



Krios User Guide

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1	June, 2016	First Release
2	September, 2016	Updated UI and added continuous probing function
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Published by:

Northern Digital Inc.
103 Randall Dr.
Waterloo, Ontario, Canada N2V 1C5

Telephone: +1 (519) 884-5142
Toll Free: +1 (877) 634 634 0
Global: ++ (800) 634 634 00
Facsimile: +1 (519) 884-5184
Website: www.ndigital.com

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Read Me First

Read this section before continuing with the rest of the guide.

Warnings



In all NDI documentation, warnings are marked by this symbol. Follow the information in the accompanying paragraph to avoid personal injury.

1. The power adapter must be located outside the patient environment under all operating conditions. It is the responsibility of the system integrator and/or the end-user to ensure that the system is appropriately configured for the operating conditions.
2. Position the system components so that they can be easily disconnected from mains power. Failure to do so may result in an electric shock hazard and possible personal injury.
3. Do not use a power bar or extension cable to connect the power adapter to the mains supply. Doing so may result in an electric shock hazard and possible personal injury.
4. Make sure the power adapter is connected to a mains supply with protective earth. Failure to do so may result in an electric shock hazard and possible personal injury.
5. Do not touch the subject and metal parts of the system at the same time. Doing so may result in an electric shock hazard and possible personal injury.
6. There are no user serviceable parts in the Krios System. All servicing must be done by NDI. Unauthorised servicing may result in personal injury.
7. Do not immerse the Krios System in liquids, or allow fluid to enter the equipment in any way. Exposing the Krios System to liquids may result in equipment damage, produce a fire or shock hazard, and result in personal injury.

-
8. Switch off power to the Krios System before cleaning it. Failure to do so may result in personal injury.
 9. The laptop power adapter that is certified with this device is Lenovo 42T4430. If a different laptop/computer is used, the power adapter must be IEC 60601-1 certified, or leakage testing must be completed by the end user for the alternate power adapter. Using an unapproved power adapter may result in an electric shock hazard and possible personal injury.
 10. Use of cables or accessories other than those delivered with the system may result in increased emissions and/or decreased immunity of the Krios System and may result in personal injury.
 11. The Krios System requires special precautions regarding EMC. It must be installed and put into service in accordance with the EMC information, detailed in this chapter. Failure to do so may result in personal injury.
 12. Radio frequency communications equipment, including portable and mobile devices, may affect the Krios System and result in personal injury.
 13. Do not use the Krios System either adjacent to, or stacked with, other equipment. Check that the Krios System is operating normally if it is used either adjacent to, or stacked with, other equipment. Failure to do so may result in personal injury.

Cautions

Caution! In all NDI documentation, cautions are marked with the word "Caution!" Follow the information in the accompanying paragraph to avoid damage to equipment.

1. Do not use aerosol sprays near the equipment as these sprays can damage circuitry.
2. Do not use any solvent to clean the Krios System. Solvents may damage the finish and remove lettering.

Contact Information

If you have any questions regarding the content of this guide or the operation of this product, please contact us:



NDI International Headquarters

CANADA
+ 1 (877) 634-6340
support@ndigital.com
www.ndigital.com

Ascension Technology Corporation (An NDI Company)

USA
+ 1 (802) 985-1114
support@ndigital.com
www.ascension-tech.com

NDI Europe GmbH

GERMANY
+ 49 (77 32) 8234-0
support@ndieurope.com
www.ndieurope.com

NDI Asia Pacific

HONG KONG
+ (852) 2802 2205
support@ndigital.com
www.ndigital.com

Updates

NDI is committed to continuous improvements in the quality and versatility of its software and hardware. To obtain the best results with your NDI system, check the NDI Support Site regularly for updated information:

<https://support.ndigital.com>

1 System Overview

This guide provides details on the installation and use of the NDI Polaris® Krios System.

The intended use of the Krios Scanner is as a hand held digitizing camera for rigid body tracking and coordinate transformations within a reference frame. The Krios System does not require any specialised training or knowledge to be operated.

There are no contra-indications for using the Krios System.

Each electrode is mapped in imaging software, saving significant setup time. This automated registration process also improves the accuracy of source-localization. The system can also capture and store digital pictures of the procedure or experiment, to form part of a record within the application software.

1.1 System Components

The Krios System consists of the following parts:

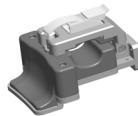
Krios Scanner

Part Number 8701087



Mounting Bracket

Part Number 8701325



Host USB Converter (HUC)

Part Number 8800810.005



Probe
Part Number 8701326



Power Adapter and cable 2 m
Part Number 8001260

USB cable Part Number
2600596

NDI Krios software (on USB stick) Part Number 8801325

Retro-reflective Markers Part
Number 2301186

Note: Do not attach any parts to the system that are not listed in the table above. Do not modify any system components.

Krios Scanner

The Krios Scanner is the main unit of the NDI Krios System, see [Figure 1-1](#). The Scanner houses the sensors and controls. It is connected to the host computer via the Host USB Converter through a keyed connector on bottom of the Scanner

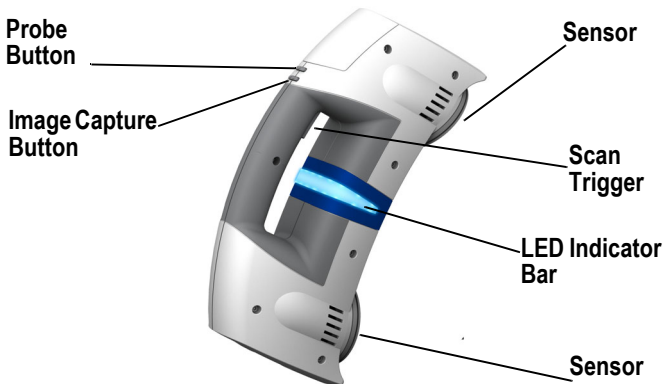


Figure 1-1 Krios Scanner

The Scanner serial number label shows the item ID, model, serial number and manufacture date of the Scanner. The label also incorporates the “Consult Operating Instructions” graphic. An example of the Scanner serial number label is shown in [Figure 1-2](#).

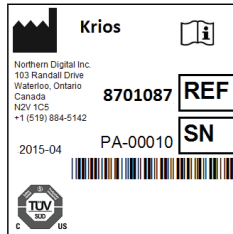


Figure 1-2 Krios Scanner Serial Number Label

1.2 Mounting Bracket

The mounting bracket allows you to securely attach the scanner to a standard 1/4”-20 tripod mount. This is useful during probing mode.

The mounting bracket fits around the scanner handle and is secured with a clamp ([Figure 1-3](#)).

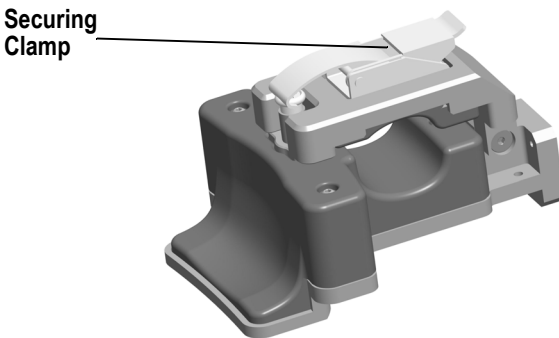


Figure 1-3 Mounting Bracket

Host USB Converter

The Host USB Converter provides the interface between the Scanner, the power adapter, and the host computer:

- The attached Scanner cable connects the Host USB Converter to the Scanner.
- The power adapter and USB cable plugs into the Host USB Converter.

The Host USB Converter serial number label shows the item ID, model, serial number and manufacture date of the Host USB Converter. The label also incorporates the “Consult Operating Instructions” graphic. An example of the Host USB Converter serial number label is shown in



Figure 1-4 Host USB Converter Serial Number Label

Power Adapter

The system is powered by an NDI supplied power adapter. Disconnecting the power adapter removes power from the system.

The power adapter connects to the mains supply and provides DC power to the Scanner via the Host USB Converter.



The laptop power adapter that is certified with this device is Lenovo 42T4430. If a different laptop/computer is used, the power adapter must be IEC 60601-1 certified, or leakage testing must be completed by the end user for the alternate power adapter. Using an unapproved power adapter may result in an electric shock hazard and possible personal injury.

Host Computer

The host computer should meet the following minimum specifications:

- 1 GHz or faster 32-bit (x86) or 64-bit (X64) processor
- 1 GB RAM (32-bit) or 2GB RAM (64 bit)
- 20 GB available hard disk space
- DirectX 9 graphics device with WDDM 1.0 or higher driver
- Operating system: Windows 7 (64 bit) and Windows 10 (64 bit)
- Screen resolution 1024 x 768 (1280 x 1024 recommended)

Software

Installation and use of the software is detailed in section 2.3.

2 System Setup

This section details the setup procedures for the NDI Krios System.

2.1 Connection Requirements

The Krios system must communicate with a host computer to pass measurement information to another application running on the host computer.

The Krios system is connected via USB. There are no special connection or security requirements for USB; any USB connection 2.0 or above will suffice. There is no power used from the USB connector.

The intended information flow from the Programmable Electrical Medical Systems (PEMS) is included in the content of this manual.

The severity of all connections related to hazardous situations are the responsibility of the system integrator. This is because there is no essential performance of the PEMS.

Note: It is possible that connection to any computer network could introduce new risks and require additional analysis. Furthermore, any

changes to the computer network including connection, disconnection, updates and upgrades to existing equipment could also lead to new risks that lead to additional analysis.

2.2 Hardware Connection

Connect the hardware as follows, see [Figure 2-1](#):



Warning! Position the system components so that they can be easily disconnected from mains power. Failure to do so may result in an electric shock hazard and possible personal injury.

1. Connect the integral cable on the USB adapter to the Scanner connector, located on the handle. Align the red mark on the Scanner connector with the corresponding red mark on the cable connector (the double keys of the connectors will be aligned).

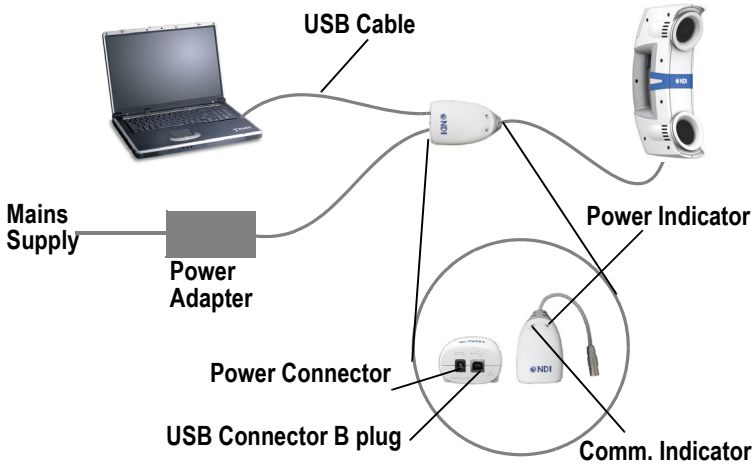


Figure 2-1 Hardware Connection

Note: Only use the 3 m USB cable that is supplied with the system.

-
2. Connect the USB cable B plug and power supply cable to the USB adapter. Locate the top and bottom cable covers in place on the USB adapter. Secure the covers with the thumbscrew, see [Figure 2-2](#).

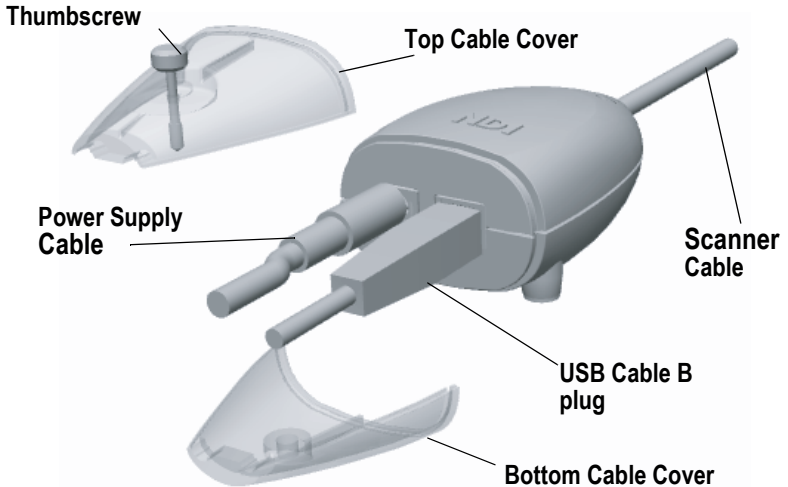


Figure 2-2 Connecting Cables to the USB Adapter

3. Plug the USB cable A plug into the host computer.
4. Make sure all the cables are connected firmly, and placed where they will not be stressed, stepped on, or bent.
5. Plug the power cable into the power adapter.



Do not use a power bar or extension cable to connect the power adapter to the mains supply. Doing so may result in an electric shock hazard and possible personal injury.

Make sure the power adapter is connected to a mains supply with protective earth. Failure to do so may result in an electric shock hazard and possible personal injury.

6. Plug the power cable into the power mains and turn on the mains.

-
7. The Scanner will begin a diagnostic evaluation. When the diagnostic evaluation is complete, the Scanner will emit two beeps.
 8. The USB adapter indicators will light as follows, see [Figure 2-1](#):
 - The power indicator lights green when power is applied to the system.
 - The communications indicator lights orange if there is a communication problem between the host computer and the system. It also flashes once when the USB adapter is first switched on.



The power adapter must be located outside the patient environment under all operating conditions. It is the responsibility of the system integrator and/or the end-user to ensure that the system is appropriately configured for the operating conditions.

2.3 Software Installation

To install the NDI Krios application, proceed as follows:

1. Run install.exe.
2. Follow the Installation Wizard to install the NDI Krios application.

After installation, the NDI Krios  icon is placed on the desktop.

Note: Installing the NDI Krios application also installs the drivers for the USB adapter. The default installation location is: `C:\Program Files (x86)\Northern Digital Inc.\Krios\USB Driver.`

Host USB Drivers

You must install drivers when you first connect the NDI Host USB Converter to the host computer. There are two sets of drivers for the NDI Host USB Converter:

- the first set of drivers enables the NDI Host USB Converter to work with the host computer

-
- the second set of drivers sets up the USB port where the NDI Host USB Converter adapter is connected to emulate a serial port

The USB drivers are downloaded as part of the NDI Krios installation. The default download location is:

- C:\Program Files (x86)\Northern Digital Inc.\Krios\USB Driver

Driver Installation - Windows 7/10 Install the drivers for Windows 7/10 as follows:

1. When you first connect the NDI Host USB Converter to the host computer, an error message may appear over the task bar. Ignore the message and complete the following steps to install the USB drivers.
2. From the Windows menu, select “Control Panel”.
3. In the top right hand corner of the Control Panel window, select “View by: Small Icons”.
4. From the Control panel, select “Device Manager”.
5. Under Other Devices, right click NDI Host USB Converter.
6. Select “Update Driver Software...” then select “Browse my computer for driver software”.
7. Select “C:\Program Files\Northern Digital Inc.\Krios\USB Driver”. Select “Next”.
8. In the Windows security dialog, select “Install this driver software anyway” option. The first set of drivers will install.
9. After the first set of drivers are installed, browse to “Other Devices” and right click USB Serial Port.
10. Select “Update Driver Software...”, then select “Browse my computer for driver software”.
11. Select “C:\Program Files\Northern Digital Inc.\Krios\USB Driver”. Select “Next”.
12. In the Windows security dialog, select “Install this driver software anyway” option. The second set of drivers will install.

Driver installation is complete and the system will now appear to be connected through a virtual COM port.

Note: If you connect the Scanner to a different USB port, you will be prompted to re-install the drivers.

3 Operation

This section details the operating procedures for the NDI Krios System.

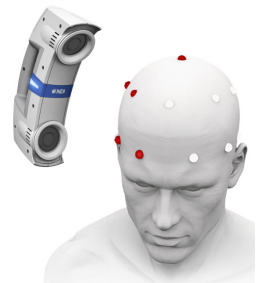
3.1 Overview

Operation of the NDI Krios System comprises a number of discrete steps as follows:

- Set up scanning environment.
- Attach each electrode (with prefixed marker) to the scalp or cap.



- Scan the head with the Krios Scanner to localise each marker's position. This process creates a digital point cloud (3D model) and rigid body of marker coordinates.



- Probe anatomical features to establish fiducial (reference) points, such as the nasion,inion and preauricular points.
- Apply transformation to define an appropriate coordinate system for the point cloud.
- Label each marker to create a template of the labelled point cloud.
- Export the results as a .csv file.
- (Optional) Capture and save a digital image.



3.2 Scanning Environment

Choose a scanning environment that meets the following criteria

- Scan against a non reflective background that is in contrast to the object you are scanning. For example, scan a white object against a dark background.
- Remove, or drape any reflective or shiny surfaces in the area
- Remove, or mask, any personal reflective items, for example, metal watches, belt buckles.
- Minimize exposure to infrared (IR) interference. (For example, sun light, ceiling lights and plasma monitors are all possible sources of infrared interference.)

3.3 Scanning Best Practices

To achieve the best possible result, follow the best practices detailed below:




Do not touch the subject and metal parts of the system at the same time. Doing so may result in an electric shock hazard and possible personal injury.

- Allow the Scanner to warm up for two minutes before use.
- Point the Scanner directly where you want to scan and move it back and forth at an even pace, in straight lines. Try not to rotate the camera left and right in your hand.
- As you scan markers and they become valid (white), move to adjacent markers, to sequentially build up the point cloud. If you “lose” the existing point cloud, you must re-acquire it before continuing.
- Try to maintain a consistent distance (approx. 300 mm to 400 mm) from the subject. If you get too close or too far, the display will zoom in or out to show that you need to reposition the Scanner.
- Plan a path to scan around the subject that will cover all the markers, checking that no markers are missed as you scan.

3.4 Krios User Interface

The User Interface for the NDI Krios System is described below.

Double click the  icon to start the NDI Krios. The system will auto-connect by default. Alternatively, select **File>Connect to** and select the com port to which the system is connected.

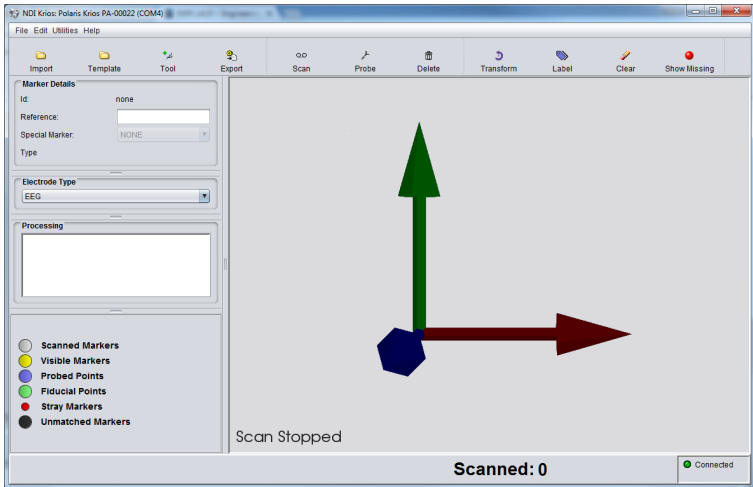


Figure 3-1 Krios Application Interface

After initialising, the NDI Krios screen launches, see [Figure 3-1](#). The current status is displayed at the bottom left of the screen.

The **Connected** status of the system is displayed at the bottom right of the screen.

The numerical count of the markers scanned is displayed at the bottom centre of the screen.

Additional windows and the menu bar are described below.

Menu Bar

The menu bar provides the following controls, see [Figure 3-2](#).



Figure 3-2 Menu Bar

1. **Import** - import a previously recorded session.
2. **Template** - import a previously recorded session for use as a template for labelling purposes.
3. **Tool** - select the applicable .rom file for the probe.
4. **Export** - export the session to one of 4 file types. See the section [3.10](#) for details.
5. **Scan** - switches to **Scan** mode (You can also select **Scan** mode using the Scan trigger on the Scanner, see “[Krios Scanner](#)” on page 2.)
6. **Probe** - select probing mode (active only after 10 or more markers have been scanned.)
7. **Delete** - delete the current session.
8. **Transform** - transforms the coordinate system from global to the probed anatomical (fiducial) points.
9. **Label** - open the Label Assist window to use a template to label a new session.
10. **Clear** - remove labels from the current session.
11. **Show Missing Labels** - display markers missing from current session when compared to template.

Legend

The **legend** window details the marker colour definitions.

Label Selected Marker

The **Label Selected Marker** window provides the following information

Marker ID - displays the (automatically assigned) number of the selected marker.

Reference - a text field that allows you to specify a name for the selected marker.

Special Marker - a drop-down list that allows you to designate the selected marker as a special marker.

Type - allows you to view the type of marker.

Processing


The **Processing** window displays the status and prompts for the current activity.

3.5 Attach the Markers

Attach the self-adhesive markers either directly to the scalp or to the sensor to be measured (e.g. electrodes for EEG or optodiodes for NIRS).

3.6 Scan the Markers

To scan the markers, follow the procedure detailed below:

1. Make sure the Scanner is connected and the software is installed as detailed in [“System Setup” on page 5](#).
2. Make sure the scanning environment meets the criteria detailed in [“Scanning Environment” on page 12](#).
3. Double click the  icon to start the NDI Krios software. The system will auto-connect by default. Alternatively, select **File>Scanner Connection** and select the com/serial port to which the system is connected.

Note: If the system has been previously connected, it will automatically reconnect at start up. To disable this feature deselect **File>Connect Options>Reconnect on Start**.

-
4. Press and hold the Scan trigger to start scanning, see [Figure 1-1](#). Alternatively you can double-click the trigger to start or stop scanning. This removes the requirement to keep the button pressed

Move the Scanner while watching the visual representation of the markers on the monitor. Continue scanning until all markers have been scanned. Make sure the subject remains in the Scanner Field-of View, see [Figure 3-4](#).

As you scan, the markers will change colour as follows:

- **Yellow** - marker is currently visible to the Scanner
- **Red** - marker is stray. Not yet valid or scanned
- **White** - marker is valid/scanned
- **Purple** - probed marker
- **Green** - special user defined marker (fiducial)
- **Pink** - missing marker (not applicable during scanning)
- **Black** - marker is unmatched (not applicable during scanning)

[Figure 3-3](#) shows an example of a scan in progress.

Note: The number of markers scanned (displayed at the bottom of the window) will show total number of markers to be scanned if a template is loaded. For example 82/256.

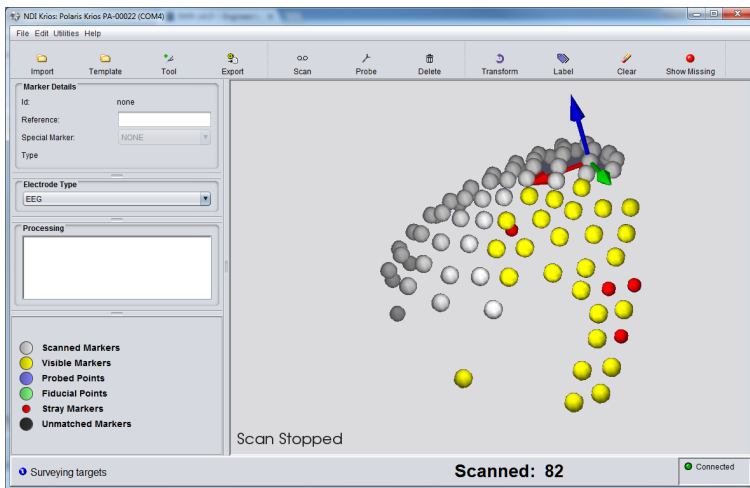


Figure 3-3 Scan in Progress

Use the mouse controls as follows to manipulate the view:

- Left click and drag rotates the view
- Middle click and drag to pan the view
- Right click and drag to zoom the view in and out

If sounds is enabled, audio tones will alert you when you are too close or too far from the subject. A low pitch tone will indicate that you are too far and a higher pitch tone indicates you are too close. Additionally, the display will zoom out when you are too far and zoom in when you are too close. Complete a few practice scans to become familiar with each tone and the scanning technique.

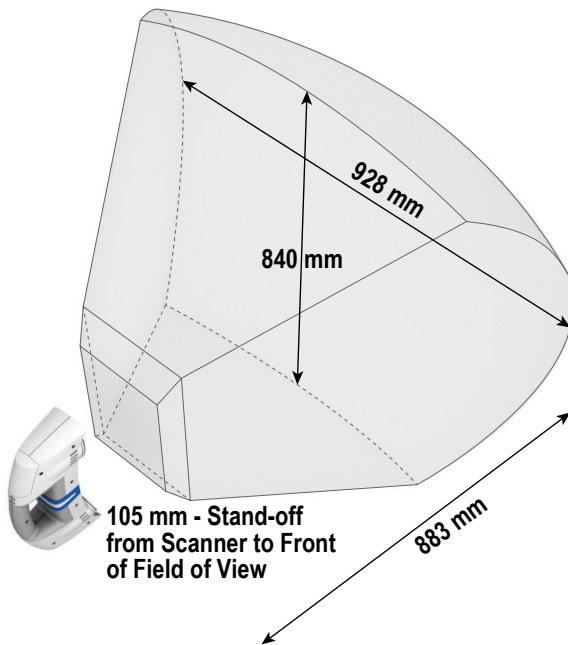


Figure 3-4 Krios Field of View

The Scanner incorporates an LED status bar that provides visual indications as shown in [Table 3-1](#).

Table 3-1: Scanner LED Status

Status	LED State
Warming Up	Fading in/out White
Power Up	White
Connected and software running	Solid Blue
Scanning	Fading in/out Blue
Too close/too far	Fading in/out Orange
Lost	Solid Orange

As each marker is acquired it will be added to the visual representation and the number of markers, shown on the bottom of the screen, will increment. Each scanned marker will automatically be assigned an ID number.

Continue scanning until all markers are acquired, then click **Done**. (You can click **Pause** and **Continue** as required during the scanning process.)

5. Continue to probing mode below.

3.7 Probing

Probing mode uses a probe to define fiducial points on anatomical features relative to the scanned markers (i.e. co-registration).

Additionally, when in continuous mode, it can provide a surface profile of anatomical features.

While in probing mode, the probe is represented dynamically in the main window and measurement volume. (The measurement volume is represented on the right of the screen, see [Figure 3-5](#).)

Probing Modes


Probing can either be by single point or continuous. The difference between single point and continuous probing is the trigger method:

- **Single** point mode is initiated by either:
 - Selecting the Probe button on the Scanner, see [Figure 1-1](#)
 - or
 - Holding the probe stationary for two seconds.
- **Continuous** mode records points automatically as soon as the probe is in view.

Set the required probing mode in **Preferences**, see “[Preferences](#)” on [page 28](#).

Set Probe tool definition

For the system to recognize a probe, its corresponding tool definition must be loaded into the application. The system will retain this definition and you only have to repeat this step if a new tool with different marker geometry is required.

To Load a tool definition, select the **Tool** icon . From the resulting dialog, select the .rom file that matches the probe you intend to use. If the correct .rom file is not visible, navigate to and select the correct file.

Probing Procedure

Note: It is useful to clamp the Scanner during the probing process. This leaves both hands free for probing.

1. Move the probe into the measurement volume. The probe will be represented dynamically in the main window and in the measurement volume.

Note: You can also select Probe mode from the Probe button on the Scanner, see [Figure 1-1](#).

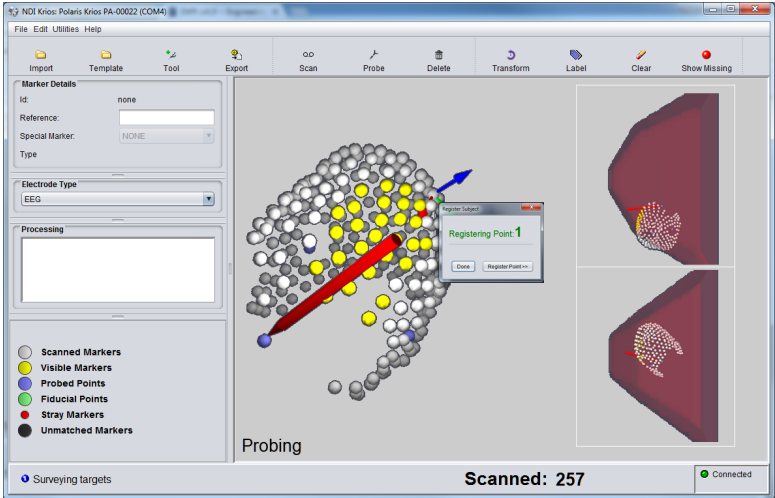


Figure 3-5 Probing in Progress

2. In Probe mode, the application provides prompts to guide you through the process.

The Probe dialog also displays self explanatory messages as required during the process, for example “Probe Missing” when the probe is not visible to the Scanner.

- When you have probed all required points, select **Done**. The probed points will change to light blue, see [Figure 3-6](#).

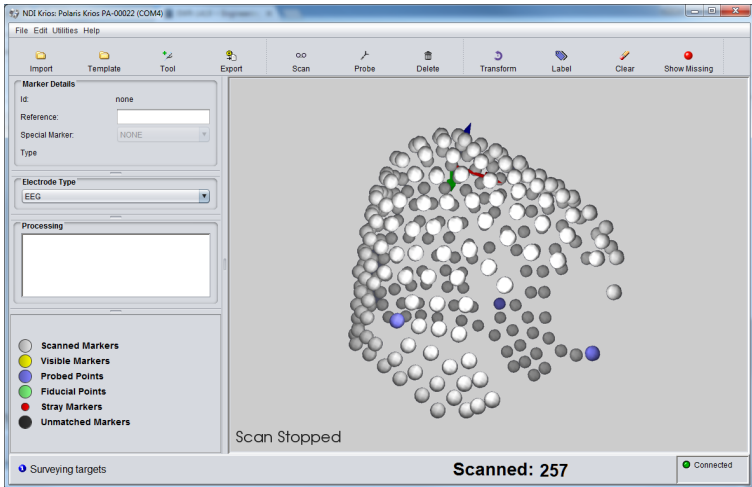


Figure 3-6 Probing Complete

3.8 Transform the Coordinate System

Once scanning and probing is complete, point cloud coordinates will be displayed in the Krios coordinate system. They are arbitrarily defined, based on the first four points scanned. You can choose to define an anatomically relevant coordinate system for the point cloud based on fiducial points using the Transform function. Follow the steps below to complete the transform.

- Select individual markers as required with the left mouse button and designate them as special markers (fiducial points) from the **Special Marker** drop-down list. The selected marker will change to green. (see [Figure 3-7](#) for an example of a Transform in progress.)

You can also select any marker and assign text to it. Left-click the required marker. Double clicking a marker will place the cursor directly into the **Reference** field. Enter text in the **Reference** field. The text will appear on the selected marker.

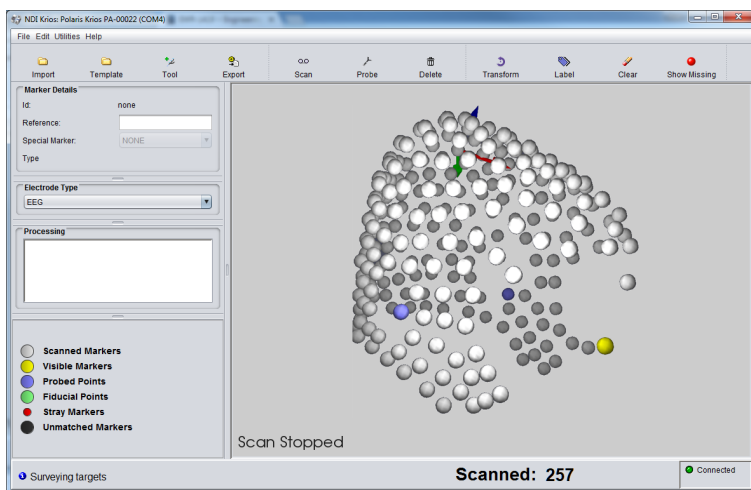


Figure 3-7 Transform - In Progress

2. Once the Nasion, Left Preauricular Point and Right Preauricular Point have all be defined, select the **Transform** button on the toolbar to transfer the point cloud coordinates from the Krios coordinate system to the standard head coordinate system. (See [Figure 3-8](#) for an example of a completed Transform.)

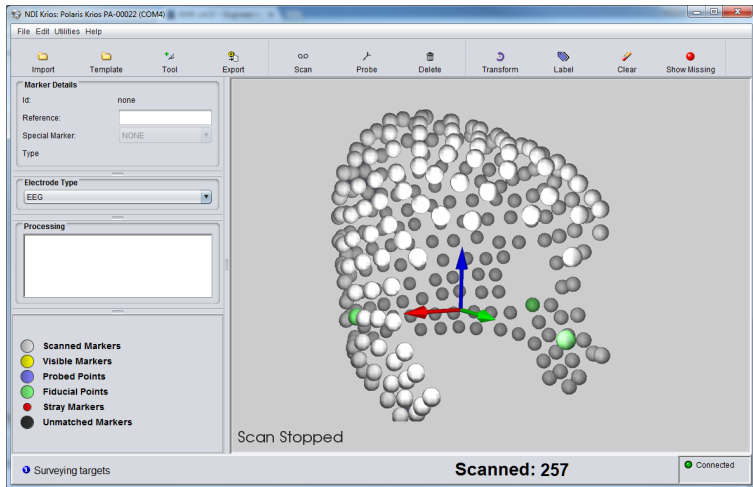


Figure 3-8 Transform - Complete

3. Export the completed session as detailed in the section [Export Results on page 27](#).

3.9 Labelling the Point Cloud

If a labelling template has previously been created, the Label Assist function can be used to automatically label the point cloud by mapping against the template. If a labelling template has not yet been created, you can manually label the point cloud and save it as a template for future use.

Note: Scanning, probing and transforming *must* be complete *before* you begin to work with labelled templates.

To create a labelling template, you must manually label the point cloud by completing the following steps:

1. Select a marker in the point cloud. The selected marker turns yellow. See [Figure 3-9](#).
2. In the **Label Selected Marker** pane, enter the label for the marker in the **Reference** text box.

3. Repeat steps 1 and 2 until all scanned markers in the point cloud have been given a unique label.
4. To save this fully labelled point cloud for use as a template, select **Export** to export the collected data as a .csv file. In the resulting dialog, specify the file name and location for the file.

Note: Ensure the point cloud coordinates have been transformed to the standard head coordinate system before exporting as a template.

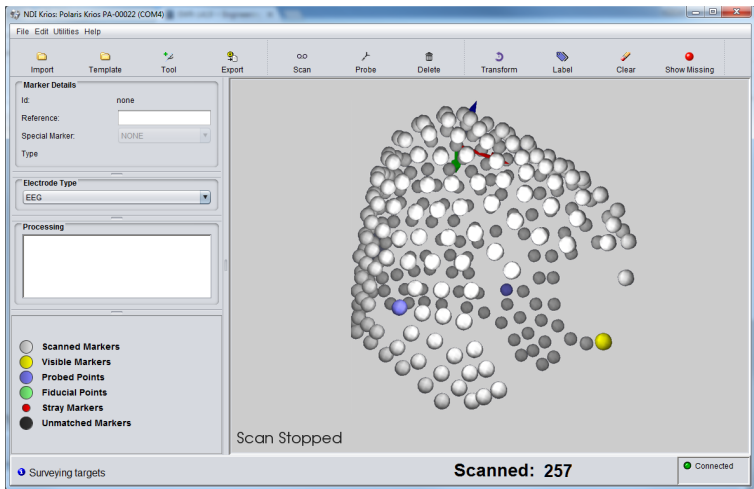


Figure 3-9 Partially Labelled Point Cloud

Using a Labelled Template for Automatic Labelling

To use a labelling template to automatically label a scanned point cloud, complete the following steps:

1. Select **Template**. In the resulting dialog, locate and double-click the .csv file containing the labelled template.
2. Select **Label**. This presents the Label Assist view, with the labelled template on the left and the unlabelled point cloud on the right. See [Figure 3-10](#).

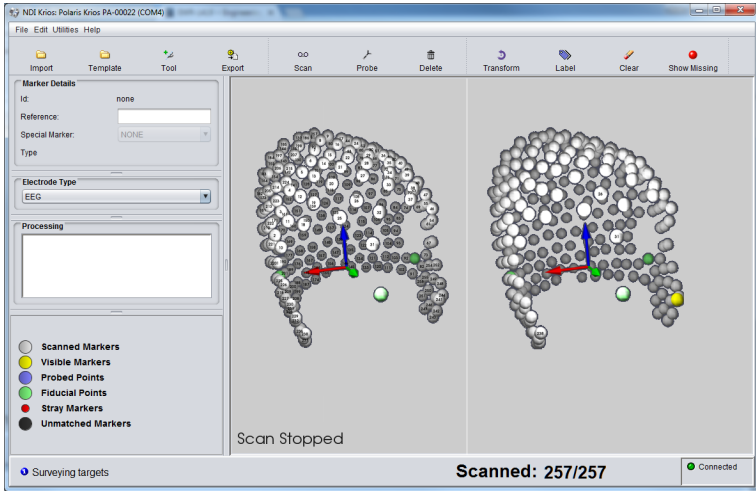


Figure 3-10 Label Assist with Unlabelled Point Cloud

Note: Ensure the unlabelled point cloud coordinates have been transformed to the standard head coordinate system before entering the Label Assist view.

3. Working in the unlabelled point cloud, label four markers. For best results, these markers should be spread across the point cloud, not clustered together in the same area.
4. Once you have four markers labelled, click off the point cloud. The template is applied to the unlabelled point cloud, which becomes fully labelled. See [Figure 3-11](#).

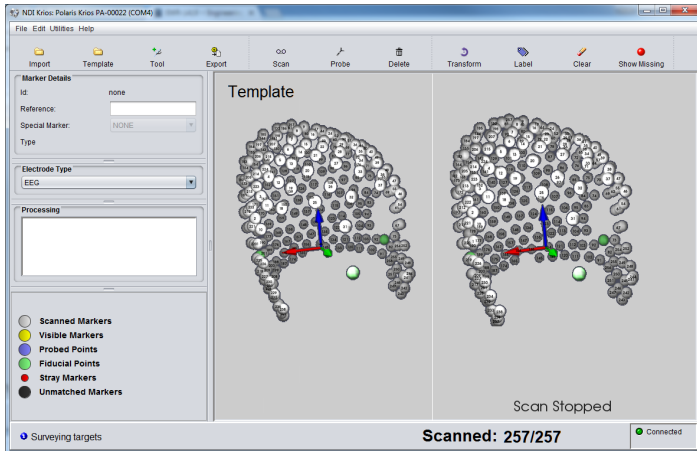


Figure 3-11 Template Assist with Labelled Point Cloud

- To exit the Label Assist view, select **Label** again.

Note: Dark grey unlabelled markers in the point cloud on the right following Step 5 indicate that Krios could not apply the template completely. This usually occurs when the initial four markers were labelled incorrectly or not spread out, or the transform was not performed correctly. You can attempt to manually correct the errors or clear all labels by selecting **Clear**, and restart the labelling process.

3.10 Export Results

Select **Export** to export the collected data. There are four different export options.

- .csv** is the standard format used by NDI
- .ela** and **.sfp** are file formats for BESA
- .rom** is for use in other NDI measurement tools

Only .csv files can be imported back into the RapidMarkr software.

3.11 Image Capture

Capture an image of the Scanner view as follows:

Press the Image Capture button on the Scanner, see [Figure 3-12](#). The Image Capture window launches and displays a progress bar.

After the image capture is complete, the file is automatically saved to the working directory. The format is .png.



Figure 3-12 Image Capture Button

4 Preferences

You can access preferences to customize various Krios settings.

1. Select **File>Preferences...** . The **Preferences** dialog opens.
2. Set as required in each field.

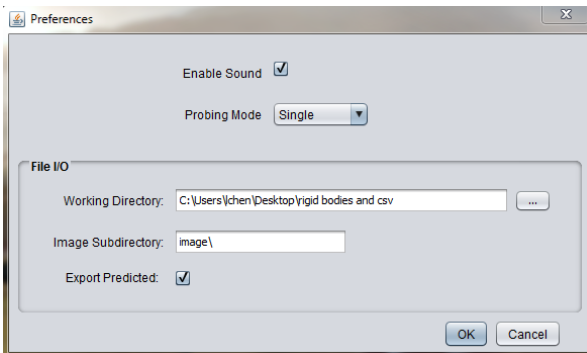


Figure 4-1 Krios Preferences

5 Maintenance

User maintenance of the Krios System is limited to cleaning.



There are no user serviceable parts in the Krios System. All servicing must be done by NDI. Unauthorised servicing may result in personal injury.



Do not immerse the Krios System in liquids, or allow fluid to enter the equipment in any way. Exposing the Krios System to liquids may result in equipment damage, produce a fire or shock hazard, and result in personal injury.



Switch off power to the Krios System before cleaning it. Failure to do so may result in personal injury.

Caution! Do not use aerosol sprays near the equipment as these sprays can damage circuitry.

Do not use any solvent to clean the Krios System. Solvents may damage the finish and remove lettering.

To clean the Krios System proceed as follows:

1. Wipe off dust with a dry, soft cloth.
2. Remove dirt or finger marks using a damp cloth and dry immediately with a clean cloth.
3. If required, gently remove any dust or finger marks from the lenses using a microfibre lens cleaning cloth.

5.1 Disposal of Equipment

To ensure environmentally responsible disposal after the equipment is decommissioned, please contact NDI. See [“Contact Information” on page vi](#).

6 Specifications

6.1 Operating Environmental Conditions

Table 6-1: Operating Environmental Conditions

Environmental Condition	Value
Atmospheric Pressure	70 kPa to 106 kPa
Relative Humidity	30% to 75%
Temperature	+10°C to +30°C (see warning below)



The power adapter must be located outside the patient environment under all operating conditions. It is the responsibility of the system integrator and/or the end-user to ensure that the system is appropriately configured for the operating conditions.

6.2 Transportation and Storage Environmental Conditions

Table 6-2: Transportation and Storage Environmental Conditions

Environmental Condition	Value
Atmospheric Pressure	50 kPa to 106 kPa
Relative Humidity	10% to 90% non-condensing
Temperature	-10°C to +50°C

6.3 Technical Specifications

Table 6-3: Krios Scanner Technical Specifications

Specification	Value
Dimensions	300 mm x 75 mm x 155 mm
Weight	860 g
Update Frequency	20, 30, 60 Hz
Scan Rate	256 markers < 2 minutes
Accuracy	Within 0.5 mm RMS

Table 6-4: Host USB Converter Technical Specifications

Specification	Value
Dimensions	88 mm x 57 mm x 39 mm
Weight	0.35 kg
Mounting	Free standing or secured via three M6 x 1 mm pitch x 3 mm deep threaded holes, located in the mounting feet
Input Voltage	24 VDC
Output Voltage	26 VDC
Power Consumption	<2 W

Table 6-5: Power Adapter Technical Specifications

Specification	Value
Model	Advanced Power Solutions APS49EMG-24021-7
Dimensions	125 mm x 62 mm x 32 mm
Weight	0.37 kg
Mounting	Free standing
Input Voltage	100 VAC to 240 VAC
Input Frequency	50/60 Hz
Input Power	0.63 A - 1.2 A
Power Output	24 VDC @ 2.1 A

7 Approvals and Classifications

7.1 Approvals

Optical Radiation Safety

Scanner Illuminators

The Polaris Krios Scanner Sensor illuminators emit invisible LED radiation. The Polaris Krios System emits IR light that may interfere with IR controlled devices, such as operating room tables. It is recommended that you test the Polaris Krios System if you intend to use it in an environment where other IR controlled devices are in use.

7.2 Classifications

Table 7-1 Classifications

Classification	Description
Electric shock protection	Class I - no applied parts
Degree of protection from electric shock	Not classified
Ordinary Equipment	IPX0
Flammable atmosphere	Not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide
Mode of operation	Continuous when supplied by mains
Method of sterilization or disinfection	Not suitable for sterilization
IREC illuminators risk group	Exempt

8 Electromagnetic Compatibility

The Krios System requires special precautions regarding EMC. It must be installed and put into service in accordance with the EMC information, detailed in this chapter. Failure to do so may result in personal injury.

Radio frequency communications equipment, including portable and mobile devices, may affect the Krios System and result in personal injury.

Do not use the Krios System either adjacent to, or stacked with, other equipment. Check that the Krios System is operating normally if it is used either adjacent to, or stacked with, other equipment. Failure to do so may result in personal injury.

This chapter contains the following information about the electromagnetic compatibility of the system:

- [“Cables and Accessories” on page 34](#)
- [“Guidance and Manufacturer’s Declaration: Electromagnetic Immunity” on page 35](#)
- [“Recommended Separation Distances” on page 38](#)
- [“Radio Frequency Emissions” on page 39](#)

8.1 Cables and Accessories

Only those cables and accessories delivered with the system may be used with the Krios System while still maintaining compliance to the emissions and immunity requirements of IEC 60601-1-3.

Use of cables or accessories other than those delivered with the system may result in increased emissions and/or decreased immunity of the Krios System and may result in personal injury. Guidance and Manufacturer’s Declaration: Electromagnetic Emissions

8.2 Guidance and Manufacturer’s Declaration: Electromagnetic Emissions

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

Table 8-1 Manufacturer’s Declaration for Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11	Group 1	The Krios System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Table 8-1 Manufacturer's Declaration for Electromagnetic Emissions

RF emissions CISPR11	Class B	The Krios System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000 3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

8.3 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

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

Table 8-2: Electromagnetic Immunity


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	±2 kV for power supply lines. ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth	±2 kV common mode	

Table 8-2: Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Krios System requires continued operation during power mains interruptions, it is recommended that the Krios System be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 5 s	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Table 8-3: Electromagnetic Immunity—Not Life Supporting

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Krios System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1,2\sqrt{P}$ See Table 8-4 on page 38.</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>See Table 8-4 on page 38.</p> <p>Where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in metres.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

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

These guidelines may not apply to all situations. Electromagnetic

propagation is affected by absorption and reflection from structures, objects, and people.

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

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

8.4 Recommended Separation Distances

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

Table 8-4: Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Krios System

Rated maximum output power of transmitter (watts)	Separation distance according to frequency of transmitter (metres)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3

Table 8-4: Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Krios System

10	3,8	3,8	7,3
100	12	12	23

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

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

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

8.5 Radio Frequency Emissions

FCC

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference and,
2. This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be

determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by Northern Digital Inc. could void the user's authority to operate the equipment.

CE Mark

CE Mark: This is a Class B product. In a domestic environment, this product may cause radio interference, in which case the user may be required to take adequate measures.

Industry Canada

Industry Canada Compliance Statement: This ISM device complies with Canadian ICES-001.

Avis de Conformité à la réglementation d'Industrie Canada: Cet appareil ISM est conforme à la norme NMB-001 du Canada.