

## **TEST REPORT**

# X-ray inspection of packaged catheters

#### **Problem description**

X-ray systems are ideal for inspection of packaged products and detection inside the package of a variety of possible foreign objects. The low energy X-ray technology is particularly suitable for inspection of packaged products and un packaged products of small thickness and / or low density (low atomic number composition). For packaged products, a great advantage is the ability to check the integrity of the packaging as well as positioning of product(s) inside the package. Also labels, sealing, etc can be assessed.

The InnospeXion HYMCIS X-ray scanners are built for in-line integration. The use of PLC as master of the HYMCIS control makes it easy to integrate a number of I/O functionalities, including alarms to different machinery along the processing line, sorting and grading auxiliary equipment, etc.

The products covered in this report are correctly and incorrectly packaged catheters wrapped in an aluminium foil outer bag- There are two types of defects, referred to as "jam" and "wide jam".



The products are inspected as packaged, as separate items.



Fig. 1 a and b. The products covered in this report, here marked "no jam" and "jam wide".



Fig. 3. The Award-winning InnospeXion HYMCIS X-ray system used in the assessment

The products with and without real defects have been inspected using the InnospeXion HYMCIS low-energy X-ray systems, at a speed between 13 and 18 m/min, and at an X-ray energy of less than 20 kV.

It is possible to inspect both product and the positioning of the individual catheters inside the plastic/aluminium foil wrapping, and also the location of the seal can be determined. As can be seen below, the sensitivity of the method is high. This implies, that it is possible to detect density and/or thickness variations down to a 0.005 mm.

See the discussion for further comments on the revelation of details.

The system has been operated in off-line (manual) mode, facilitating the acquisition of images. No specific sorting and/or automatic detection has been accomplished.

The X-ray system is ultra compact, and based on the newest and most effective X-ray detection technology. This involves high stability X-ray source, closed water cooling system, ultra high sensitivity detector with 0.1 mm resolution, PLC master configuration, etc. Maximum conveyor speed at optimal detection settings is about 0.5 m/s. In the present set-up, a detector width of plus 200 mm has been used.

Maximum sample height for the 15-40 kV system is 120 mm. Specific system details are available upon request.

#### **Results - comments**

Below are provided images of the products with and without defects, as described above. The X-ray images are compressed (reduced in size) and converted from 16-bit TIFF to 8-bit JPEG format, and the contrast has been optimized to display the grey level range of interest.



### A. Samples marked No Jam – series 1.

CAT1. No jam. Note that alignment (length-wise) is not ideal.



CAT2. No jam. Note almost perfect alignment



CAT3. No jam.



CAT4. Jam wide. Note a layer of catheters extend significantly from the others.



CAT5. Jam wide. Note a layer of catheters extend significantly from the others.



CAT6. Jam wide. Note that the layers of catheters vary in positioning.



CAT7. Jam wide. Large variation in the layer positioning



CAT8. Jam wide. Note a layer of catheters extend significantly from the others.



CAT9. Jam. Note a layer of catheters extend significantly from the others.



CAT10. Jam. Large variation in layer positioning.



CAT 11. Jam. Large variation in layer positioning



CAT 12. Jam. Catheter positioning variation



CAT 13. Jam. Catheters position shifted towards the left.



CAT 14. No Jam sample. No major variation, central positioning



CAT 15. No jam. Well positioned – marginal shift towards left. Fig. 4. (1-15) above: Products with and without defects.

#### Discussion

The results unveil the capability of the low X-ray energy technology to detect variations in the positioning of the catheters in the package.

With adequate image analysis tools, the analysis on-line may also facilitate detection of other types of defects including manufacturing irregularities, etc.

The detection of the position variation is relatively straightforward, however the analysis of the product integrity and other aspects of the packaging may require further efforts.

Note also that low energy X-rays stipulate much smaller radiation levels are intrinsically safer than conventional X-ray systems. They use less power and do not include any lead. Hygienic design requirements can be accommodated for, including water jet cleaning.

The InnospeXion low energy X-ray scanner is available in a number of tailored versions, specifically suited to specific tasks concerning overall interfacing, design of conveyor, conveyor attachment to existing production line and integrated software with triggering methods for ejection and sorting. The system is available as stand-alone units or as completely integrated PLC controlled systems operating in automatic, self-regulating mode.

InnospeXion technology has been implemented in different pharmaceutical applications, as well as numerous applications in food inspection, packaging, etc.

Please contact InnospeXion or your local representative for further information.

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