DESCRIPTION

GEX B3, B3 WINdose and B3 DoseStix radiochromic film dosimeters are used for absorbed dose measurements in radiation processing. When irradiated, a chemical reaction occurs within the film causing a change in the visible light spectrum which is quantifiable and directly related to the absorbed dose of ionizing radiation the dosimeter receives.

APPLICATION(S)

GEX B3, B3 WINdose and B3 DoseStix dosimeters are used for measuring the absorbed dose in commercial/industrial radiation processes, such as medical device sterilization, surface decontamination of foods and packaging materials, and the crosslinking and curing of inks and coatings. They can be used to measure ionizing radiation doses from gamma, X-ray, and electron beam sources. B3 dosimeters are often used as part of a dosimetry system designed to meet the requirements in ISO 11137. Some of the processes for which the dosimeters are used are described below:

- Product conformance assessment of irradiated products
- Dosimetric qualification (IQ/OQ/PQ) of irradiation facilities (for example, per ISO 11137-1)
- Minimum and Maximum dose setting for products (see ISO 11137-2)
- Research of irradiation effects on products

SPECIFICATIONS

B3 FILM GENERAL

Description:	Polyvinyl butyral (PVB) polymer film with proprietary B3 dye.
Color:	Film - clear before irradiation; pink to purple post-irradiation.
Nominal Film Thickness:	0.0180 mm (18.0µ)
Thickness Variation:	± 0.0005 mm (0.5µ) at k=2 or less; actual value certified with each shipment
Measurement Instrument:	Spectrophotometer; Flatbed scanner
Analysis wavelength:	552 nm
Spectral bandwidth (SBW):	≥ 4nm. Best performance below 5 kGy using 8nm or larger.
Photometric range:	0.035 to 1.700 A
Dose range:	1.0 kGy to 160 kGy
Electron Energy Range:	≈ 70 KeV to 50 MeV
Photon Energy Range:	≈ 0.1 MeV to 50 MeV
Pre-irradiation signal stability:	Stable with controlled storage conditions (see Pre-irradiation Storage).
Post-irradiation signal stability:	Stable with heat treatment after irradiation and controlled storage conditions.

GEX B3 Dosimeter (B350x)

Tradename:	GEX B3
DSM Color:	White
DSM Outer Dimensions:	10mm x 20mm
DSM Aperture Dimension:	4.76mm diameter
DSM Paper Material:	70# smooth text
DSM Paper Thickness:	0.12mm
DSM Adhesive Material:	Permanent vinyl acrylic
Pouch Color:	Silver
Pouch Dimensions:	Width: 1.5” ± 0.0625" Length: 2.278” ± 0.125"
Pouch Seal Width:	≥ 0.25”
Pouch Material:	Top material: UV blocking coated PET 23/ Aiox PET 12 / LLDPE 80 Clear Bottom material: 48 GA PET / .70 LDPE / .35 F / .57 EAA / 2.0 LLDPE
Printing (dosimeter):	Front: Batch ID, Serial Number, S/N Format: 1234567, Data matrix ECC200 compliant Back: None
Printing (label):	N/A
Printing (pouch):	None

Product Photos

B3 WINdose (B300x)

Tradename:	WINdose
DSM Color:	White
DSM Outer Dimensions:	10mm x 10mm
DSM Aperture Dimension:	5.5mm diameter
DSM Paper Material:	60# text
DSM Paper Thickness:	0.127mm
DSM Adhesive Material:	Permanent vinyl acrylic
Pouch Color:	Silver
Pouch Dimensions:	Width: 1.5” ± 0.0625" Length: 2.278” ± 0.125"
Pouch Seal Width:	≥ 0.25”
Pouch Material:	Top material: UV blocking coated PET 23/ Aiox PET 12 / LLDPE 80 Clear Bottom material: 48 GA PET / .70 LDPE / .35 F / .57 EAA / 2.0 LLDPE
Printing (dosimeter):	Front: Batch ID, Serial Number, and replicate ID (A or B); S/N Format: AA-1234567 Back: None
Printing (label):	Barcode Label: Code 128 font matching S/N format
Printing (pouch):	None

Product Photos

B3 DoseStix (B300xDS)

Tradename:	DoseStix
DSM Color:	White
DSM Outer Dimensions:	15mm x 50mm
DSM Aperture Dimension:	5.0mm x 11.0mm
DSM Paper Material:	10 Tango C1S
DSM Paper Thickness:	0.254 mm
DSM Adhesive Material:	Permanent vinyl acrylic
Pouch Color:	Silver
Pouch Dimensions:	Width: 1.50” ± 0.0625" Length: 3.264” ± 0.125"
Pouch Seal Width:	≥ 0.25”
Pouch Material	Top material: UV blocking coated PET 23/ Aiox PET 12 / LLDPE 80 Clear Bottom material: 48 GA PET / .70 LDPE / .35 F / .57 EAA / 2.0 LLDPE
Printing (dosimeter):	Front: Batch ID, Serial Number, and replicate ID (A or B); Barcode Font: Code 128 matching S/N format: AA_1234567A Back: GEX logo
Printing (label):	N/A
Printing (pouch):	None

Product Photos

Box (Packaging)

Material:	Paperboard SBS .024
Dimensions:	Length: 8.0” ± 0.5”, Width: 7.0” ± 0.5”, Height: 1.625" ± 0.5”

Boxing Pack Quantities:

GEX Part#	GEX Part # / Product	Pouches/ Box	Dosimeters/ Pouch	Total Dosimeters QTY
B3500	GEX B3 - Bulk	200	10	2000
B3501	GEX B3 - 1/pouch	1000	1	1000
B3000	B3 WINdose - Bulk	200	10	2000
B3001	B3 WINdose - 1/pouch	1000	1	1000
B3002	B3 WINdose - 2/pouch	1000	2	2000
B3000DS	B3 DoseStix - Bulk	5	200	1000
B3001DS	B3 DoseStix - 1/pouch	500	1	500
B3002DS	B3 DoseStix - 2/pouch	500	2	1000
B3003DS	B3 DoseStix - 3/pouch	350	3	1050

Film Thickness and Certification

- A specified average thickness and variability is measured, assigned, and printed on each box of B3 dosimeters. A Certificate of Compliance is included with each shipment to end-users. Measurements are executed using a calibrated optical gauge.

Packaging

- The box of the B3 dosimeter product is labeled with the following information:
    - *GEX Product number*
    - *Dosimeter batch identifier*
    - *Dosimeter average thickness value*
    - *Manufacturing lot number*
    - *Product's expiration date*
- B3 dosimeter products are supplied in sealed pouches to protect the B3 dosimeters from UV light and maintain the moisture content of the film.
- All transparent packaging materials that are used in the pouches contain a UV blocking film.
- Pouches are opened by the tear-notch along the top side of the pouch.

Pre-irradiation Storage

- Store factory-pouched dosimeters at 15°C to 30°C in darkness (inside their GEX boxes or equivalent). Brief exposure exceeding 45°C prior to irradiation (for example, during transport) may cause a shift in response function. Therefore, if the storage temperature has any excursion >45°C the user should verify the response function of the stock and assess the suitability of any existing calibration function for the stock.
- Relative humidity of storage does not affect factory-sealed dosimeters; it is suggested to store the dosimeters at a target of 30% R.H. if it can be controlled, but excursions are not detrimental to the product. See influence quantities section below for more information.

Shelf Life

- GEX factory packaged B3 dosimeter products have a 5-year shelf life dictated by the performance of the packaging with respect to its barrier properties and the risk of changes to the conditions inside the package.
- Refer to the label on the product box and the Certificate of Compliance issued with the product shipment to confirm shelf life/expiration date.
- Any change in the performance of the dosimeter due to aging beyond 5 years will not be catastrophic. On the contrary changes will be slow to develop.

Packing/Delivery

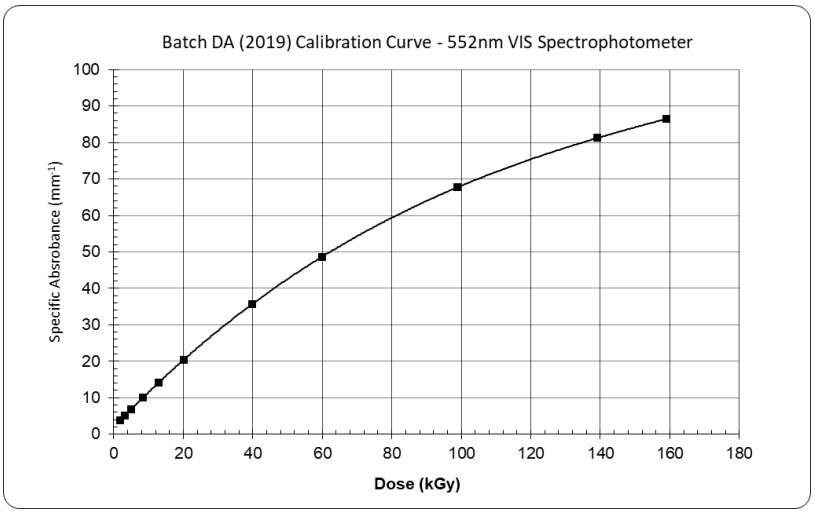
- Product is shipped in cardboard boxes designed to withstand the duration of expected travel. Inspect all packages upon receipt and report any damage or discrepancies to GEX with photographs.
- GEX includes irreversible temperature monitoring labels inside every cardboard box in a shipment of dosimeters to monitor maximum temperature in transit for informational purposes only. Knowledge of the maximum temperature during transport of the dosimeters does not preclude the user from testing the response of the dosimeters before use.

- The user is responsible for determining the performance of any shipment GEX B3 film dosimeters before use by means of dosimetry system calibration or verification of the suitability of an existing calibration function for the dosimeter batch and determination of measurement uncertainty. Testing may include comparison with existing stock of dosimeters held by the user prior to acceptance of the new stock.

OVERVIEW

B3 dosimeters should be used in accordance with *ISO/ASTM 51275: Practice for Use of a Radiochromic Film Dosimetry System*. Below is some fundamental information about the dosimeters:

- The response (*R*) of the dosimeter to ionizing radiation is defined in terms of optical absorbance (A_i) per unit thickness (*t*), also referred to as the "specific absorbance".
- Users may occasionally subtract the unirradiated, original absorbance (A_o), sometimes called "background", from the Ai to derive the "net specific absorbance". This is not beneficial when using GEX B3, B3 WINdose and B3 DoseStix dosimeters because the A_o is stable over long periods of time. In addition, the dosimeter thickness is both thin and uniform and the measurement of the A_o (also known as 'background') cannot help the user to resolve the small variances in thickness between dosimeters in the same batch and average thickness group. Since there is no technical gain in subtracting A_o, GEX recommends that the user ignore the A_o in any calculation of *R*.
- The relationship of *R* with absorbed dose (*D*) is expressed as $A_i/t = R = f(D)$ where the dosimeter response is a function of the quantity of absorbed dose received by the dosimeter.
- The response of the dosimeter (*R*) will vary from one dosimeter to another within the same batch having the same certified average thickness. Therefore, the process of calibration involves irradiation and measurement of representative samples of a stock of dosimeters that is owned and stored by the user.
- The response of the dosimeter (*R*) measured on one spectrophotometer will vary slightly from the value measured with another spectrophotometer. To ensure measurement accuracy, it is standard industry practice to calibrate the dosimeter response on each instrument. Instrument data may be combined, or one instrument demonstrated to be "equivalent" to another, but proper treatment of the data and assessment of additional measurement uncertainty components may be required.
- The dosimeter response (*R*) will vary from one dosimeter batch to another, and it is industry standard practice to calibrate each new batch of dosimeters.
- The dosimeter response (*R*) is affected by the various influence quantities discussed in the next section.
- The dosimeter response (*R*) will vary from one irradiator to another based on irradiation geometry and environmental differences between one irradiator and another. In addition to differences in irradiation geometry that may be present from one irradiator or irradiation pathway to another, the effect of influence quantities may also be different. Users should calibrate each irradiator or pathway independently unless they have evidence that they are equivalent and have accounted for allowed variability in their measurement uncertainty budget.
- B3 has a calculated dose resolution of one/tenth (0.1) kGy at 25 kGy. Every 0.001 A_i change results in a change of approximately 0.1 kGy.
- The response (*R*) has a slope of 2.0 at 2.0 kGy, reducing to a slope of 1.0 near 25 kGy, and a slope near 0.6 at approximately 100 kGy.
- The dose range of the B3 film is approximately 1 kGy to 160 kGy though some users have been successful in using the product above and below these values. Saturation of response begins near 150 kGy with full response saturation occurring at a dose of approximately 165 kGy or a specific absorbance of approximately 90.0 $A*mm^{-1}$ (approximately 1.700 A) under normal temperature conditions.
- Response Measurement Reproducibility – The user should be able to achieve the following percentage coefficient of variation (C.V.%) for repeated measurement of the same dosimeter:
    - 1.5% or better at 1.0 kGy
    - 1.0% or better at 10.0 kGy
    - 0.5% or better at 20.0 kGy and higher



Example B3 Dosimeter Response

- Response to environmental factors
  - UV Light – The response is permanently increased with or without exposure to ionizing radiation
  - Relative Humidity (R.H.) – The dosimeter response is best when R.H. values are low. See more information below with respect to temperature and dose combined effects with R.H.
  - Temperature – The response is directly proportional to absorbed dose but the effects of temperature on dosimeter response are affected differently at certain R.H. levels and certain dose levels, specifically:
- The B3 film performs exceptionally well at lower temperatures (< 35.0°C) and has been calibrated and used well below 0°C; the response function is depressed at freezing temperatures or lower. For example, in an environment with average temperature of -24.0°C the B3 response was greater than 90% of the response at room temperature over the entire dose range.
- Irradiation facilities located in temperate climates may experience a "seasonal" effect on their dosimetry due to the change in the temperature inside the facility with the seasons. Magnitude of the effect is not fully understood but is estimated at a couple percent. See Influence Quantities during irradiation below for details.
- Calibration and Curve Fitting for B3
  - In-situ calibration of the film is recommended whenever possible.
  - The slope of the response up to 10 kGy is nearly linear and can readily support the use of a linear fit.
  - Over the dose range from 5.0 kGy up to 60 kGy the film response function is typically best described and fitted with a second order polynomial (quadratic fit). Curve ranges that go above or below that range will typically involve use of third or fourth order polynomial for best fit.
  - The user may find it beneficial to produce multiple fits over multiple ranges to reduce overall uncertainty. For example, a fit of 1.0 to 10 kGy for low dose work and another from 5 to 75 kGy for all other measurements may reduce the overall uncertainty versus a single curve fit from 1.0 to 75 kGy.

EFFECTS OF INFLUENCE QUANTITIES

The best method for controlling the effect of many influence quantities is to calibrate the dosimeters under the conditions of use. Conditions of use include the packaging status (factory sealed or not which affects the moisture content of the film), temperature maximum during irradiation, temperature profile during irradiation (fractionation), post-irradiation handling/treatment times and temperatures, as well as all other details of the user's SOP's when using the dosimetry system. (See the Usage section below on post-irradiation for more information).

Before Irradiation

- **Dosimeter Conditioning and Packaging:** The B3 film is hydrophilic, and the paper overlay traps moisture and oxygen as well. Dosimeters are conditioned before packaging. Removal from the pouch prior to irradiation is often required for many reasons but doing so may alter the response function during irradiation.

- **Exposure to UV-light:** Dosimeters should be stored in the dark when not in use and protected from UV exposure prior to irradiation. See *GEX Doc# 100-250, UV Control and Monitoring* for additional information.
- **Relative Humidity:** Store packaged and unpackaged dosimeters in a cool, dry location. The effect of frequent, large variations in relative humidity during storage has not been tested.
- **Temperature:** Consistent storage temperature is recommended; also, exposure of the dosimeters to temperatures greater than 45°C prior to irradiation may alter the response function. Users should verify the dosimeter response if such an event occurs.
- **Time Since Manufacture (Dosimeter Aging):** The response of B3 film is suspected to slowly decrease over a period of many years. Storage of the dosimeters under consistent temperature conditions is recommended to minimize any effect. Continual temperature fluctuation during storage will result in the continual change in absolute humidity in the pouches. No testing has confirmed, but it is assumed that more stable storage conditions will reduce any effect.

During Irradiation

- **Dose Rate:** Absorbed dose rates > 0.01 Gy/s. No known dose rate effects. The response has been compared with irradiation in a cobalt-60 gamma cell (dose rate 0.5 $Gy \cdot s^{-1}$) and irradiation at a 10 MeV electron accelerator (average dose rate 250 $Gy \cdot s^{-1}$, dose rate during the pulse $2 \cdot 10^5$ $Gy \cdot s^{-1}$). The responses agreed with each other within 4% for each type of irradiation.
- **Dose Fractionation:** Dose fractionation has not been studied independent from the temperature effects. It is assumed that variations that occur due to fractionation are due to a combination of temperature and post irradiation stability effects. The user should calibrate using the method of fractionation that will be used to eliminate any effect.
- **Exposure to UV-light:** Exposure to UV light sources just before and during irradiation may not be avoided in some instances. Users should cover the dosimeter test with material to block the UV just prior to and immediately after the test is completed until the dosimeters can be returned to a UV-controlled environment. See *GEX Doc# 100-250, UV Control and Monitoring* for additional information.
- **Irradiation Temperature:** The influence of temperature on B3 response is not significant at the lower end of the B3 dose range. Temperatures above 60°C can cause a reduction of the response function of B3 film, thereby creating variable dose measurements. Use of B3 Film products in irradiation temperatures above 60°C is at the user's discretion per ISO/ASTM 51275.
- **Radiation Energy:** The response is independent of radiation energy, but the user must consider any dose gradients when using low energies.
- **Relative Humidity (R.H.):**
  - The dosimeter response is affected by the water content in the film during exposure to ionizing radiation. Irradiation in factory sealed packages (or equivalent) is recommended to minimize the influence of R.H. because the packaging preserves the condition under which it was pouched.
  - The magnitude of R.H. influence is minimal below 10 kGy.
  - For R.H. > 90% (approximate) the dosimeter response is depressed at all dose levels > 10 kGy when temperature exceeds 40°C. Therefore, if the facility is very hot and very humid the user must calibrate under those conditions and should always use dosimeters inside of sealed pouches.
  - At R.H. > 60% (approximate) the dosimeter response is depressed for doses above approximately 40 kGy and the user should calibrate under these conditions.
  - There is no evidence that low R.H. levels are detrimental at any temperature or dose magnitude. The lowest R.H. tested is 11.3%. Therefore, users should exercise caution at R.H% values < 10% until they evidence consistent performance with testing or should calibrate under these conditions.

Post Irradiation and During Measurement

- **Exposure to UV-light:** Control exposure of film dosimeters to UV-light sources after irradiation. UV filters on windows in the measurement area are often necessary. LED lighting is suggested for rooms where the measurements will be performed. Alternatively, use UV-blocking material on the lighting. See *GEX Doc# 100-250, UV Control and Monitoring* for additional information.

- **Relative Humidity (RH) and Temperature:** Stability of the dosimeter response (*R*) after proper heat treatment of the dosimeters is best when conditions are controlled; however, the magnitude of any effect is minor for heat-treated dosimeters in the first 30 days after irradiation.
- **Time Since Irradiation (Stability):** Post-irradiation heat treatment of B3 film is necessary to catalyze the chemical reaction and finalize the color change. Heat treatment is required for all users except those users exclusively using high doses (> 40 kGy) and high temperatures (> 55.0°C). After proper heat treatment, B3 film and dosimeter products are stable for 1 year when stored under ambient conditions (15°C to 30°C). The dosimeter can be used without heat treatment, but this is not recommended or best practice.

USAGE

Dosimeter Receipt

Users must verify the product upon receipt and should treat each shipment as a separate stock unless they can be demonstrated to be equivalent. For more information on receiving inspection refer to GEX Doc# 100-256, *Procedure for Dosimeter Batch Receiving Inspection*.

Dosimeter System Qualification (includes Calibration)

Before any measurement devices and related software are used to measure GEX B3, B3 WINdose, and B3 DoseStix dosimeters, users should qualify the measurement process. It is further recommended that users qualify the entire process of dosimetry from dosimeter provision to placement in the irradiator, retrieval, heat treatment, sample measurement, data analysis, and reporting to the extent required by the application for which the dosimetry system will be used. Refer to GEX Doc# 100-280, *IQ/OQ Protocol for the DoseControl Dosimetry System* as an example.

Calibration of the Dosimetry System

GEX recommends in-plant calibration, under normal process and environmental conditions for all applications and processes and done in accordance with ISO/ASTM 51261 Method 2. The film should be calibrated using the standard SOPs for dosimeter handling, measurement, and all other parameters the user can control to best capture the response under routine conditions. In general, a phantom absorber is required to ensure the dose to both the GEX dosimeters, and the reference dosimeter is equivalent. For detailed guidance on calibration refer to GEX DOC# 100-203, *Dosimetry System Calibration.*

Placement, Irradiation, and Retrieval

- GEX's serialization of dosimeters provides traceability and data integrity for dosimeter measurements. The dosimeter batch ID and unique dosimeter identification number found on each GEX B3, B3 WINdose, and B3 DoseStix dosimeter forms a unique string that will never be duplicated.
- B3 dosimeters may be irradiated in the sealed pouch, as applicable, if the radiation source has sufficient penetration energy.
- Use care to avoid damaging the packaging when placing dosimeters. If the pouch material or seal is breached and the environment inside the pouch is compromised, then the measurement with the dosimeter may also be compromised.
- The film can be bent or folded for placement in small, irregular locations typically without damaging the optical properties.
- User's may find measurable variance between different packaging configurations such and 1 or 2 dosimeters in a pouch, between GEX B3, B3 WINdose and B3 DoseStix, or between pouched and un-pouched dosimeters. The user should determine which configurations that require unique calibration functions to meet the end user application requirements.

Dosimeter Handling

- Also see *Precautions – Handling* below.
- Remove dosimeter from the pouch, then place the dosimeter into the dosimeter holder for measurement in the spectrophotometer.
- GEX B3 and B3 DoseStix dosimeters can be held using bare hands; the user should hold the dosimeter by the paper tag or overlay. Do not touch the film with bare fingers.
- Use forceps when handling the B3 WINdose dosimeters.
- Cut or tear the pouch at an angle to access the dosimeter. **WARNING: Use caution to avoid tearing the film portion of the dosimeter**.

- Clean work surfaces prior to use to avoid particulate attaching to the dosimeter.
- Static conditions may cause particulate to be drawn to the dosimeter surface which can negatively affect the measurement accuracy. Remove visible particulate with a soft brush or piece of soft anti-static cloth. Gently tapping or 'flicking' the dosimeter can also dislodge particulate.

Post Irradiation Heat Treatment

- Users may heat treat the dosimeter in the pouch or the dosimeters may be removed from the pouch. However, the same procedure should always be followed for post irradiation handling and heat treatment that the user applied during the dosimeter batch calibration.
- Users should determine appropriate post-irradiation heat treatment procedures, specific to the user's application and should validate any procedural variables they wish to allow.
- When heat-treating dosimeters in the GEX factory sealed pouch the main considerations are:
    - Selecting a low enough set point to avoid damage to the films
    - Selecting a high enough set point combined with a sufficient dwell time to render the absorbance 'stable'.
- General heat treatment guidelines are given in the table below:

INCUBATOR TYPE	DOSIMETER TYPES	TIME	TEMPERATURE
MICRO INCUBATOR	Pouched GEX B3, B3 WINdose and B3 DoseStix	5 minutes^	58.5°C^
FORCED AIR INCUBATOR	Pouched B3 WINdose and DoseStix	20 minutes^	58.5°C^
FORCED AIR INCUBATOR	Unpouched GEX B3, B3 WINdose and B3 DoseStix	10 minutes^	60.0°C^

^Values given are basic recommendations. Lower and higher temperatures and shorter times have been successfully used.

- Refer to *Post-Irradiation Heat Treatment of B3 Dosimeter Products Technical Report* GEX TIR #100-201 for detailed information.

Measurement

- GEX B3, B3 WINdose and B3 DoseStix dosimeters are typically measured using a spectrophotometer. GEX offers Thermo Scientific GENESYS 30 (GEX Part# P4400) and Evolution (GEX Part# P4300) spectrophotometers with custom dosimeter holder systems (refer to Accessories).
- A holder is necessary to position the dosimeter perpendicular to the light source in the spectrophotometer without introducing optical interference by the paper overlay on the dosimeter. We recommend using GEX dosimeter holders (or equivalent) for measuring B3 dosimeters.
- It is suggested to use the serial number of the dosimeter as a unique sample ID when measuring.

- Heat treated B3 dosimeters can be re-measured as many times as the user requires in the first 30 days after irradiation if the user has qualified their heat-treatment process. There should be no need to keep the dosimeters longer than 30 days.

PRECAUTIONS

General: The user is responsible to calibrate or verify the calibration of the dosimeter under the conditions of use. Guidance herein is based on experience. It is the user's calibration that defines the performance qualification of the batch of dosimeters and is only valid for the conditions of use. Use outside of those conditions requires assessment of impact on measurement uncertainty. For example, storing dosimeters outside of their factory-sealed package may not result in the same performance of the dosimeter as the performance defined by the batch calibration created with dosimeters that were stored in the factory-sealed package.

Packaging: The UV protective barrier is designed to protect the dosimeter from UV light during routine handling in commercial irradiation facilities. The barrier properties for prolonged exposure or under sustained or intense UV conditions have not been studied.

Handling: Dosimeter handling recommendations:

- Do not touch the film with bare fingers. The oils from fingers can influence the optical measurement.
- To clean fingerprints or non-particulate smudges on the film, gently clean the film surface with a dry, lint-free cloth. Be gentle when cleaning the film to avoid denting or causing physical damage to the film.
- Do not clean the film with any type of alcohol or alcohol-based cleaning wipes. Alcohol will destroy the film.
- Use caution when using scissors to open dosimeter pouches. Do not cut or tear the film.

Storage: Exposure to temperatures >45.0°C before irradiation may permanently affect the dosimeter response.

Application: B3 dosimeters are not suitable for personnel monitoring or radiation safety applications.

HEALTH / ENVIRONMENTAL INFORMATION

B3 film dosimeters contain a radiochromic dye dissolved in a polymeric matrix. In this format, they are considered completely safe to work with although no detailed study has been performed. Dosimeter films can be disposed of as regular refuse since the amount of dye per unit mass is very small. No MSDS is required.

WARRANTY / GUARANTEE

Warranty:

The user assumes all responsibility for the proper characterization, qualification, calibration, and use of the product in accordance with industry standards. The product is not warranted against misuse.

Guarantee:

1-year GEX satisfaction guarantee. May be returned with or without reason with one year from the date of delivery.

QUALITY ASSURANCE

GEX's Quality Management System (QMS) is ISO 9001:2015 accredited. More information is available https://www.gexcorp.com/quality.html

USER REFERENCE DOCUMENTS

1. NPL CIRM 29 Guidelines for the Calibration of Dosimeters for use in Radiation Processing, Peter Sharpe and Arne Miller, 1999; National Physical Laboratory, Teddington, UK.
2. Abdel-Fattah A. A. and Miller A. (1996); Temperature, Humidity, and Time. Combined Effects on Radiochromic Film Dosimeters; Radiation Physics and Chem. Vol. 47, No. 4 pp 611-621, Elsevier Science Ltd. Pergamon Press, Great Britain.
3. Miller A., Batsberg W. and Karman W. (1988); A New Radiochromic Thin-Film Dosimeter System; Radiation Physics and Chem. Volume 31, Nos 4-6, Elsevier Science Ltd. Pergamon Press, Great Britain.
4. ISO/ASTM 52628: Practice for Dosimetry for Radiation Processing
5. ISO/ASTM 51275: Practice for Use of a Radiochromic Film Dosimetry System

6. ISO/ASTM 51261: Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

RELATED GEX DOCUMENTS

- 100-201 Post Irradiation Heat Treatment of B3 Dosimeters – Technical Information Report
- 100-209 Developing and Using Uncertainty Statements – Technical Information Report
- 100-250 Procedure for UV Control and Monitoring
- 100-253 Dosimetry Lab Requirements
- 100-256 Procedure for Dosimeter Batch Receiving Inspection
- 100-258 Procedure for Measuring GEX Dosimeters
- 100-263 Procedure for Calibrating B3 Dosimeters
- 100-280 DoseControl Dosimetry System IQOQ

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
02/06/2023	- Added GEX B3 dosimeter product to Specifications sections. - Added Dosimeter Handling section with instructions for how to best open the pouch to access the dosimeter without forceps. - Updated photo of the product box to show the new label. - Added details to Precautions – Handling for how to clean fingerprints and smudges from film. Added cautions regarding how to open the pouch and not tear or cut the film. ECO 70633	D
03/14/2023	- 'Effects of Influence Quantities', page 6 – Before Irradiation, Relative R/H language clarified. "Store packaged and unpackaged dosimeters in a cool, dry location. The effect of frequent, large variations in relative humidity during storage has not been tested." - Usage, page 7 – Placement, Irradiation, and Retrieval: clarified last bullet point. "User's may find measurable variance between different packaging configurations such and 1 or 2 dosimeters in a pouch, or between GEX B3, B3 WINdose and B3 DoseStix, or between pouched and un-pouched dosimeters." - Precautions, page 10 – added 'General' statement. ECO 70642	E
10/31/2023	- Changed section title from "Packing/Shipping" to "Packing/Delivery". - Revised the content to remove any suggestion that delivered dosimeters without temperature information do not require any different handling by the user than those with temperature monitoring. The section explicitly states that users must test the response function of all shipments. - Removed statement about "additional testing". In practice, the user must determine suitability of dosimeter performance regardless of the temperature of the shipment. Thus, temperature monitoring is informational in nature only. - Other minor changes to language were made without changing the intent of contents. ECO 70650	F