****

**GEX CORPORATION**

**RisøScan Dosimetry System**

**Installation and Operational Qualification (IO/IQ) Protocol**

Customer Name:

Customer Site/Address:

Execution Date(s):

**Dosimetry System:**

**Software S/N:**

**Measurement Instrument S/N:**

Executed by:

|  |  |
| --- | --- |
|  |  |
| Name and Title | Signature |

|  |  |
| --- | --- |
|  |  |
| Name and Title | Signature |

Authored by:

|  |  |
| --- | --- |
| Michelle CowanSystems Support Engineer |  |
| Name and Title | Signature |

Approval

**GEX Corporation Representatives Approval**

Your signature indicates that you have reviewed this document and that it accurately and completely reflects the applicable tasks per GEX policies and procedures, and current Good Manufacturing Practices.

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| Name, Company and Title | Signature | Date |

**Customer/Site Representatives Approval**

Your signature indicates that you have reviewed this document and that it accurately and completely reflects the applicable tasks per GEX policies and procedures, and current Good Manufacturing Practices.

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| Customer/Site Primary Representative:Name:Title: |  |  |
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| Customer/Site Representative:Name:Title: |  |  |
| Name/Title | Signature | Date |

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# INTRODUCTION

## Objective

The installation and qualification (IQOQ) of the RisøScan Dosimetry System.

## Scope

The scope of this IQ/OQ protocol includes the module/system’s associated components, utilities, instrumentation, and automation.

|  |  |
| --- | --- |
| **ID** | **Description** |
|  |  |
|  |  |
|  |  |

## Roles

**Executer:** The GEX representative executing this Protocol has met all training requirements for the DoseControl dosimetry systems installation and qualification services and related hardware and software. Verified training records available upon request.

**Reviewer:** The GEX representative reviewer of this Protocol has met all the training and experience requirements necessary to review this Protocol and assess that it accurately and completely reflects the applicable tasks per GEX policies and procedures, in accordance with current Good Manufacturing Practices.

**Customer/Site representative:** Person with approval authority to assess and review this document.

##  Definitions

**Dosimetry system:** A dosimetry system is comprised of three main parts:

* 1. Software – typically used in IQ/OQ and PQ dose mapping applications, as well as testing and research. RisøScan software is a MS Windows based software and is installed on a single PC workstation.
	2. Hardware – a flatbed scanner is used to obtain the images used for analysis with the RisøScan software.
	3. Dosimeters – radiochromic film dosimeters, such as B3.

## References

|  |  |  |
| --- | --- | --- |
| **Reference Identification** | **Title/Description** | **Publication Date/Revision Date** |
| Risø-R-1487(EN) | RisøScan 1.03 – User Manual and Toolset for Retrospective Validation Authored by Jakob Helt-Hansen, Department of Radiation Research Department, Risø National Laboratory, Roskilde, Denmark  | Publication date December 2004Revised March 2006 |
| HDRL-I-36 | Instruction 36: HDRL Quality Manual, sect 5.5.3., RisøScan. Authored by Jakob Helt-Hansen, Risø National Laboratory | 16 Mar 2003 |
| GEX Doc #100-284 | RisøScan Measurement Repeatability Procedure | A |
| GEX Doc #100-285 | RisøScan Measurement Repeatability Form | A |

# INSTALLATION QUALIFICATION

## Test Case 1: System IQ

**Objective:**  To confirm all dosimetry system components are received, in operable condition, with all the necessary product documents.

**Procedure:** Review the following questions for each item in the table and record any deviations:

* + 1. For each dosimetry system component, enter the GEX part number, description, and quantity that is present.
		2. Confirm each component is received in operable condition, undamaged, and instruments can be powered on without errors. Enter **Pass/Fail.**
		3. Confirm a user manual or equivalent product information is delivered with the item or downloaded for the item from the supplier website. Enter **Yes/No**.
		4. If applicable, confirm a certificate of compliance or analysis is provided with the item. Enter **Yes/No**.
		5. If applicable, confirm the item is supplied with a calibration certificate. Enter **Yes/No**.
		6. Is calibration of this item required per internal standard operating procedure? Enter **Yes/No**.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **GEX Part #** | **Part Description** | **Qty** | **Condition** | **Manual** | **COC/COA** | **Cal. Cert**  | **Cal Req.**  |
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| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

## Test Case 2: Dosimeters IQ

**Objective:**  Verification that dosimeters are received in good condition, with all the necessary product documents.

**Procedure:** Review the following questions for each item in the table and record any deviations:

|  |  |  |  |
| --- | --- | --- | --- |
| **Dosimeters Batch ID:**  |  | **Shipment Receipt Date:** |  |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
|  | Complete for all GEX B3 film dosimeter shipments. For other dosimeter types mark test case result “N/A”.1. Locate all irreversible temperature labels that were included in the shipment.
2. Attach to a sheet of paper with shipment date labeled on the paper.
3. Make a color copy of all labels and ***attach as evidence.***
 | The maximum temperature is equal to or less than 45°C.***(Attach color scan of labels.)*** | The Maximum temperature recorded on the temp. label (in °C ) was ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** | [ ] Pass[ ] Fail[ ] N/A |
|  | Review the Certificate(s) of Compliance accompanying the dosimeters and compare the certificate(s) to the actual product. Make copies of the certificate(s) of compliance and ***attach as evidence.*** | 1. The boxes received are all accounted for on the certificate(s)
2. There is no discrepancy of any information about the dosimeters on the box labels versus the certificate(s).

***(Attach copy of certificate)*** |  | [ ] Pass[ ] Fail |
|  | 1. Examine each box of dosimeters to find a labeled expiration date.
2. If no label of expiration date exists, create a label for each box showing the expiration date. Refer to the certificate of compliance and product literature for the dosimeters to determine the expiration date if no label exists from the vendor.
 | a) The dosimeter film samples are within the expiration date.b) The expiration date is labeled on every box of dosimeters. |  | [ ] Pass[ ] Fail |
| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

## Test Case 3: Software IQ

**Objective:**  Verify that RisøScan software is installed and operable on the specified PC workstation.

**Procedure:** Review the following questions for each item in the table and record any deviations:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step** | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
| 1. **1**
 | Log into the MS Windows PC with a valid username and password.  | The user can log into the PC. |  | [ ] Pass[ ] Fail |
| 1. **2**
 | Open the RisøScan Application using the Windows start menu > All Programs or the Risoescan application icon (desktop or taskbar). | The user can open the RisøScan software. |  | [ ]  Pass[ ] Fail |
| 1. **3**
 | Confirm the software version number from the “About” menu item on the RisoScan main screen matches the recorded version number in the Objective section of this Test Case 3. | The version ID is recorded and confirmed.***(Attach screenshot as evidence RisoeScan Software Version.)*** |  | [ ] Pass[ ] Fail |
| 1. **4**
 | Confirm the PC name/ID matches the recorded PC name in the Objective section of this Test Case 3. | The PC name/ID is recorded and confirmed.***(Attach screenshot as evidence PC name/ID.)*** |  | [ ] Pass[ ] Fail |
| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ]  Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

## Test Case 4: Scanner IQ

**Objective:**  Verification that scanner and any related drivers and software are installed and functioning as intended for use with the RisøScan dosimetry system.

**Procedure:** Review the following questions for each item in the table and record any deviations:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
|  | 1. Read and understand the manufacturer’s safety and installation instructions, as per the instrument user manual.
 | The instructions for the Safety and Installation information provided in the User Manual have been read and understood. |  | [ ] Pass[ ] Fail |
|  | Position the scanner in a suitable environment, in accordance with the environmental requirements that are listed in the user manual. Do not power on the scanner.  | The scanner has been placed in a suitable location and the appropriate power is ready to be applied to the instrument. |  | [ ] Pass[ ] Fail |
|  | Confirm the appropriate scanner software is installed on the PC workstation. | The scanner software is installed on the PC. |  | [ ] Pass[ ] Fail |
|  | Confirm the appropriate driver for the scanner software is installed, if appropriate. | The scanner driver is installed. |  | [ ] Pass[ ] Fail |
|  | 1. Plug the scanner into an appropriate power source. Power on the unit as per the instructions given in the manufacturer user manual.
 | The scanner is plugged into an appropriate power source and powered on successfully. |  | [ ] Pass[ ] Fail |
|  | 1. Open any \*.bmp or \*.png image file on the PC workstation to verify that an image editing software is installed on the PC.
 | Able to open a \*.bmp or \*.png image file on the PC. |  | [ ] Pass[ ] Fail |
| **Comments:**  |  | **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

# OPERATIONAL QUALIFICATION

## Test Case 5: Software OQ

**Objective:**  To verify that RisøScan is operating in accordance with Riso product specifications and expectations. (Reference: RisøScan 1.03 – User Manual and Toolset for Retrospective Validation)

**Procedure:** Follow the instructions and execute all test cases described in *Risø-R-1487, Toolkit for Retrospective Validation*. Record all test case data in the Toolkit’s Appendix tables, as instructed. Capture screenshots of the test case execution in RisøScan as directed in each step below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 1. Applying weighting factors to RGB value and conversion to Response value. Record test case data as instructed. Capture screenshot(s) of test execution. | Able to apply weighting factors to RGB value and conversion to Response value in the software in accordance with Risø validation tool kit instructions. **(Attach test case results table and screenshot as evidence.)** |  | [ ] Pass[ ] Fail |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 2. Calibration procedure. Record test case data as instructed. Capture screenshot(s) of test execution. | The software’s calibration procedure functions in accordance with Risø validation tool kit instructions.**(Attach test case results table(s) and screenshots as evidence.)** |  | [ ] Pass[ ] Fail |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 3: Reference correction. Record test case data as instructed. Capture screenshot(s) of test execution. | The software’s reference correction functions in accordance with Risø validation tool kit instructions. **(Attach test case results table(s) and screenshots as evidence.)** |  | [ ] Pass[ ] Fail |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 4: Standard deviation. Record test case data as instructed. Capture screenshot(s) of test execution. | The software’s standard deviation functions in accordance with Risø validation tool kit instructions. **(Attach test case results table(s) and screenshots as evidence.)** |  | [ ] Pass[ ] Fail |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 5: Minimum and Maximum values (Surface profile). Record test case data as instructed. Capture screenshot(s) of test execution. | The software’s surface profile functions in accordance with Risø validation tool kit instructions. **(Attach test case results table(s) and screenshots as evidence.)** |  | [ ] Pass[ ] Fail |
|  | Execute Risø-R-1487, Toolkit for Retrospective Validation TEST 6: Depth dose profile. Record test case data as instructed. Capture screenshot(s) of test execution. | The software’s depth-dose profile functions in accordance with Risø validation tool kit instructions. **(Attach test case results table(s) and screenshots as evidence.)** |  | [ ] Pass[ ] Fail |
| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

## Test Case 6: Scanner OQ

**Objective:**  Verification of the scanner operational functionality, and the scanner software functionality to verify the scanned image quality meets the requirements of RisøScan dosimetry.

**Procedure:** Review the following questions for each item in the table and record any deviations:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
|  | Scan Reference Tablet or other irradiated B3 dosimeter on the Background. | Able to scan B3 film on the scanner.  |  | [ ] Pass[ ] Fail |
|  | Save scanned image as a \*.bmp file and \*.png file to the PC desktop | Able to save scanned image to PC desktop in \*.bmp and \*.png file formats.  |  | [ ] Pass[ ] Fail |
|  | Execute GEX Doc# 100-284 Risoscan Measurement Repeatability Procedure. | All tests “Pass” as applicable on the test form, *GEX Doc#100-285, Risoscan Measurement Repeatability Form*.**(Attach printed copy of completed test form as evidence.)** |  | [ ] Pass[ ] Fail |
| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
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| Reviewed By - Print Name | Reviewed By - Signature | Date |

## Test Case 7: Dosimetry System OQ

**Objective:**  To verify that the RisøScan dosimetry system produces the required outputs.

**Procedure:** Review the following questions for each item in the table and record any deviations:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **Step**  | **Instruction** | **Expected Result** | **Actual Result (Yes/No)** | **Result of Step** |
|  | Ensure a calibration function is saved in RisøScan, to be used to apply to a scanned image. Using the scanner, scan an irradiated B3 film on the Background. Save scanned image as a \*.bmp file and \*.png file to the PC desktop. | Able to 1. Scan B3 film
2. Save image to desktop
3. Open image in software
4. Apply a calibration to the image.
 | 1.
2.
3.
4.
 | [ ] Pass[ ] Fail |
|  | Create a report by clicking Ctrl+P or File>Print and select “print report to printer”.Enable all contents of the report to be printed by enabling all the check boxes:1. Print information about the Image.
2. Print information about the Calibration.
3. Print information about the Reference.
4. Print the Original Image.
5. Print the Calibrated Image.
6. Print only the selected part of the image.
7. Scale graphs by a factor of (select scale factor).
8. Print the image as it appears on the screen.
 | Verify report prints on a printer for each and all of the content areas.***(Attach a copy of printed report output with all content areas.)*** |  | [ ] Pass[ ] Fail[ ] N/A |
|  | Create an HTML report by clicking Ctrl+P or File>Print, and select “write report to HTML”. Save HTML file to the PC’s desktop.Enable all contents of the report to be printed by enabling all the check boxes:1. Print information about the Image.
2. Print information about the Calibration.
3. Print information about the Reference.
4. Print the Original Image.
5. Print the Calibrated Image.
6. Print only the selected part of the image.
7. Scale graphs by a factor of (select scale factor).
8. Print the image as it appears on the screen.
 | Verify report compiles to HTML for each and all of the content areas. ***(Attach a copy of HTHML report output with all content areas.)*** |  | [ ] Pass[ ] Fail[ ] N/A |
|  | Start an “open image” task, and ensure that “wedge angle” has been selected. Next, select the Depth Profile button. Select an area of the image, covering as much of the depth dose profile as possible without going outside the edge of the dosimeter. Make sure that “Intensity” displays “Dose”. Follow the instructions in Risø-R-1487(EN), section 10.1 and perform a manual energy measurement, or section 10.2 and perform an automatic energy measurement. Create a graph from the data of a task by clicking on Ctrl+W or File>Graph to file to write data from the graphs of the current task to an ASCII file. Save ASCII file to desktop. | Verify “graph values to ASCII file” functionality. ***(Attach a copy of ASCII file output.)*** |  | [ ] Pass[ ] Fail[ ] N/A |
|  | Document a measurement by making a screen dump. Use the same task as step 10, and click on Ctrl+S or File>Save to display a dialog box where it is possible to write a comment.1. Type a comment for the screen dump in the dialog box. Take a screenshot and save screenshot to desktop.
2. Select the type of image file to create and click “Save”.
 | Verify “screen dump” functionality. ***(Attach a copy of all steps below as evidence.)***1. A comment for the screen dump can be written in the dialog box.
2. A screen dump image file can be saved.
 | 1.
2.
 | [ ] Pass[ ] Fail[ ] N/A |
| **Comments:**  |  |
| **Deviations:** |  |
| **Result of Test Case:** | [ ] Pass [ ] Fail |
|  |  |  |
| Completed By - Print Name | Completed By - Signature | Date |
|  |  |  |
| Reviewed By - Print Name | Reviewed By - Signature | Date |

# APPENDICES

APPENDIX 1 – Signature Log

APPENDIX 2 – Exceptions Register and Attachments

APPENDIX 3 – Test Case Evidence and Attachments

## APPENDIX 1 – Signature Log

Any person who participates in the preparation and/or execution of this protocol must provide their printed name, initials, signature, and company/department in the table below. Document approvers do not need to sign the signature log unless they complete another part of the document.

|  |  |  |  |
| --- | --- | --- | --- |
| **Printed Name** | **Initials** | **Signature** | **Company/Department** |
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**Reviewed by (initials/date):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## APPENDIX 2 – Deviations Log

Individual Deviation Test Cases are listed in the log below. Deviation test case attachments will be attached behind the log in this appendix.

|  |  |  |  |
| --- | --- | --- | --- |
| **Exception Number** | **Protocol Section Number/Step Number** | **Closure Date** | **Performed by (Initials/Date)** |
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**Reviewed by (initials/date):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## APPENDIX 3 – Test Case Evidence Log

The following table lists the Test Case attachments. Individual Test Case attachments will be attached behind the log in this appendix.

|  |  |  |
| --- | --- | --- |
| **Test Case Number** | **Step** | **Attachment Number** |
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**Reviewed by (initials/date):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_