

# The VIU<sup>®</sup> Visual Inspection Unit

Repeatable illumination and magnification for evaluating medical pouch seals

Safe to patient medical device packaging depends on regular testing and inspection. The VIU<sup>®</sup> Visual Inspection Unit gives line operators a reliable way to evaluate raw visual seal performance directly at the point of packaging.



## Standardize Your Visual Inspection Process

The VIU<sup>®</sup> system is engineered to bring consistency to the visual inspection of medical device pouch seals. Every inspector evaluates the sealed area under the same lighting conditions and the same magnification level. This creates a uniform pass or fail standard that supports a more defensible visual inspection plan.

The system stores line-item data for each inspection event, including date, time, operator name, pass or fail status, and optional failure identification numbers. Lot numbers can also be added for improved traceability. With both administrator and operator access levels, it is easy to build a tiered user plan that supports your quality system.

The bright backlit display is easy to read, and the menu structure is simple and intuitive. Adding visual inspection to your medical device packaging workflow provides a nondestructive and highly informative method of seal evaluation.

## Patented Side Lighting for Enhanced Seal Visibility

Our patented side lighting technology allows operators to observe how light interacts with the sealed surface. This lighting method highlights subtle seal irregularities that may not be visible under standard overhead illumination.

The integrated magnification lens provides a close, detailed view of the sealed area while still offering a wide enough field of vision to maintain context. The open-ended design accommodates a wide range of pouch sizes, making the VIU<sup>®</sup> system suitable for diverse packaging operations.

## Electronic Data Input for Better Traceability

Inspection results can be stored electronically after each evaluation, allowing teams to identify trends and isolate potential seal issues across lots and over time. The intuitive pass or fail button reduces the likelihood of operator input errors. The bright backlit display provides an ergonomic and easy to read interface for daily use.

## Data Purge for Clean Lot-to-Lot Management

After each packaging run, stored inspection events can be purged. These records may include lot numbers, inspection dates, operator names, pass or fail status, and failure codes. This data can serve as a valuable reference for internal audits and long-term quality documentation.

## Remove Variables and Strengthen Seal Evaluation

In medical device packaging, the goal is always to remove or control variables. The VIU<sup>®</sup> system ensures that every operator inspects pouch seals under identical lighting and magnification conditions. With the included visual inspection guide, operators can compare known defect types to their observations, improving accuracy and helping isolate the specific failure mode.

The VIU<sup>®</sup> Visual Inspection Unit brings structure, repeatability, and clarity to one of the most important nondestructive evaluations in sterile packaging.

## Visual Seal Inspection Reference Sheet For Medical Device Pouch

### 1. CHANNEL

**Image 1** A thin, continuous unsealed pathway across the seal width. Channels may appear in various shapes or locations and can allow leakage or microbial ingress, compromising sterile integrity. Common causes include platen damage, uneven pressure, or contamination.



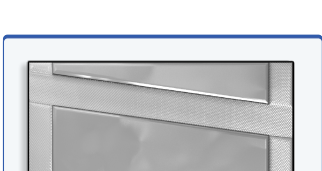
### 2. UNSEALED AREA

**Image 2** A visibly open gap or void within the seal. This defect may result from improper sealing parameters, inadequate pressure, or post-seal stress such as handling or environmental forces. Any unsealed region represents a potential breach of the sterile barrier.



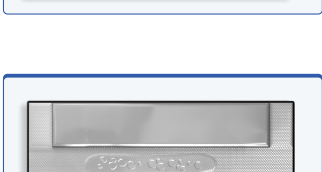
### 3. SEAL TOO CLOSE TO EDGE

**Image 3** Seal positioned closer to the pouch edge than specified. This may occur at one end or along the entire length. Misalignment during sealing is the most common cause. Operator alignment guides or fixtures can help ensure consistent placement.



### 4. OVER-SEALED

**Image 4** Seal surface appears rough, bubbly, distorted, translucent, or burnt. Tyvek<sup>®</sup> may appear transparent in the seal zone. Over-sealing is generally caused by excessive heat, dwell time, or pressure. This condition may weaken the seal or distort material properties.



### 5. NARROW SEAL

**Image 5** Seal width is less than the minimum specification. This may result from seal creep, partial rupture, contamination, or equipment requiring maintenance. Narrow seals reduce the effective sealing area and may compromise strength.



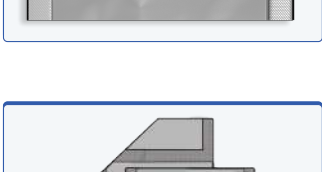
### 6. UNDER-SEALED

**Image 6** Portions of the seal show lifting, incomplete bonding, or lighter-colored areas. Under-sealing is often caused by insufficient temperature, inadequate pressure, or too short a dwell time. This defect may lead to reduced seal strength or incomplete adhesion.



### 7. FOLDOVERS & PLEATS

**Image 7** Material folds or pleats trapped within the seal area. These folds can create channels or weak points, reducing seal integrity. They may occur at the edge or within the center of the seal due to improper handling or material tension.



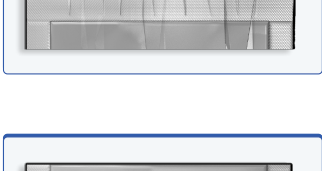
### 8. SEVERE WRINKLES

**Image 8** Pronounced creases, puckers, or distortions along the seal. Minor wrinkles are generally acceptable, but severe wrinkles may interfere with seal continuity. They often result from improper handling, uneven pressure, or packaging that is too small for its contents.



### 9. FOREIGN MATERIAL

**Image 9** Debris, product, or particulate matter embedded in the seal area. Foreign material can prevent full bonding and create pathways for contamination. Inspect seals from both top and side angles for best visibility.



## VISUAL INSPECTION

|                            |   |
|----------------------------|---|
| Sensor                     | Film Detection Sensor   |
| LED                        | 3 piece white LED. The LED has the brightness of 2000 to 2900mcd.<br>When we calculate with 2500mcd x 3 each, the brightness is 535 lumens x 3 =1600 lumens.<br>(The angle is 30 degrees) |
| User adjustable brightness | 1. 320 lumens<br>2. 576 lumens<br>3. 864 lumens<br>4. 1088 lumens<br>5. 1600 lumens   |

# van der stahl

SCIENTIFIC

Connecting medical device packaging to patient safety.

Call Customer Care: 800-550-3854