

NORLAND



Data Import Tool

For Norland IlluminatusDXA Software

435S149 Rev A

Copyright ©2020 Norland at Swissray

Software License Agreement

Please read this software license agreement carefully before using the software. By using the software, you are agreeing that this software license agreement forms a legally binding contract between you and Norland and that this agreement constitutes a “writing signed by you” under any applicable law or regulation. Any rights not expressly granted herein are reserved by Norland. If you do not agree to the terms of this license, do not use the software and return the bone assessment product to Norland.

- 1) **DEFINITIONS.** The word “**Software**” means the software in object code form and any documentation which you have received from Norland in connection with the Norland Bone Assessment Product, whether incorporated into the Product or not. The phrase “**Claims or Losses**” means any and all liabilities, obligations, losses, damages, penalties, claims, actions, suits, costs, judgments, settlements, and expenses of whatever nature, whether incurred by or issued against an indemnified party or a third party, including, without limitation: (a) indirect, special, punitive, consequential or incidental loss or damage (including, but not limited to, trading losses, loss of anticipated profits, loss by reason of shutdown in operation or increased expenses of operation, or other indirect loss or damage) and (b) administrative costs, investigatory costs, litigation costs, and auditors’ and attorneys’ fees and disbursements (including in-house personnel). The word “**Licensee**” or “**you**” shall mean you, the individual or entity which has purchased the Bone Assessment Product and accompanying Software, and has agreed to this License by using the Software and has not returned the Bone Assessment Product to Norland.
- 2) **LICENSE; INTELLECTUAL PROPERTY RIGHTS.** Norland grants to Licensee a nonexclusive, royalty-free, non-transferable license during the term of the Agreement to receive and use the Software solely in connection with Licensee’s use of the Bone Assessment Product. The Software is licensed only for the internal use of Licensee and its employees. Licensee may not sell, lease, furnish, redistribute, retransmit, or otherwise permit or provide access to the Software to any other person. Licensee will not engage in the operation of any illegal business or use or permit anyone else to use the Software, or any part thereof, for any illegal purpose. Licensee shall take reasonable security precautions to prevent unauthorized persons from gaining access to the Software. Licensee acknowledges that Norland retains proprietary rights in the Software. In the event of any misappropriation or misuse, in addition to its right to damages Norland shall have the right to obtain injunctive relief. Licensee agrees not to decompile, disassemble or reverse engineer the Software.
- 3) **NORLAND’S WARRANTIES/DISCLAIMER OF WARRANTIES.** The Software is designated for use with the Norland Bone Assessment Product and is warranted to execute its programming instructions when properly installed in that product. Accessory products, including software, not manufactured by Norland carry the warranties of their respective manufacturers. Norland does not warrant that the operation of the Software shall be uninterrupted or error free. **BEYOND THE WARRANTIES STATED IN THIS SECTION, THERE ARE NO OTHER WARRANTIES OF ANY KIND, EXPRESS, IMPLIED OR STATUTORY (INCLUDING, WITHOUT LIMITATION, TIMELINESS, TRUTHFULNESS, SEQUENCE, COMPLETENESS, ACCURACY, FREEDOM FROM INTERRUPTION), ANY IMPLIED WARRANTIES ARISING FROM TRADE USAGE, COURSE OF DEALING, OR COURSE OF PERFORMANCE, OR THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.**

- 4) NORLAND'S LIMITATION OF LIABILITY.
 - a) Under no circumstances, including negligence, shall Norland shall be liable to Licensee or any other person for indirect, special, punitive, consequential or incidental loss or damage (including, but not limited to trading losses, loss of anticipated profits, loss by reason of shutdown in operation or increased expenses of operation, cost of cover, or other indirect loss or damage) of any nature arising from any cause whatsoever, even if Norland has been advised of the possibility of such damages. In no event shall Norland's total liability to you or any other person for all damages exceed fifty dollars (\$50).
 - b) Norland shall not be liable to Licensee or any other person for any unavailability, interruption, delay, incompleteness, or inaccuracy of the Software.
 - c) The Parties acknowledge that the terms of this section reflect a reasonable allocation of risk and limitation of liability.
- 5) FORCE MAJEURE. Notwithstanding any other term or condition of this Agreement, Norland or Licensee shall not be obligated to perform or observe their respective obligations undertaken in this Agreement (except for obligations to make payments hereunder and regulatory obligations) if prevented or hindered from doing so by any circumstances found to be beyond their control.
- 6) LICENSEE INDEMNITY. Licensee will indemnify and hold harmless Norland and its employees, officers, directors, and other agents from any and all Claims or Losses imposed on, incurred by or asserted as a result of or relating to: (a) any noncompliance by Licensee with the terms and conditions hereof; or (b) any third-party actions related to Licensee's receipt and use of the Software, whether authorized or unauthorized under the Agreement.
- 7) ENFORCEMENT. Norland may enforce the terms of this Agreement against Licensee itself or against any person, whether or not Licensee is a party to such action. In any action there shall be available injunctive relief or damages, with the prevailing party being awarded costs and attorneys' fees (including in-house counsel).
- 8) TERMINATION In the event of (a) Licensee breach or (b) where directed to do so by any person in its regulatory authority, Norland may terminate this Agreement at any time immediately upon written notice to Licensee provided by Norland.
- 9) MISCELLANEOUS. Except as otherwise provided herein, no provision of this Agreement may be amended, modified, or waived, unless by an instrument in writing executed by a duly authorized officer of the party against whom enforcement of such amendment, modification or waiver is sought. No failure on the part of Norland or Licensee to exercise any right, power or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of such right, power or privilege preclude any other or further exercise thereof or the exercise of any other right, power or privilege under this Agreement. If any of the provisions of this Agreement, or application thereof to any person or circumstance, shall to any extent be held invalid or unenforceable, the remainder of this Agreement, or the application of such terms or provisions to persons or circumstances other than those as to which they are held invalid or unenforceable, shall not be affected thereby and each such term and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

- 10) SURVIVAL. The terms of this relating to intellectual property and indemnification shall survive termination of this Agreement.
- 11) GOVERNING LAW AND FORUM. Each party hereby irrevocably and unconditionally submits for itself and its property, to the jurisdiction of any New York State court or federal court of the United States of America sitting in New York County and to any other court in any jurisdiction in which an action is brought against a party to this agreement by a third party asserting a claim against which Norland is entitled under this agreement to be indemnified. In any action or proceeding arising out of or relating to this agreement or for recognition or enforcement of any judgment, all claims in respect of any such action or proceeding may be heard and determined in any such New York State court or by such federal or other court. A final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.
Each party irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection that it may have or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this agreement in any New York State or federal court sitting in New York County or such other court. Each party irrevocably waives to the fullest extent permitted by law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

Contents

Software License Agreement	2
Overview	6
Software Installation	7
Importing Patient Data	9
Preparing IlluminatusDXA Databases	9
Logging In	9
Import Settings	10
Source Database	10
Destination Database	11
Patient Selection	11
Verbose Mode	11
Import Data	11
Patient Details Prompt	11
Patient Record Conflict Prompt	12
Final Status	13
Results Trending	14
Enable/Disable Trending	15
Viewing and Deleting Imported Records	16
Deleting Imported Records	17
References	18

Overview

The Data Import Tool is a software application which aids the customer in transferring patient demographics and (optionally) scan results from other DXA devices for the purposes of patient data entry and results trending.

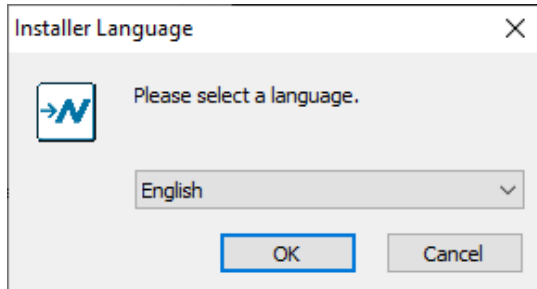
If scan results are imported, the numerical results for each region are transferred and stored without modification, reanalysis, or conversion. Scan images are not transferred.

The Data Import Tool is to be used in conjunction with Norland IlluminatusDXA software for applicable Norland DXA scanners. This application is not intended to be used as a stand-alone product or for any other purposes. Other uses are not intended or implied.

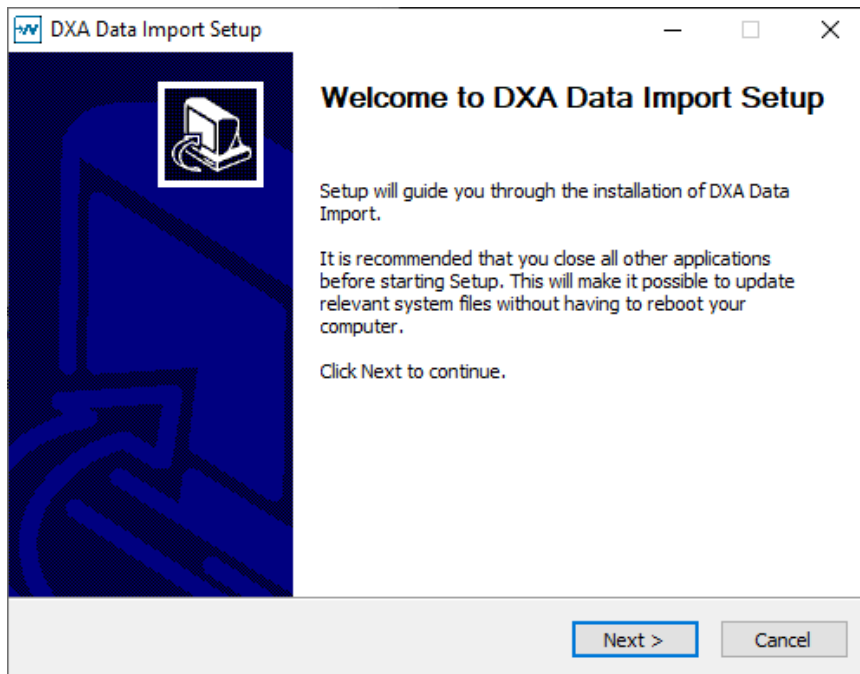
Software Installation

The software installation media includes the Data Import application as well as database runtime libraries. The database runtime libraries only need to be installed once for a system unless an updated version is required. Runtimes for 64-bit and 32-bit systems are included where applicable.

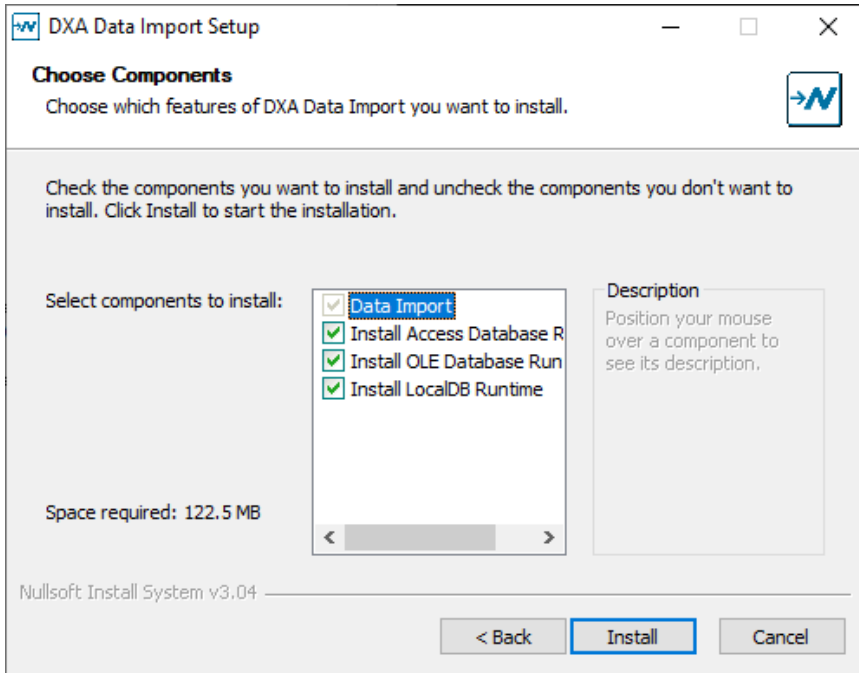
1. Run the Data Import installation program. Select the installation language and click OK.



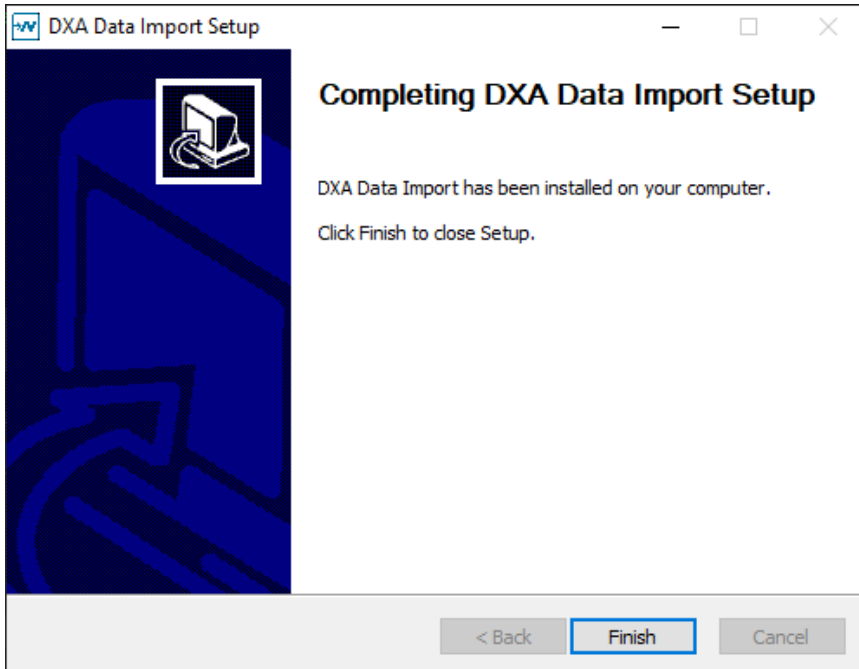
2. At the Welcome screen click **Next**.



- For first-time installations, the database runtime libraries will be installed by default. Click **Install**.



- The application files will be installed, then the selected runtime libraries will each be installed. Follow any applicable prompts to install each library with default settings.
- Click **Finish** to close the installation.



Importing Patient Data

Preparing IlluminatusDXA Databases


The IlluminatusDXA application must be installed and run at least once before importing data so the appropriate databases and system files are available.

A valid OAC (Option Authorization Code) enabling the Data Import feature for your scanner must be entered in the IlluminatusDXA Scanner Preferences before the Data Import software can be used.

The patient data may be imported into the IlluminatusDXA default database, or into any additional patient database. To import into any other database path, create or add the database in the IlluminatusDXA application first.

Exit the IlluminatusDXA application before running the Data Import application. The patient databases may only be accessed by one application at a time, and the import will not proceed if the IlluminatusDXA software is still connected to the database.

Logging In

Run the  Data Import application. The login window will appear.

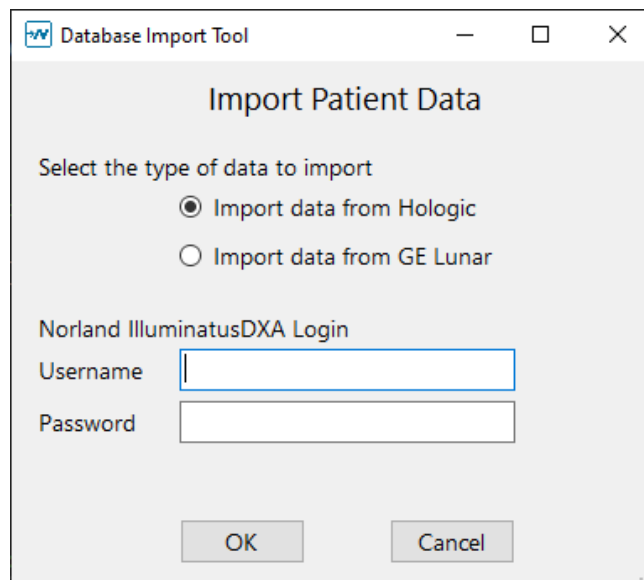


Figure 1 - Login Window

Select to import data from Hologic systems or GE Lunar systems. The import process for both sources is identical.

- Hologic data may be imported from .MDF database files or from an active MS SQL Server.
- GE Lunar data may be imported from .MDB files, .MDF files, or from an active MS SQL Server.

Enter a valid username and password from IlluminatusDXA to log in.

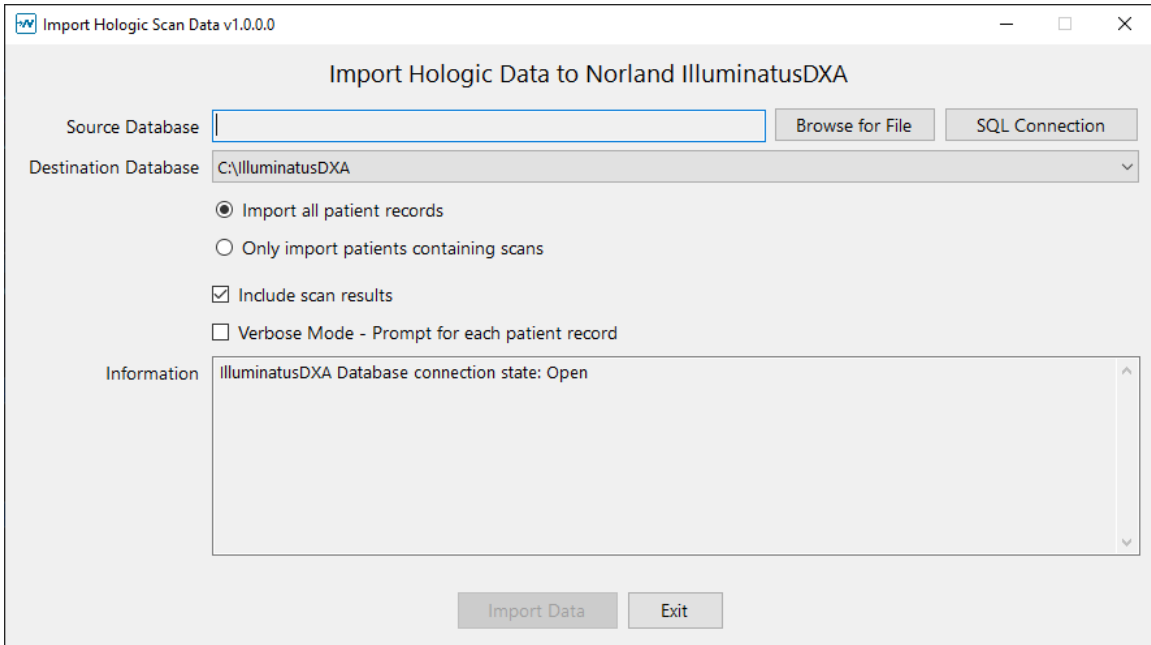


Figure 2 - Import Window

Import Settings

Source Database

For .MDB or .MDF database files, click **Browse for File** to locate the source database file.

To connect to an active SQL Server, click the **SQL Connection** button. Enter the server connection information and credentials. Click **Test Connection** to connect the server and validate the settings. Click **OK** to continue.

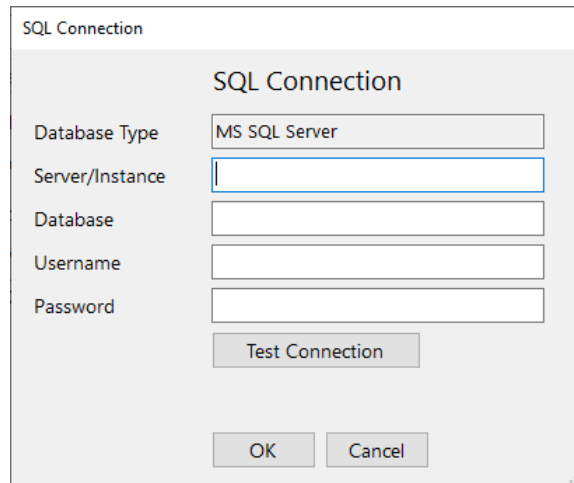


Figure 3 - SQL Server Connection Window

Once a Source Database is set, the database will be connected and summary of the number of patients and scans will be shown.

Destination Database

Select the desired destination database from the list. The default selection will be the path last used by the IlluminatusDXA program. To import into a database not in the list, add or create the database in the IlluminatusDXA application.

Patient Selection

By default, all patients in the source database will be imported. To import only patients which include scans in the source database, select the applicable option.

By default, the import process will include scan results from the source database. To import only patient demographics details, uncheck the “Include Scan Results” option.

Verbose Mode

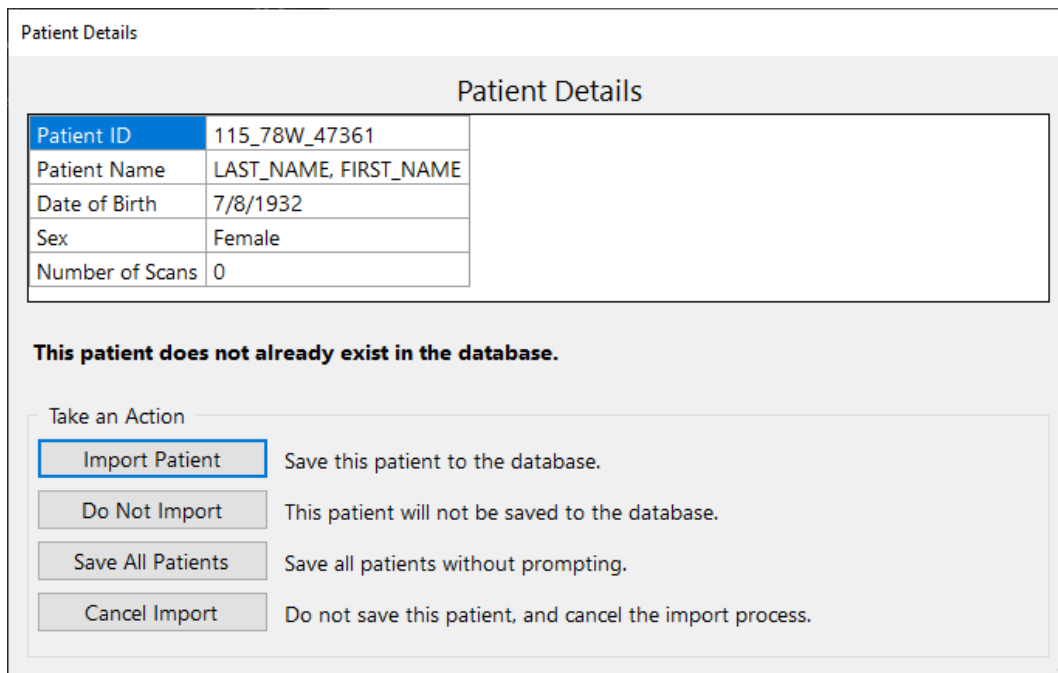
If the Verbose Mode option is enabled, the details for every patient will be shown before being imported. The user may select to import the record or skip the record. See the Patient Details Prompt section below for further details.

Import Data

After setting the source and destination databases and selecting all desired options, click **Import Data** to begin the import process. All records will be read from the source database, then imported into the IlluminatusDXA database.

Patient Details Prompt

If the Verbose Mode was enabled, the Patient Details window will appear for each patient prior to importing. The Patient ID, Patient Name, Date of Birth, Sex, and Number of Scans will be shown for each patient.



The screenshot shows a window titled "Patient Details" with a table of patient information and a section for actions. The table contains the following data:

Patient Details	
Patient ID	115_78W_47361
Patient Name	LAST_NAME, FIRST_NAME
Date of Birth	7/8/1932
Sex	Female
Number of Scans	0

Below the table, a message states: **This patient does not already exist in the database.**

Under the heading "Take an Action", there are four buttons with descriptions:

- Import Patient**: Save this patient to the database.
- Do Not Import**: This patient will not be saved to the database.
- Save All Patients**: Save all patients without prompting.
- Cancel Import**: Do not save this patient, and cancel the import process.

Figure 4 - Patient Details Window

The user must decide the action to take for each patient.

- **Import Patient:** Import the current patient into the IlluminatusDXA database.
- **Do Not Import:** Skip this patient, do not import it.
- **Save All Patients:** Disable prompting for each patient. Import this patient record and all remaining records.
- **Cancel Import:** Cancel the import process. Do not import this patient record.

Patient Record Conflict Prompt

When importing each record, the application will check if the Patient ID matches any existing patients in the IlluminatusDXA destination database. If a patient with the same Patient ID exists, but the Patient Name, Date of Birth, or Sex does not match the import record, the information from both records will be shown.

Patient Record Conflict

Patient Record Conflict

The imported patient record matches the Patient ID of an existing patient.
One or more demographics details do not match the existing patient record.

	Existing Patient	Imported Record
Patient ID	1JY2260S1J0287880	1JY2260S1J0287880
Patient Name	Last_Name, First_Name M	LAST_NAME, FIRST_NAME
Date of Birth	11/8/1961	11/8/1961
Sex	Female	Female
Number of Scans	0	13

Take an Action

Do Not Import SKIP THIS RECORD. This imported record will not be saved to the database.

Merge Data IT IS THE SAME PATIENT. Import the scan data into the existing patient record.

Save as New Patient IT IS A DIFFERENT PATIENT. A new patient record will be created for the imported patient.
New Patient ID: 1JY2260S1J0287880_imp

Cancel Import Do not save this patient, and cancel the import process.

Figure 5 - Patient Record Conflict Window

The user must decide the action to take for this record conflict.

- **Do Not Import:** If the existing patient (in the IlluminatusDXA database) does not appear to be the same as the import record, skip this record and do not change the IlluminatusDXA database.
- **Merge Data:** If the patient can be confirmed to be the same, save the import data to the existing patient record in the IlluminatusDXA database. The patient demographics will not be modified, only the Hologic or GE Lunar data will be stored in the existing patient record.
- **Save As New Patient:** If the existing patient is not the same individual as the import record, save the import record with a new unique Patient ID. The proposed Patient ID is shown, which may be modified in the IlluminatusDXA software after the import process is complete.
- **Cancel Import:** Cancel the import process. Do not import this patient record.

Final Status

After the import process is completed or cancelled, a summary of the number of imported patients and scans is shown.

Results Trending

If scan results are imported from the Hologic or GE Lunar database, they will be trended with new scans acquired in the IlluminatusDXA software for each patient. The trending will appear in the reference data or trending graphs and will be included in the Short Term % Change and Long Term % Change calculations.

Native Norland DXA scans are shown in trending graphs with white and black markers. White markers show the current scan result, and black markers show results for any other scans of the same type.

Scan results imported from Hologic or GE Lunar systems for the same scan type will be shown with a violet marker on trending graphs.

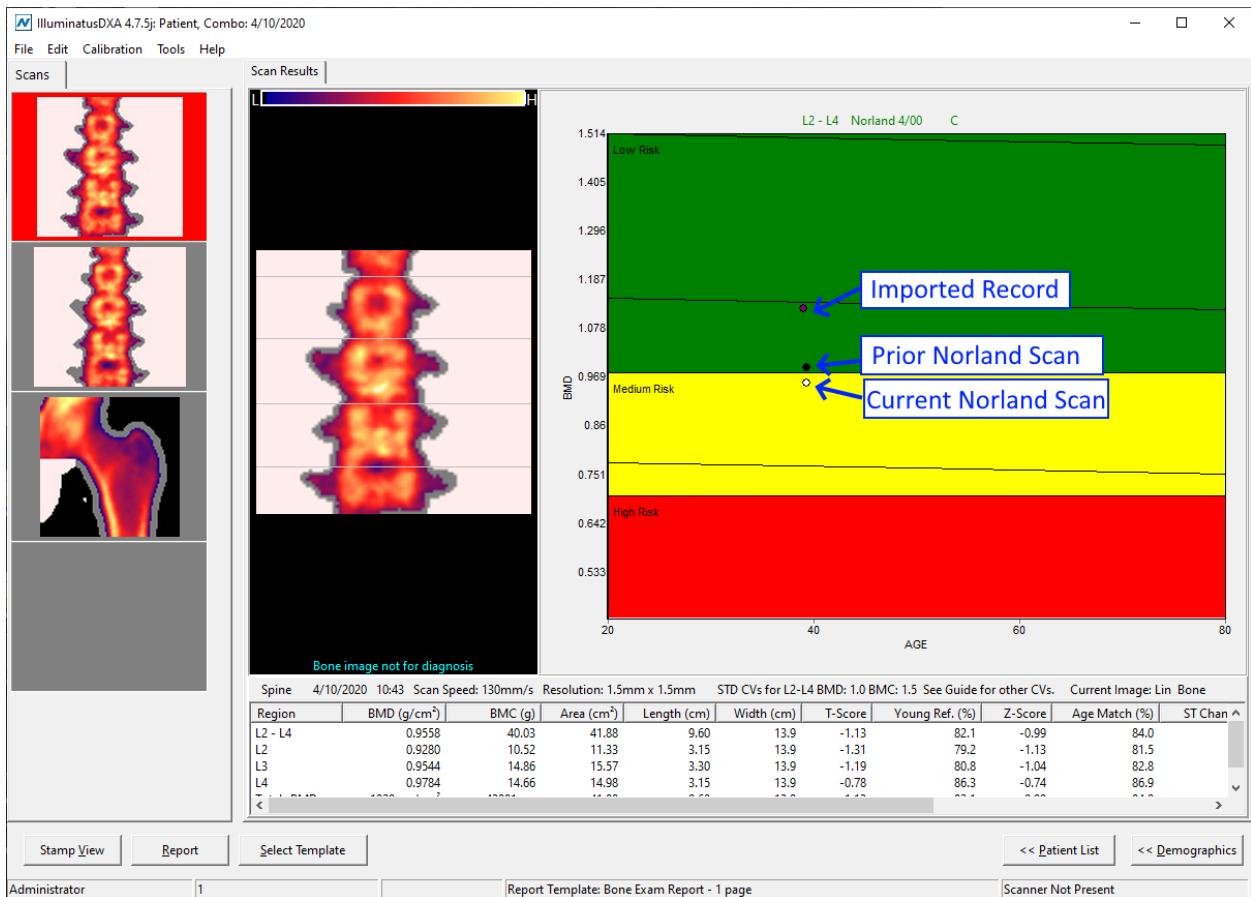


Figure 6 - Reference/Trending Graphs

Enable/Disable Trending

Trending with imported records is enabled by default on all IlluminatusDXA systems. It may be disabled so the imported records are not calculated in trending results or shown on reference data graphs.

In IlluminatusDXA, select the **Edit** menu then **Scanner Preferences**. Change to the **Analysis** tab.

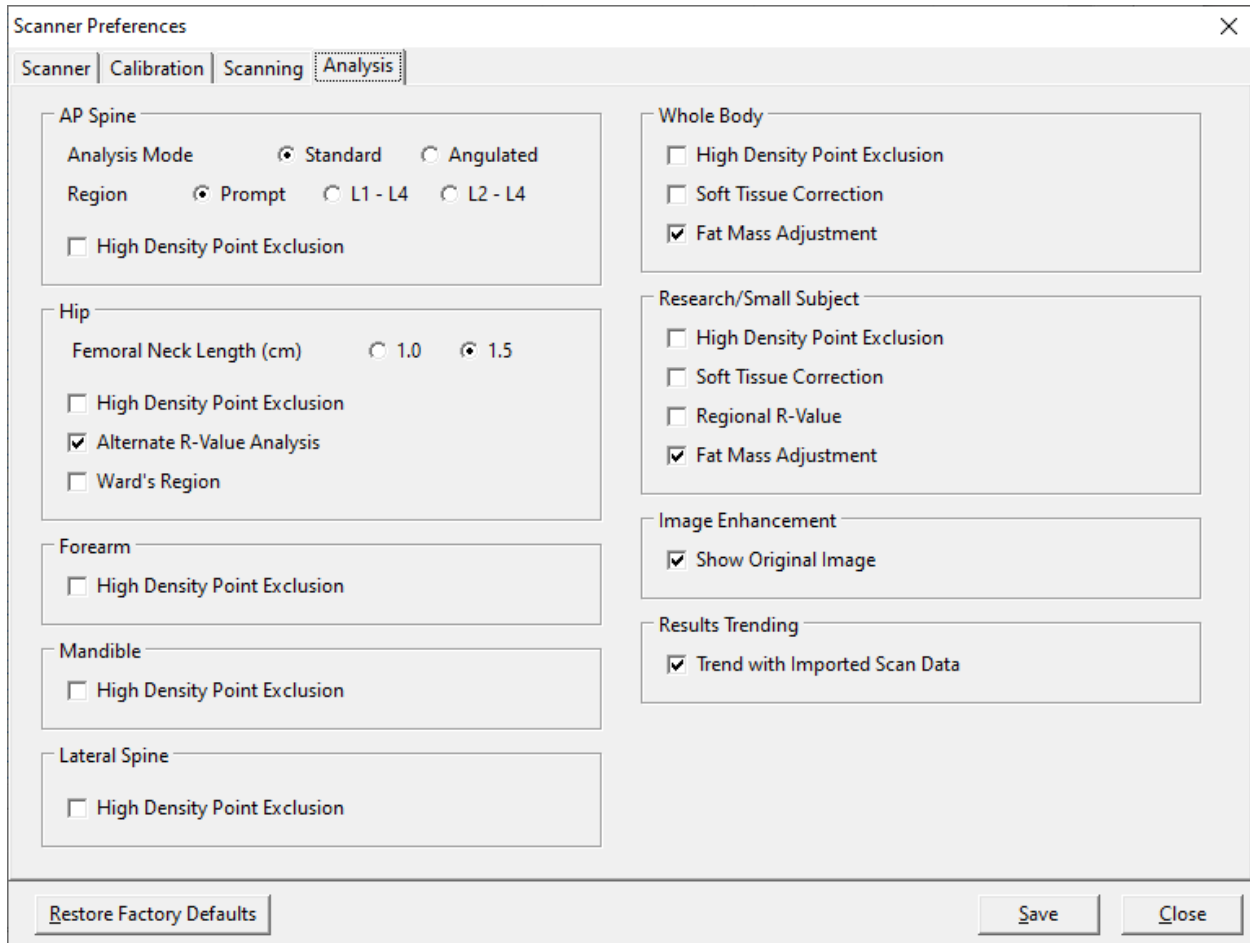


Figure 7 - Scanner Preferences, Analysis tab

In the Results Trending section, uncheck the option for “Trend with Imported Scan Data” to disable trending, or check the option to enable trending. Click **Save** to update your software preferences.

Viewing and Deleting Imported Records

If a patient record contains imported records, the details may be viewed from the Patient Demographics screen. The message “This patient record contains imported patient information or scan results” will appear in the lower right area of the Demographics window.

The screenshot shows the 'IlluminatusDXA 4.7.5j' application window. The 'Patient Demographics' section contains the following fields: Last Name (LAST_NAME), First Name (FIRST_NAME), Patient ID (1JY3240UN10887880), Sex (Female, Male, N/A), Ethnicity, Date of Birth (6/26/1930), Address, City, State, ZIP, and Phone. The 'Medical History' section includes Menopause Year, Bone History (checked), Treatment, Osteoporosis Medications (checked), Technologist, Physician, and Referring Physician. The 'Visit Information' section includes Height and Weight. The 'Billing Information' section is a large text area. A blue link at the bottom right of the window reads 'This patient record contains imported patient information or scan results.' The window also features a menu bar (File, Edit, Calibration, Tools, Help) and a toolbar with buttons for Save, Clear Edits, Fracture Risk Questionnaire, Patient List, Scan, and Stamp View.

Figure 8 - Demographics with Imported Data

Click the message link to view the details for the selected patient. The date of import will be shown, with the number of each imported scan type stored in the patient record.

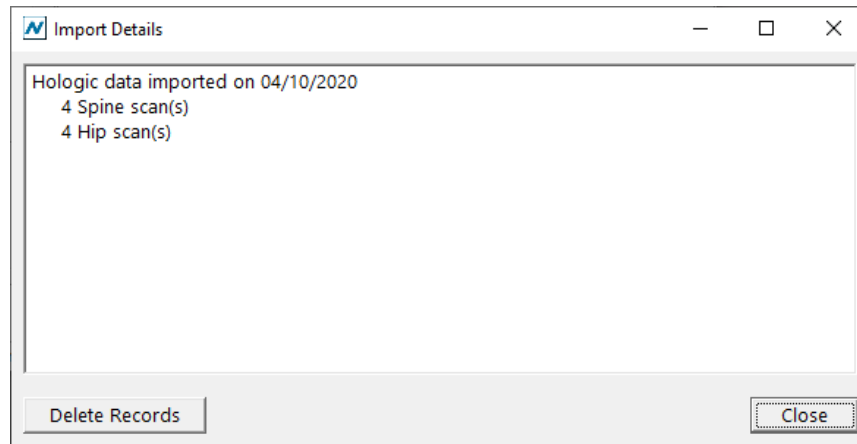


Figure 9 - Import Details

Deleting Imported Records

To delete the imported scan data from the patient record, click the **Delete Records** button. This will remove all Hologic and GE Lunar scan results from the patient record. Any Norland DXA scans and results will not be modified.

A confirmation prompt will appear to verify deletion of the data. Click **OK** to delete the information or click **Cancel** to keep the existing information.

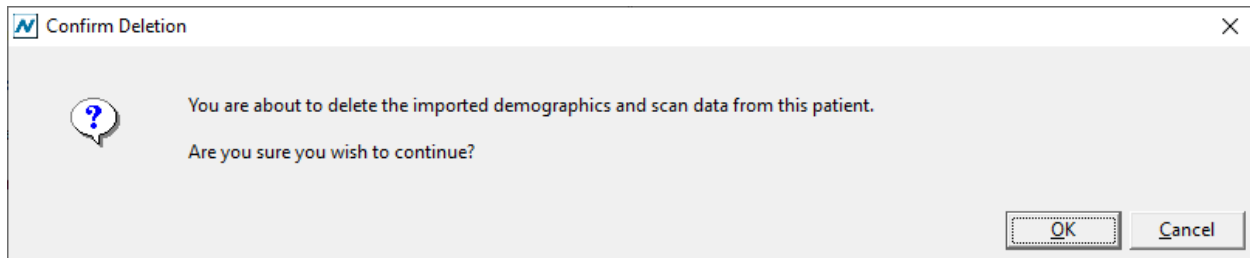


Figure 10 - Delete Confirmation Prompt

If the imported results are deleted from the patient record, the imported data will no longer be included in trending for the current patient.

References

Microsoft Access Database Engine 2010 Redistributable:

<https://www.microsoft.com/en-us/download/details.aspx?id=13255>

Microsoft® OLE DB Driver 18 for SQL Server®

<https://www.microsoft.com/en-us/download/details.aspx?id=56730>

Microsoft SQL Server (LocalDB):

<https://www.microsoft.com/en-us/sql-server/sql-server-downloads>