

## XRM for Pharmaceuticals and Medical Devices

- From R&D to Production, Inspection and Failure Analysis

# Nondestructive Testing at Your Fingertips

X-ray Microscopy (XRM) is one of the most powerful method for getting 3D insights products and devices. It is nondestructive requiring minimal to no sample preparation, eliminating the tedious task of embedding, coating, or thin slicing.

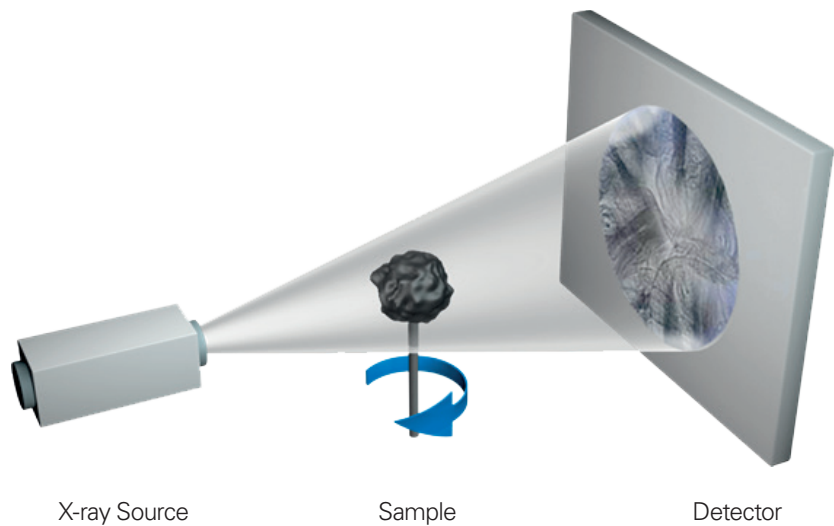
Bruker XRM combines high-resolution  $\mu$ CT technology with the advanced 3D.SUITE analysis software into a complete imaging solution supporting a wide range of applications.

From the R&D center to product development and quality control, Bruker XRM offers speed and ease-of-use, in small footprint, Plug'n-Analyze™ desktop solutions.

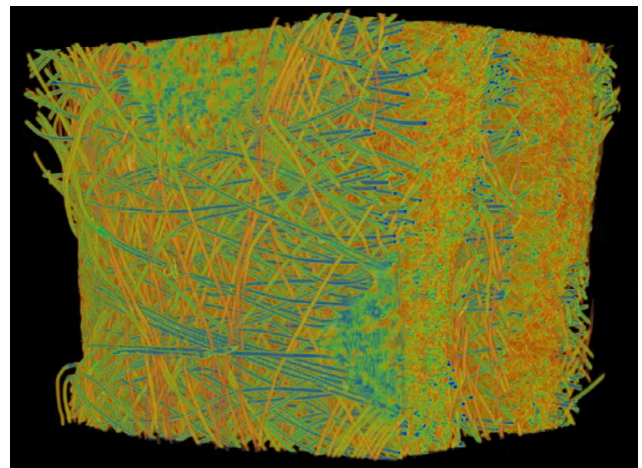
Intuitive design features such as the Genius-Mode™ for smart parameter selection, automated sample loading, and Push-Button-XRM™ scanning, allow high-throughput data collection with a touch of your finger.

## How it works

- 1 X-ray projections are taken as the sample rotates
- 2 Reconstruction software creates magnified 3D image of the object's internal structure
- 3 The internal structure is analyzed and modeled from the reconstructed data

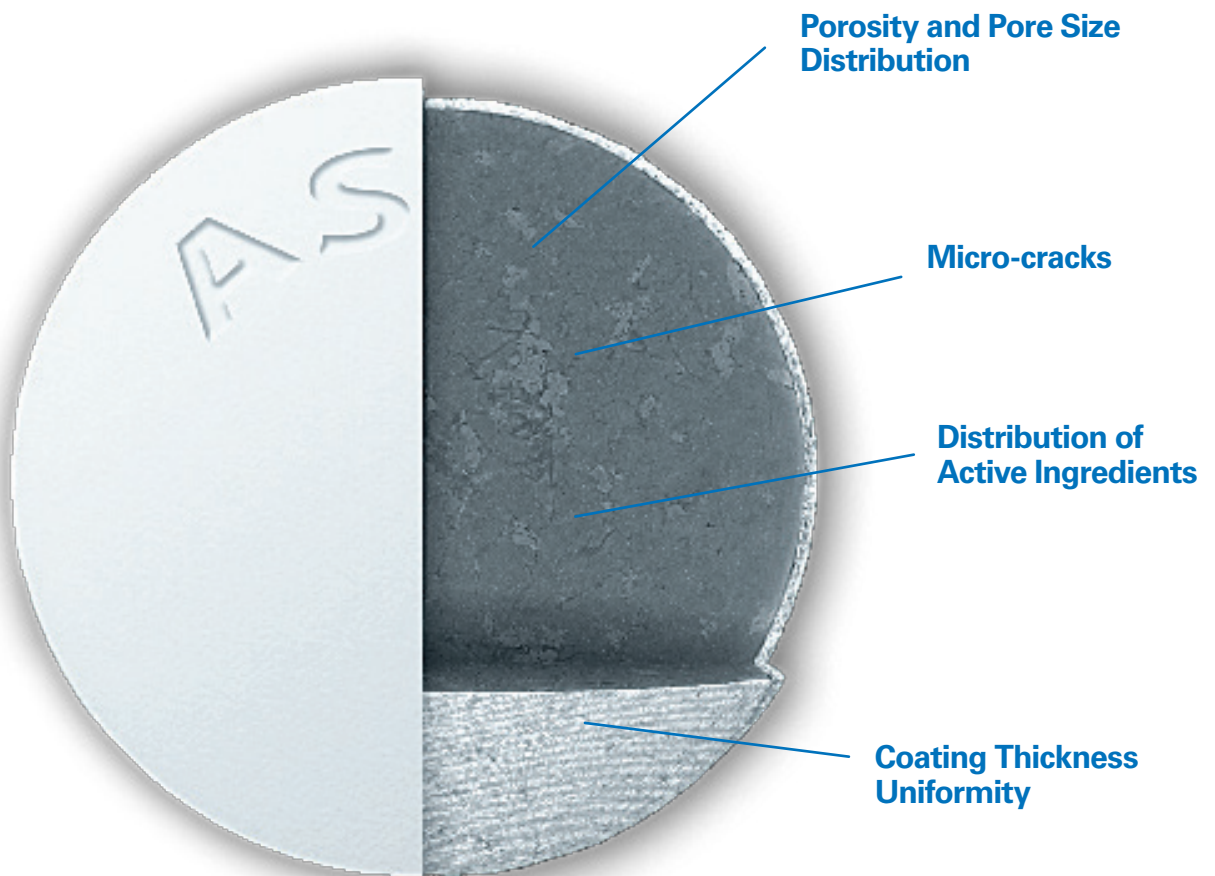
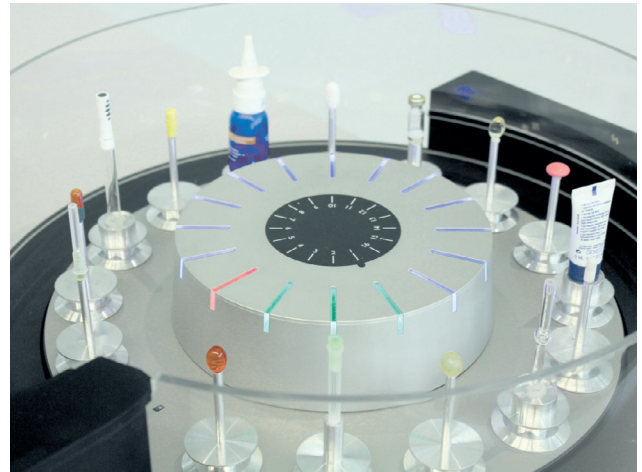


Additive Manufactured Ti Implant  
Analyzed with the SKYSCAN 1273



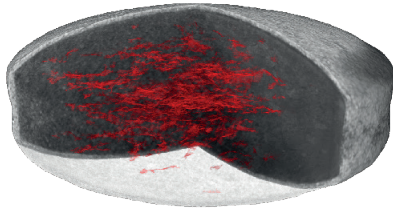
FFP-2 Face Mask  
Analyzed with the SKYSCAN 1272

# Find out what's inside



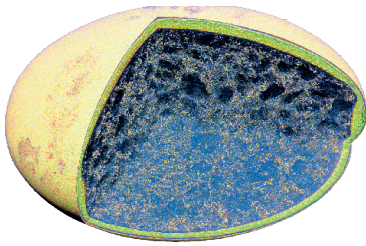
# Tablet Development & Ramp-up

## Pill Pores and Micro-cracks



Tablet with front corner virtually made transparent, visualizing internal cracks in red – Scanned with the SKYSCAN 1272

## Tablet Coatings



Coating analysis of a pharmaceutical tablet Scanned with the SKYSCAN 1272

## Save Time and Money

Development of a new product or process can be a time consuming and costly endeavor. XRM can accelerate time-to-market by providing immediate feedback on a tablet's internal structure, identifying discrepancies between the expected result and the actual outcome. XRM provides understanding to the key production factors such as compressive force, vacuum strength, mixing ratio, and much more.

**Tablet Compaction Density** Calculate percent porosity, pore size, and pore size distribution for whole tablets.

**Micro-cracking** Identify stress induced micro-cracks in tablets and multi-layer products.

**Distribution of Active Ingredients** Determine total volume and percent volume of active ingredients.

**In-situ Testing of Compression** Perform in-situ compression for dynamic testing of mechanical properties.

**Coating Thickness** Assess coating thickness uniformity.

# Packaging and Sealing

## Vial Top

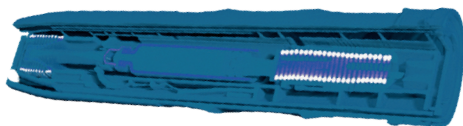


Volume render of a glass vial with rubber seal and aluminum cap Scanned with the SKYSCAN 1275

## Ensure Product Integrity

Package and seal integrity for injectable drugs can be just as critical as the drug formulation itself. Poor seals can allow moisture to enter the container, changing the stability of the drug and causing a decrease in efficacy. In worst-case scenarios, the patient can be exposed to contaminants or microbes resulting in a major illness or fatality. XRM can help recognize nonconforming packaging machines, discover supplier variation in components, and isolate problematic design issues.

## Autoinjector



Virtual cross section of an autoinjector Scanned with the SKYSCAN 1273

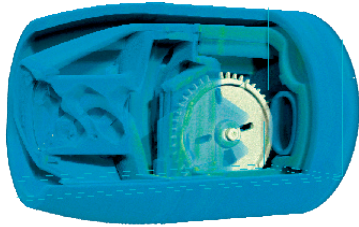
**Seal Integrity** Locate gaps in seal interfaces or other leakage pathways.

**Process Comparison** Compare changes in sealing and closure processes for production optimization.

**Component Variation** Measure dimensional variation of components from suppliers.

# Inspection

## Inhaler – Spray Nozzle



Inhaler head  
Scanned with the SKYSCAN 1275

## Cochlear implant



Cochlear implant  
Scanned with the SKYSCAN 1275

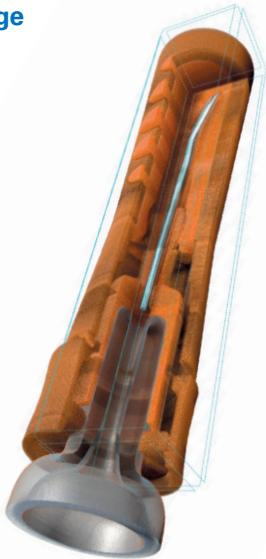
## Fast Nondestructive Inspection

When cutting your sample is not an option, XRM provides the solution. Designing and testing packaging assembly is a critical task to ensuring medical devices function properly when it matters most. Fast, nondestructive testing can you give confidence in your production process and the resulting product's performance.

<b>Component Alignment</b>	Visualize misalignment of internal components without disassembling the final packaging.
<b>Measurements</b>	Perform quantitative measurement on parts in 3D space.
<b>Performance Evaluation</b>	Conduct pre- and post-usage performance tests.

# Failure Analysis

## Syringe



Non-destructive analysis of a syringe needle  
Scanned with the SKYSCAN 1275

## Looking Without Cutting

When failures occur, it can not only be costly, it can be deadly. Pinpointing the root cause of the failure is essential to safeguarding against it happening again. Typical failure analysis can involve serial sectioning the part to observe the microstructure, but this destroys the evidence and may prevent further testing – sometimes even inducing unwanted damage such as micro-cracking, which can be misleading to the investigation. Because XRM does not require the destruction of the sample, it can be used in combination with other analysis techniques for a more comprehensive investigation into the failure mechanism.

<b>Nondestructive Investigation</b>	Obtain crucial insights as to where and how the failure occurred.
<b>Root Cause Analysis</b>	Compare both known “good” and “bad” samples for a side-by-side assessment.
<b>Digital Archiving</b>	Preserve essential information about the sample in a digital format.

# The Bruker Advantage

Bruker's development of the SKYSCAN XRM platform has been driven by over two decades of direct customer feedback, providing real solutions for the pharmaceutical industries, drug packaging, and medical device markets. Designed for intuitive use, high throughput, and low overhead, Bruker XRM systems deliver on your investment.



## Large Field of View with High Pixel Density

The bigger the data, the better. Many applications, such as porosity analysis on tablets or failure analysis of long syringes, require the whole product to be scanned. The use of large format detectors in the SKYSCAN systems means more data can be collected at higher resolution in a single scan. Further extending this capability, seamlessly integrated image stitching allows for an even larger field of view while maintaining a high spatial resolution for the best image quality and fastest scan time.

- SKYSCAN 1272: up to 14,450 x 14,450 pixels per slice
- SKYSCAN 1275: 96mm x 120mm capacity
- SKYSCAN 1273: 300 mm diam x 500 mm capacity

## Exceptional Speed

Scan in as little as 3 minutes. Bruker has reinvented the workflow of XRM scanning that has traditionally taken hours and reduced them to minutes. Highly efficient X-ray detectors with a flexible setup allow you to engineer your workflow to fit your schedule, not the other way around.

- SKYSCAN 1272: Best-Scan-Geometry
- SKYSCAN 1275: Push-Button-XRM™
- SKYSCAN 1273: High Capacity 3D XRM

## Automated Workflow

Fully Automatic. Simply load the 16-slot sample changer, select "AUTO" or a predefined protocol, and then let the scanner take care of the rest! Feel confident that your work is being done – all day, all night, or over the weekend – with system-generated email reports sent directly to your INBOX, including a link to access data remotely.

- LED Status lights
- Load new samples while live scanning
- SKYSCAN 1272: Genius Mode smart parameters

## Maintenance Free, Desktop XRM

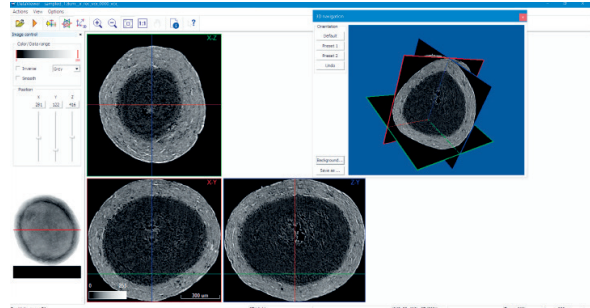
Powerful Imaging in a Small Space. Bruker's desktop scanners are designed with one of the smallest footprints on the market and require no additional infrastructural investment. Systems can be placed directly on a sturdy lab bench.

- Desktop systems plug into a standard wall outlet
- Require no water cooling or compressed air
- Scanners fit through standard doorways
- Require no additional radiation shielding

# Included 3D.SUITE Software Package

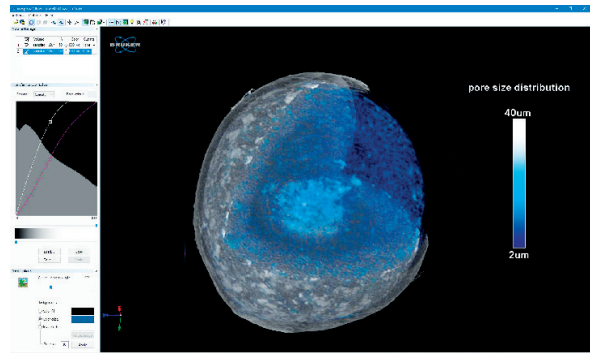
## DATAVIEWER – Slice-by-Slice Inspection of 3D Volumes and 2D/3D Image Registration

DATAVIEWER allows for inspection of the reconstructed volume using orthogonal slices in any direction. Datasets can be rotated, resliced, cropped in 3D, or co-registered to a reference dataset for convenient visualization and data management. Image registration enables the exact alignment of multiple scans of the same sample, even when acquired at different times.



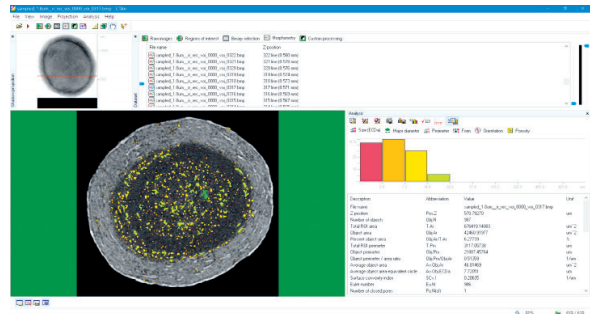
## CTVOX – Realistic Visualization by Volume Rendering

CTVOX is an easy-to-use, volume rendering visualization package that provides precise control of visualization parameters, ensuring a realistic representation of all types of samples. CTVOX offers intuitive manipulation of the point-of-view; virtual slicing through objects; and full control of light, shadow, and surface properties. Creating attractive cover images and movies that impress has never been so easy.



## CTAN – 2D/3D Image Analysis and Processing

The CTAN package includes an extensive range of tools for region-of-interest selection, image segmentation, and 3D measurements. Using the comprehensive library of embedded plugins or user customized protocols, quantifying complex microstructures such as porosity, thickness, orientation, and many other properties is easy. The analysis of large study sets can be simplified and automated by using the batch mode feature in CTAN.



## CTVOL – Built-in Surface Rendering

Surface models can be visualized in CTVOL, using a flexible 3D viewing environment. Volumes can be exported in STL format to allow 3D printing of the acquired scan data or for the further use in CAD and modeling programs.



All software is Windows 10 based and GLP compliant.

# Welcome to the BRUKER Family

Specifications SKYSCAN 1275	
<b>X-ray source</b>	20 – 100 kV, 10 W, < 5 µm spot size at 4 W
<b>X-ray detector</b>	3 MP (1944 x 1536 pixels) active pixel CMOS flat panel
<b>Maximum object size</b>	96 mm in diameter, 120 mm height
<b>Detail detectability</b>	4 µm at highest resolution
<b>Optional stages</b>	Cooling, heating, compression/tension
<b>Radiation safety</b>	< 1 µSv/h at 10 cm from the instrument surface. The operation of the device is subject to registration.

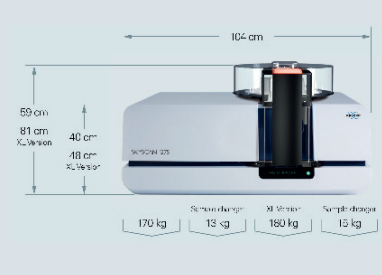


Diagram showing SKYSCAN 1275 dimensions: 104 cm width, 81 cm height, 40 cm depth, and 48 cm depth. Weights: 170 kg (main unit), 13 kg (Sample changer), 180 kg (X-ray source), 15 kg (Sample stage).

**SKYSCAN 1275**  
High-speed Desktop XRM with optional sample changer

Specifications SKYSCAN 1272	
<b>X-ray source</b>	20 – 100 kV, 10 W, < 5 µm spot size at 4 W
<b>X-ray detector</b>	16 MP or 11 MP, CCD fiber-optically coupled to scintillator
<b>Maximum object size</b>	75 mm in diameter, 70 mm height
<b>Detail detectability</b>	0.35 µm (16 Mp) or 0.45 µm (11 Mp) at highest resolution
<b>Optional stages</b>	Cooling, heating, compression/tension
<b>Radiation protection</b>	Dose rate < 1 µSv/h at 10 cm from the instrument surface on the instrument surface

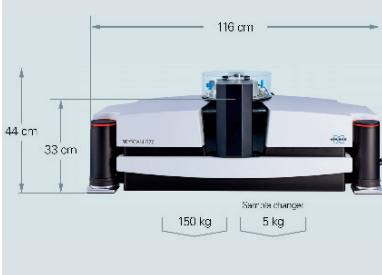


Diagram showing SKYSCAN 1272 dimensions: 116 cm width, 44 cm height, 33 cm depth. Weights: 150 kg (main unit), 5 kg (Sample changer).

**SKYSCAN 1272**  
High-Resolution Desktop XRM with optional sample changer

Specifications SKYSCAN 1273	
<b>X-ray source</b>	40-130 kV, 39 W, < 5 µm spot size at 4 W
<b>X-ray detector</b>	6 MP (3072 x 1944 pixels) active pixel CMOS flat panel
<b>Maximum object size</b>	300 mm in diameter, 500 mm height
<b>Detail detectability</b>	<3 µm at highest resolution
<b>Optional stages</b>	Cooling, heating, compression/tension
<b>Radiation protection</b>	< 1 µSv/h on the instrument surface. The operation of the device is subject to registration

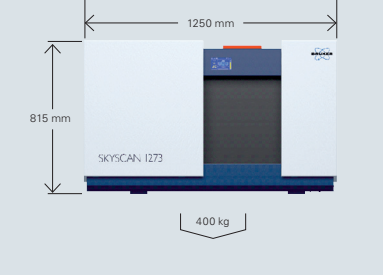


Diagram showing SKYSCAN 1273 dimensions: 1250 mm width, 815 mm height. Weight: 400 kg.

**SKYSCAN 1273**  
High Capacity Desktop XRM

Bruker is continually improving its products and reserves the right to change specifications without notice. Order No. DOC-B76-EXS005 © 2021 Bruker AXS.

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