PHOENIX IMAGING Ltd.
19045 Farmington Road
Livonia, MI 48152
(248) 476 - 4200

MIB-50

Manual Inspection Booth

Compact Table-Top
Referee Level Inspection Environment

The MIB-50™ provides long-term use!

New light booth design provides a uniform lighting environment in a compact size. The design implements our patented parallel lighting technology that provides a large volume of uniform illumination for the inspection of a wide range of products. The same features that made our MIB-100™ so popular have been incorporated into a system that can sit on your desktop.

The design allows the user to change the intensity of the illumination electronically (potentiometer on the front of enclosure) or by physically altering the optical path length from the lamps to the center of the inspection volume. The intensity can be adjusted from 2000 to 7500 Lux (200 to 700 ft-cd). The inspection volume is an impressive 8 Liters (~500 cubic inches). The illumination system implements a pair of state-of-the-art power supplies that drive very effecient biax lamps at >50 KHz for flicker-free observation. The power supplies incorporate active feedback circuits that monitor the lamp output to maintain virtually constant flux over the life of the lamps. When the lamps degrade to the point where the preset illumination conditions can no longer be met, the operator interface will display a message. The customer can specify a number of lamp temperatures when ordering, the most common are 5000K and 6700K.

The user can select either the standard Black / White background or the optional 18% Graycard background for the inspection. The background cards can be easily exchanged or replaced if they become dirty or damaged. There is a nominal charge for replacement background cards.

Rendering of the MIB-50™ Manual Inspection Booth

The MIB-50™ offers a great deal functionality at a cost effective price. The system is heavy duty 14-gauge steel that is painted Artic White and will provide years of service. The lamps can be easily replaced by removing the background card to expose the lamp holding fixtures.

The MIB-50™ uses a PLC pacer to insure that inspection times are consistent. The operator interface allows the user to perform indexed or continuous inspection procedures. The operator interface permits the user to change the duration of inspections and the time delays between inspections. The system can also be used to count the number of Good and Bad containers for reconcilation of batch samples.

MIB-50 Background Information

Harmonization of in-process measurements, announced as a target area by the FDA, requires accurately transferable data. The high priority for this requirement stems from the USP affirmation of the manual clinical inspection at the injection site as the reference performance standard that must be matched or exceeded. This benchmark inspection is a single container inspection which uses manual manipulation to inspect the injectable dose for freedom from visible particle contamination. The USP affirmation imposes specific requirements on the validation of any alternative visible particle inspection system. The first requirement is an accurate assessment of the human inspection capability for visible contaminating particles. Following this initial determination, in accordance with cGMP, any alternative inspection method must be shown to be at least as effective in the elimination of particle contaminated containers from a batch of injectable products. Accurate measurement of the single container human inspection capability for visual contamination in parenteral products is an essential prerequisite. It supplies the benchmark performance against which any alternative inspection method or device is validated. To achieve replicable measurements from human performance, the conditions and action sequence of the inspection must be accurately defined and reproduced.

Knapp's 1980 PDA Journal Paper established the fact that the primary data describing the inspection for contaminating particles in injectable products is the probability of particle detection. This determination has, since first publication, been widely repeated and accepted. The direct use of the procedure described by Knapp requires multiple inspections of each container in a sampled set to determine the containers experimental rejection probability. Following this determination the containers are sorted into two groups. RZN, is the number of containers in the Reject Zone. The Reject Zone Effeciency is the average rejection probability of containers in the reject zone. The rejects in the Accept and Gray Zones do not contribute to product quality: they are an excess inspection cost. Visible particle rejects have been shown to be randomly distributed. No sampling assay can evaluate their effect. Any evaluation of their effect must be based on a 100% validated inspection.

A Calibration Curve relating particle size to particle detection probability is used to define the commencement of the visible contaminating particle region. Such a curve can be prepared with a set of durable NIST traceably sized microspheres. The rejection probability for each container in this set is evaluated within 95% confidence limits by trained inspectors using standard methodology in standard conditions. The particle size detected with a probability of 0.7071, approximately 95µm from initial data, defines the onset of the Reject Zone. From the data on hand a 50µm particle is detected with 10% probability and a 33µm particle is detected with 4% probability.

The Calibration Curve is determined with a single particle per container. The presence of multiple sub-visible particles can also be rejected with probability >0.7071 since each additional particle increases the rejection probablity of the container.

Conversion of this research procedure, which requires multiple inspections of a sample to determine the experimental rejection probability of each container in a sampled set, can now be converted to the measurement of the size of any contaminating particles in each container. This measurement can be approximated manually using a low power stereo microscope with a horizontal manipulator and a calibrated comparator. An alternative is the automated NIST traceable particle size measurements provided by the Phoenix Imaging ParticleScope™ Instrument.

The Phoenix Imaging Manual Inspection Booth (**MIB-50**) has been designed to provide an optimum test environment for critical visible particle inspections. Earlier standardization efforts were based on measured light intensity at a specific inspection point under a light source. The exponential variation of light intensity with distance from the light source limited the utility and replicability of such specifications. When manual inspection point variability is considered, a spatial volume in which the light intensity is maintained constant is required for practical inspection applications. A recently patented design achieves such a test environment. The variation of light intensity in a 8 liter volume was reduced to ± 10%, less than ½ the light intensity variation that is manually detectable. When inspections for contaminating particles are conducted within the controlled light intensity volume, data variability due to light intensity variation is eliminated.

The **Manual inspection Booth**, following the current recommendations of the Illumination Engineering Society, operates with 550 foot-candles in the light intensity stabilized inspection volume. NOTE: This illumination intensity is in the range recommended for critical inspections for long periods. The particular value has been selected to provide separation between sub-visible and visible contaminating particle measurements. This higher intensity also minimizes the effect of the reduction in contrast sensitivity that accompanies the aging process.

Other drawbacks associated with earlier generations of fluorescent lights used for inspection purposes have also been eliminated. These drawbacks include light intensity variation as the lamps aged and as the line voltage varied. The current sources employ phosphors with improved color rendering capability. The variation of light intensity as the line voltage varied has also been eliminated. The lamps are feedback stabilized to maintain set point light intensity until end-of-life. Predicted end-of-life is now 5 times longer than any available in 1980. Also eliminated was the inspector fatigue resulting from the stroboscopic images that result for any movement in a volume illuminated with fluorescent lamps excited with 60 cycle line voltage. [This effect is increased in regions in which 50 cycle line voltage is standard. The specially designed negative feedback stabilized 50 kHz fluorescent excitation source reduces the flicker intensity of the fluorescent light sources below human detection limits].

Inspector fatigue has been shown to adversely affect the accuracy of the inspection for visible contaminating particles by as much as 30%. The Phoenix Imaging Manual Inspection Booth has been designed so that the sequence of motions required from an inspector during the inspection are smoothly continuous. The large inspection volume will compensate for the various body dimensions of the inspector base. The inspection volume of the patented parallel lighting system allows for variation in product position with minimal intensity variations.

The minimum reach concept normalizes the onset of fatigue for all inspectors. It departs in an important way from the design concept of commercially available test booths in which inspectors of all physical dimensions are required to perform a sequence of motions between spatially identical positions. In presently available manual inspection stations the movements required during the inspection are the same for all inspectors. A consequence of this arbitrary requirement is that shorter inspectors must stretch between the required movement points and tall inspectors are cramped in performing the required movements. Both extremes impose additional fatigue elements.

The Phoenix Imaging MIB-50™ offers a wide range of controlled intensity in the inspection volume. The lamps are mounted on tracks that can vary their position relative to the center line of the inspection volume. The long optical path insures that the illumination volume is uniform. The power supplies can be adjusted electronically to fine tune the illumination intensity.

The primary adjustment makes the optical path equal to the center-point between the two vertically disposed inspection light sources. This adjustment places the nominal inspection point position at the center of the stabilized light volume. The illumination path is folded to bring the inspection volume closer to the inspector as illustrated by light yellow shaded area in Figure 1 below. Lamps positioned close to the the mirrors increase intensity in the inspection volume.

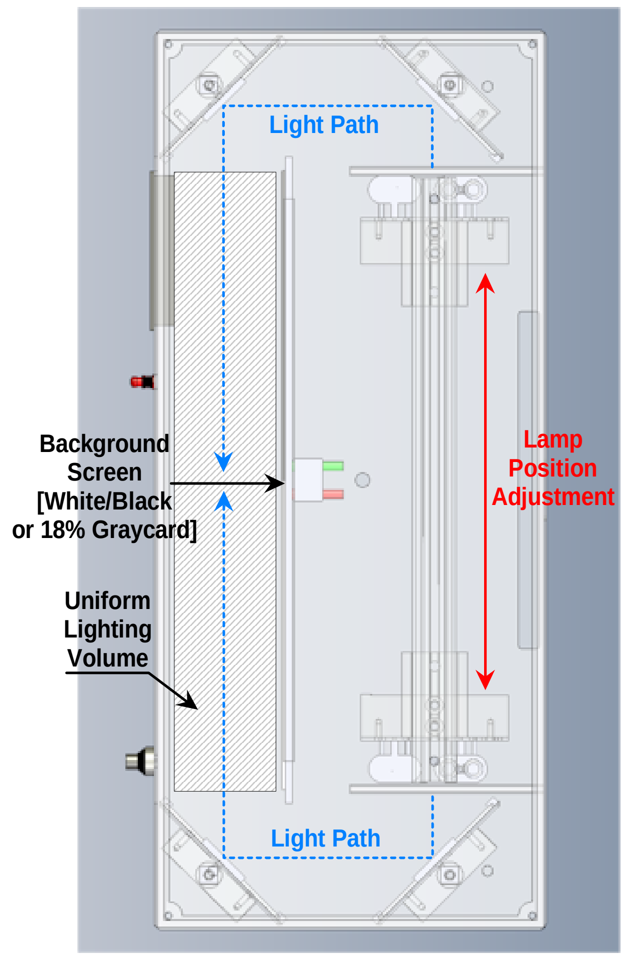

Figure 1 - MIB-50™ Illumination Path

This unique arrangement of placing the lighting sources behind the inspection background and folding the optical paths allows the overall depth of the inspection booth to be extremely shallow. This permits two inspection booths to be placed back-to-back on a normal width lab bench or table.

Patent No. 5,940176 granted and others patents pending.

RLPS™

Standard Calibration Set

A **Referee Level Particle Standard** Set (Level - I) is available for the training of inspectors and determination of the human visual inspector baseline using the MIB product. The Standard set provides samples seeded with a single particle of a specific size in stainless steel, glass, polystyrene, glass sards,nylon fiber. The samples are produced using customer specified containers, stoppers, seals and fill level. The standard particle sizes range from 50µm to 900µm in diameter. This sample set is designed to train and evaluate the detection capability of individual inspectors. Following the training mode, the Standard Calibration Set is used to generate a calibration curve. The calibration curve relates particle size to particle rejection probability. The use of the calibration curve provides an economically effective alternative to the re-determination of the rejection probability of each particle in the sampled container set. Without the calibration curve the rejection probability of each container in the sampled container set must be independently generated. This would entail multiple inspection of each container in the sample set to achieve 0.95% confidence results.

The RLPS™ can be extended to include fibers, floaters, metal shards and other materials found in the manufacturing process. The test solution is WFI with or without a preservative and is clear in appearance. The RLPS™ samples may also be prepared with color, turbidity or a specific viscosity to meet customer requirements. All particles are of known sizes and are NIST traceable.

Referee Level Particle Standards (RLPS™) with NIST Traceable Single Seed Particle per Container

MIB-50™ Specifications

Patent No. 5,940176 granted and others patents pending.

- Power supply: 115 VAC (60 Hz) NA or 200-230 VAC (50 Hz) EU (+/-10%), must specify voltage at time of order.
- Power Consumption: ~470 Watts
- Easy Lamp Replacement with documented intial lamp output values.
- Operating Humidity: 35-85% RH ,
- Operating Temperature: 0 to 40 degrees C
- Dimension & Weight: (Main Unit) 32.0" W x 14" D x 32.2" H, 155 lbs.
- Optional Foot Switch is attached with an umbilical cable to main enclosure, 6 ft. cable, 2 position, heavy duty, 8 lbs.

Standard MIB-50 Configuration (White / Black background)

PHOENIX IMAGING Ltd. 19045 Farmington Road
Livonia, Michigan USA 48152
Voice (248) 476 - 4200, Fax (248) 476 - 5705

Revision MIB-2013-2.3.6