visix Imaging is medical imaging software that acquires, displays, enhances, stores, and prints images. The images are acquired from various hardware sources such as scanners, digital video cameras, digital image files, etc.

Software Level of Concern:

According to the *Guidance for the Submission of Premarket Notifications for Medical Image Management Devices* dated July 27, 2000, software for most medical image management devices is considered a minor level of concern.

Based on the information provided for determining the level of concern in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005, Visix Imaging is considered a moderate level of concern and the following information is provided.

- A list and brief description of the functions performed by the software including revision history log;
- A description of the software development methods including changes and configuration management;
- A description of the software test methods;
- A list of hazards related to the functions performed by the software and the means taken to mitigate each of these hazards; and
- A certification statement regarding the software.

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Functions:

The following is a list of the Visix Imaging functions with a brief description of each.

Function Number	Function	Description
1	Acquire Images	Save images taken by hardware device sources such as scanners, digital video cameras, digital sensors, etc., or import digital image files that were saved on computer media such as hard drives, floppies, CDs, DVDs, the internet, thumb drives, etc.
2	Save images in a Searchable Image Library	Store images using cross referencing database information that allows images to be located later by such information as patient name, image date, what hardware acquired the image, keywords, tooth number, etc.
3	Display Images	Present images for viewing on either a computer or TV monitor, or a paper printout.
4	Enhance Images	Make minor, non-permanent image adjustments (e.g., rotate, zoom, flip, etc.). to create the clearest and most detailed view possible of the image.
5	Link Information to Images	In database tables, link information such as the anatomical region represented by the image, keywords that describe the image, notes about the image, the date the image was taken, the hardware device used to acquire the image, and the patient that the image was taken of, to the image.
6	Delete Images	Remove images from the Visix Imaging database.
7	Print Image Copies	Print a copy of an image plus image information such as patient name, doctor name, etc.
8	Export Images	Save a copy of an image to a user specified export location.

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Revision History Log:

Rev.	Date	Modification description

(b)(4)

[redacted]

August 29, 2008

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Rev.	Date	Modification description

(b)(4)

[redacted]

August 29, 2008

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Rev.	Date	Modification description

(b)(4)

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Rev.	Date	Modification description

(b)(4)

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Rev.	Date	Modification description

(b)(4)

[redacted]

August 29, 2008

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Software Development Methods:

(b)(4)

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(b)(4)

Figure 1. Enhancement Request Form:

(b)(4)

The software development process is summarized below.

(b)(4)

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(b)(4) Software Development Process

(b)(4) Software Development Process

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(b)(4) Software Development Process

[redacted]

Configuration Management

(b)(4)

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(b)(4)

[redacted]

Software Testing Methods

(b)(4)

[redacted]

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Hazard Analysis:

(b)(4)

[redacted]

Software Certification:

The software certification statement immediately follows this page.

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I hereby certify that the software development process was followed for the Visix Imaging software, good quality assurance procedures were adhered to, and test results demonstrate functional requirements were met.

9-4-2008

Paul Davies-White
Manager of Engineering
Televere Systems

Date

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CONFIDENTIAL

Hazard Number	Hazard	Level of Concern	Potential Cause(s) of the Hazard	Mitigation	Remaining Level of Concern

(b)(4) Hazard Analysis

[redacted]

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(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

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Visix Imaging Hazard Analysis

Hazard Analysis Conclusion:

Visix software meets its acceptance criteria and functions as planned.

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

[redacted]

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ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This section does not apply as the proposed device is software only and does not contain an electronic component.

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PERFORMANCE TESTING—BENCH

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4) Testing

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PERFORMANCE TESTING—ANIMAL

This section does not apply as no animal studies were necessary to support this 510(k) submission.

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

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PERFORMANCE TESTING CLINICAL

This section does not apply as no clinical studies were necessary to support this 510(k) submission.

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

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Software Requirements Specification

1. Hardware Requirements

Computer Platform	Hardware Specifications/Requirements
Computer Workstation	Operating System: Windows 2000 SP 4 or later, Windows XP Professional SP 1A or later CPU: 2 GHz Pentium class or higher RAM: 256MB or higher CD-ROM Drive: 4x speed or higher Hard Drive: 70MB or more of free space for the program Monitor: 1024x786 setting minimum Motherboards should avoid SIS USB ports
Computer Printer	720dpi or higher inkjet or photo printer, black and white laserjets can be used but are not recommended
Computer Network	Not required. If there is one it should be a Client/Server topology. Microsoft. Network speed: 100mbps or faster.
Computer Network Server	Hard Drive: 80GB or more free space for the image database and images

2. Programming Language Requirements
   Languages: Microsoft Visual Basic 6, Microsoft Visual Basic .NET, Microsoft Visual C++
   Language issues: no relevant language issues are known at this time
   How the language issues are compensated for: N/A

3. Performance and Functional Requirements

   Visix Imaging is a small PACS that is comprised of five major functions (Patients, Images, Acquire, Mount, and View) plus two minor functions (Export and Print). Visix accepts digital images from various imaging devices made by other manufacturers, such as the Acclaim intra-oral camera, the ScanX scanner and the Accent sensor. Visix stores the images, allowing them to be viewed, manipulated, printed, exported, and grouped together in a mount. Visix also stores some patient information such as the patient's name, address and date of birth.

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Note: the Visix database and Images folder are frequently located on a network server and connected to using mapped drives. Mapped drives are created using the Microsoft Map Network Drive function that allows remote drives to be used by a computer as if they are local drives. Microsoft handles all network operations that involve these drives.

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(b)(4) Software Requirements Specifications

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Architecture Design Chart

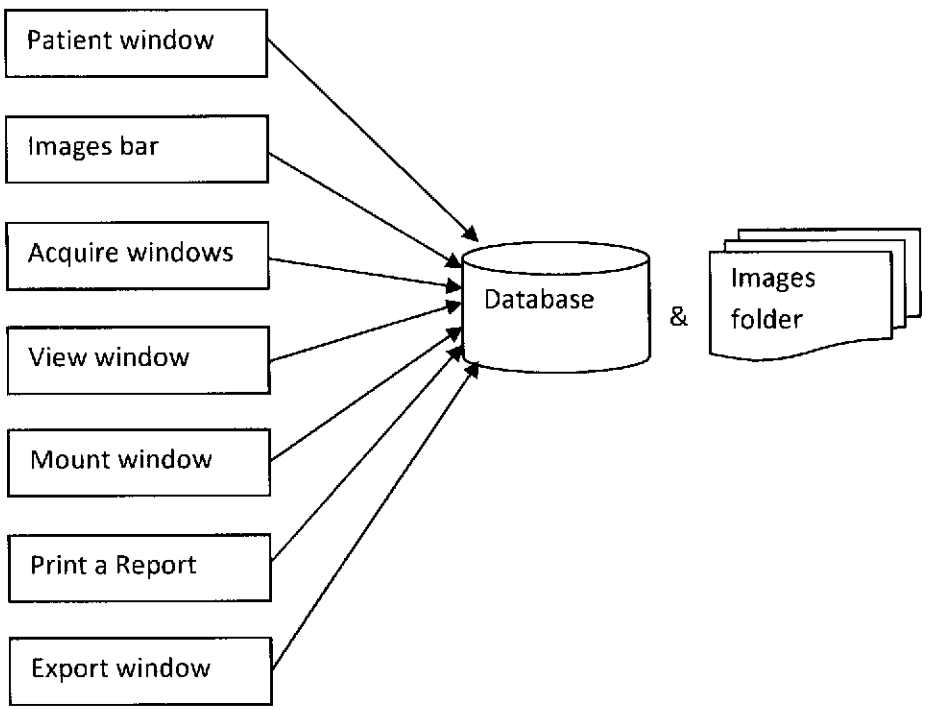
System Overview

Visix Imaging is a small PACS that is comprised of five major functions (Patients, Images, Acquire, Mount, and View) plus two minor functions (Export and Print). Visix accepts digital images from various imaging devices made by other manufacturers, such as the Acclaim intra-oral camera, the ScanX scanner and the Accent sensor. Visix stores the images, allowing them to be viewed, manipulated, printed, exported, and grouped together in a mount. Visix also stores some patient information such as the patient's name, address and date of birth.

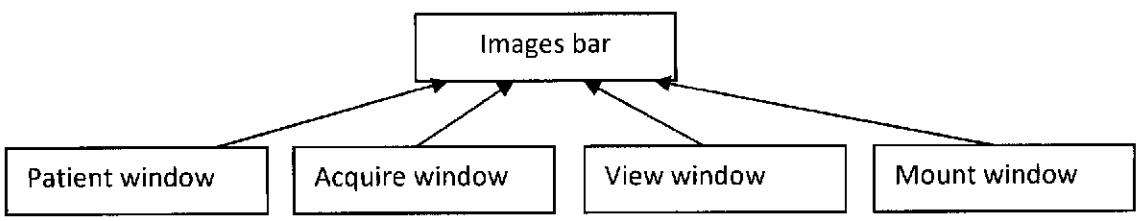
Note that the Visix database and Images folder are frequently located on a network server and connected to using mapped drives. Mapped drives are created using the Microsoft Map Network Drive function that allows remote drives to be used by a computer as if they are local drives. Microsoft handles all network operations that involve these drives.

Relationships between Visix Functions

Each of the functions interfaces with the Visix database and the Visix Images folder.



Some of the functions also relate to each other as they pass images.



A description of each Visix function is listed below. In the flowcharts, the Visix functions are in blue.

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

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Software Design Specification

System Overview

Visix Imaging is a small PACS that is comprised of five major functions (Patients, Images, Acquire, Mount, and View) plus two minor functions (Export and Print). Visix accepts digital images from various imaging devices made by other manufacturers, such as the Acclaim intra-oral camera, the ScanX scanner and the Accent sensor. Visix stores the images, allowing them to be viewed, manipulated, printed, exported, and grouped together in a mount. Visix also stores some patient information such as the patient's name, address and date of birth.

Note that the Visix database and Images folder are frequently located on a network server and connected to using mapped drives. Mapped drives are created using the Microsoft Map Network Drive function that allows remote drives to be used by a computer as if they are local drives. Microsoft handles all network operations that involve these drives.

Flowchart Explanation

Sections start at the top of a page using a box with rounded corners and larger, bold face type.
Buttons that are event driven (something happens when you click on them) are listed separately toward the end of each section
Things that could logically be grouped together are frequently found in the same box.

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(b)(4) Software Design Specification

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Traceability Analysis

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Unresolved Anomalies

I have included the Revision History Log as part of section 016_Software. We actually don't have any unresolved anomalies at this time. Visix is a small, simple system. The occasional bug that pops up gets fixed right away

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