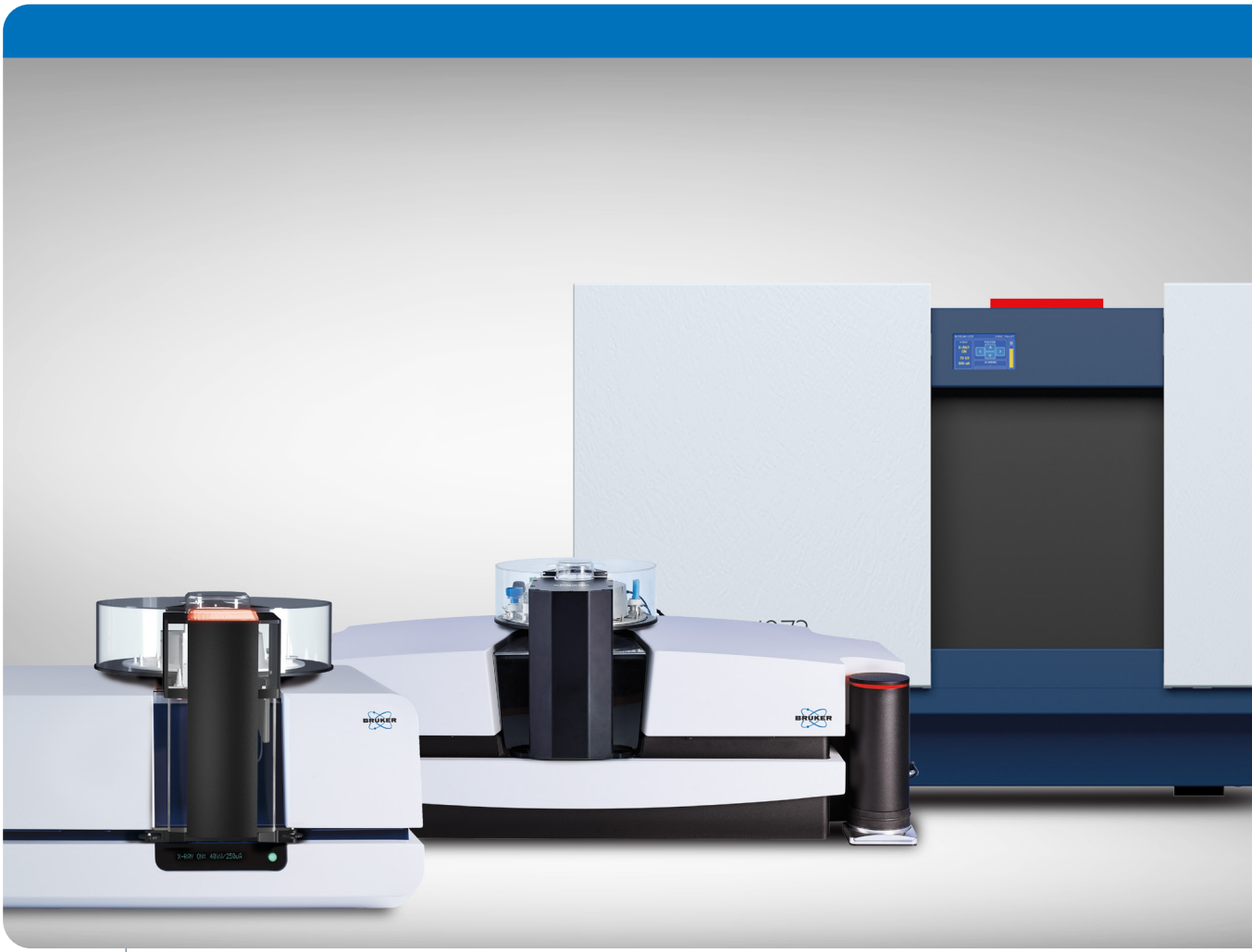


XRM for Pharmaceuticals and Medical Devices

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

Innovation with Integrity

X-ray Microscopy

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.

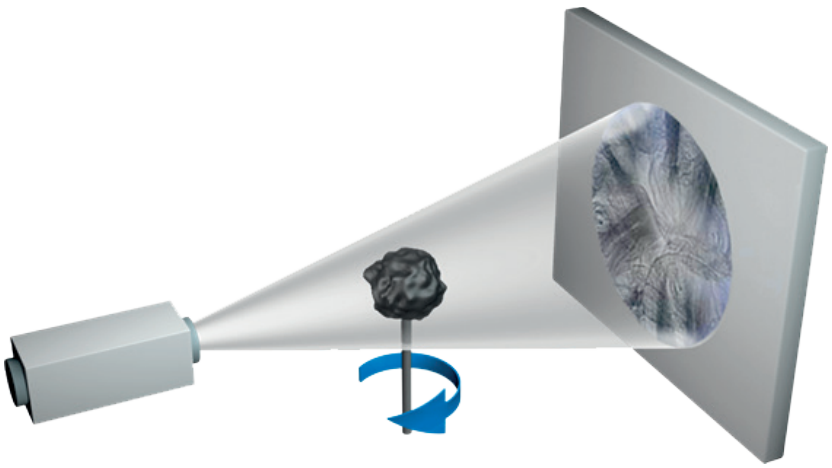
Bruker XRM combines high-resolution µCT technology with the advanced 3D.SUITE analysis software into a complete imaging solution supporting a wide range of applications.

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.

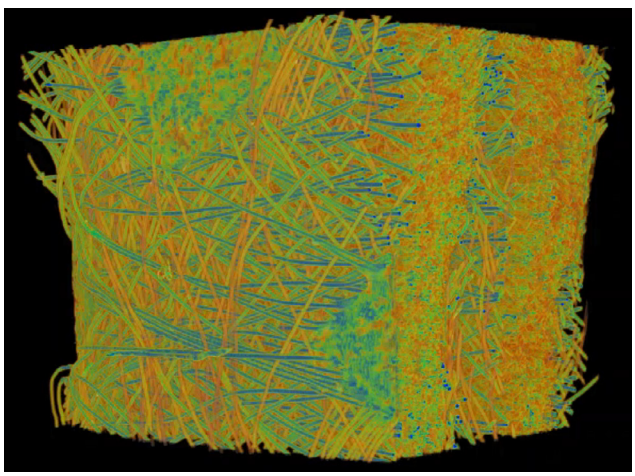
Intuitive design features such as the Genius-Mode™ for smart parameter selection, automated sample loading, and Push-Button-XRM™ scanning, allow high-throughput data collection with a touch of your finger.

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

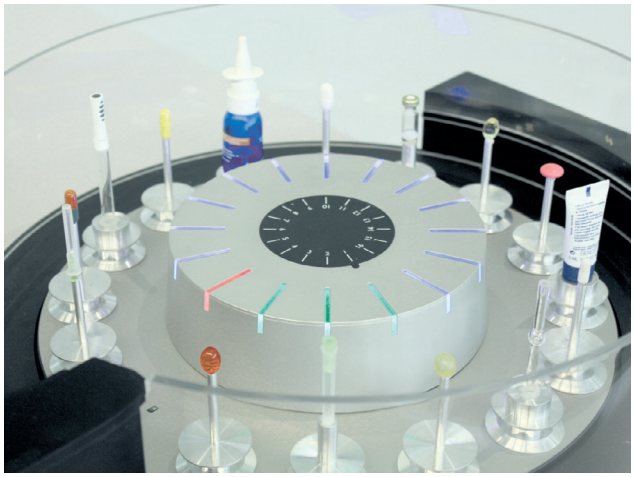


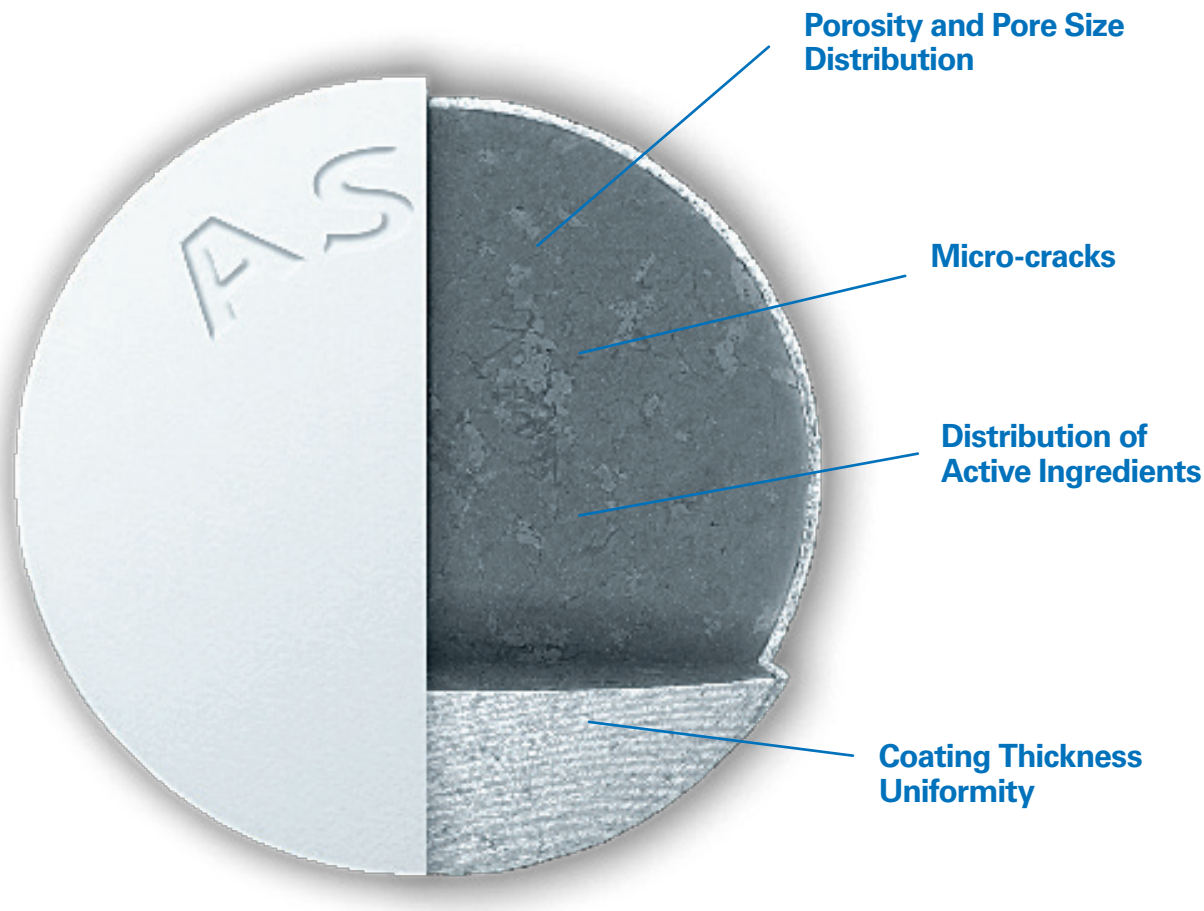
Additive Manufactured Ti Implant
Analyzed with the SKYSCAN 1273



FFP-2 Face Mask
Analyzed with the SKYSCAN 1272

Find out what's inside

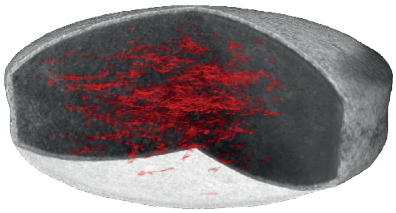




Pharmaceutical tablet (Aspirin)
SKYSCAN 1272

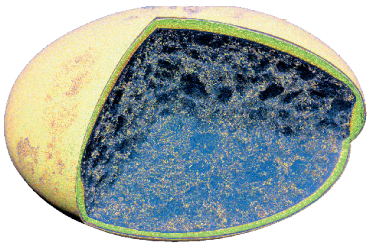
Tablet Development & Ramp-up

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.

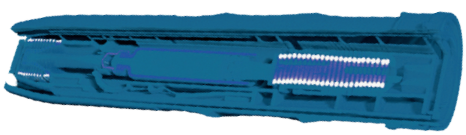
Tablet Compaction Density	Calculate percent porosity, pore size, and pore size distribution for whole tablets.
Micro-cracking	Identify stress induced micro-cracks in tablets and multi-layer products.
Distribution of Active Ingredients	Determine total volume and percent volume of active ingredients.
In-situ 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

Autoinjector



Virtual cross section of an autoinjector
Scanned with the SKYSCAN 1273

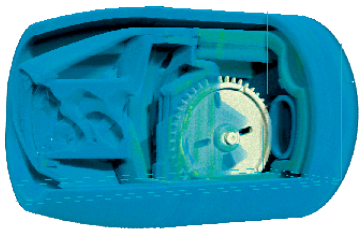
Ensure Product Integrity

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 efficancy. 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.

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.

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

Failure Analysis

Syringe

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

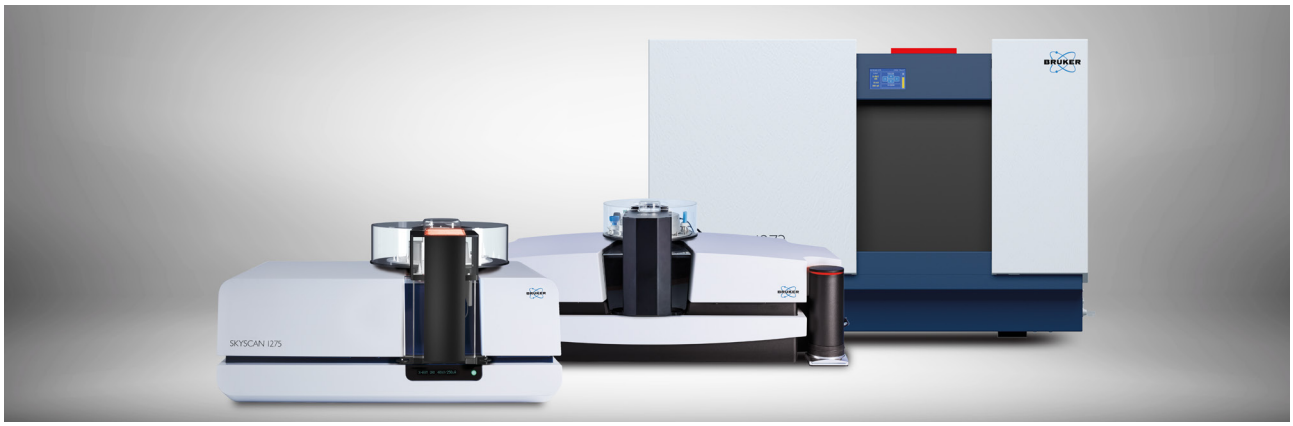
Looking Without Cutting

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.

Nondestructive Investigation	Obtain crucial insights as to where and how the failure occurred.
Root Cause Analysis	Compare both known "good" and "bad" samples for a side-by-side assessment.
Digital Archiving	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 XRMs

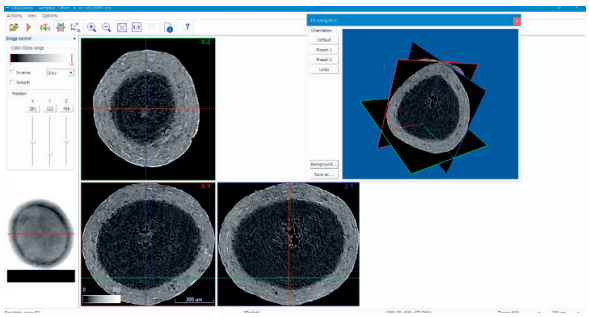
Powerful Imaging in a Small Space. Bruker's desktop scanners are designed with one of the smallest footprints on the market and require no additional infrastructural investment. Systems can be placed directly on a sturdy lab bench.

- 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

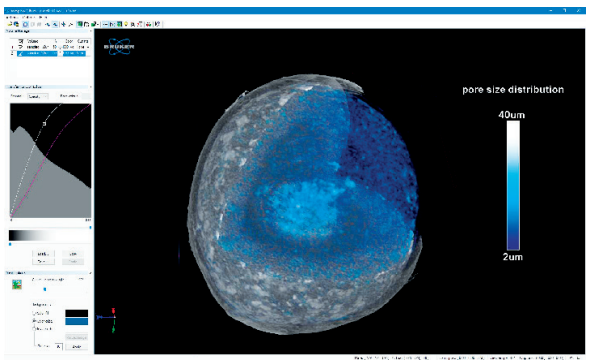
DATAVIEWER – Slice-by-Slice Inspection of 3D Volumes and 2D/3D Image Registration

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.



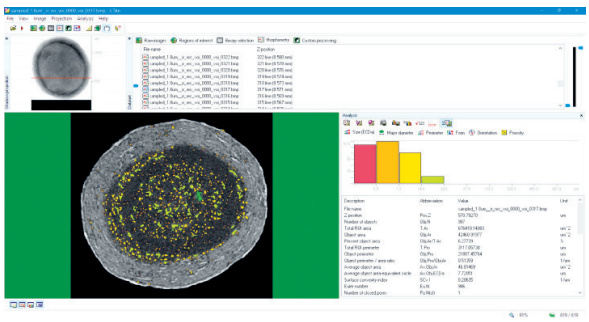
CTVOX – Realistic Visualization by Volume Rendering

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.



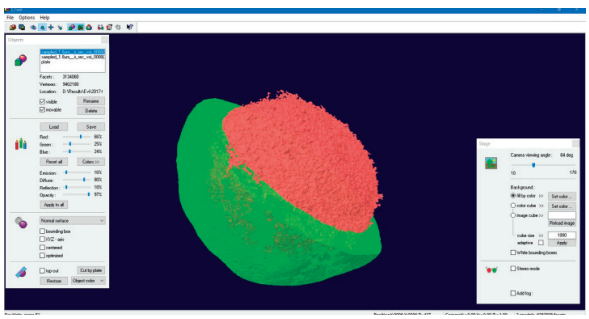
CTAN – 2D/3D Image Analysis and Processing

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

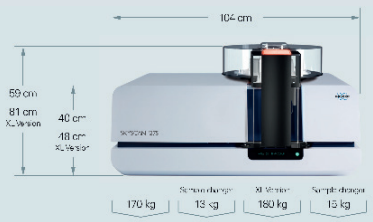
Surface models can be visualized in CTVOL, using a flexible 3D viewing environment. Volumes can be exported in STL format to allow 3D printing of the acquired scan data or for the further use in CAD and modeling programs.



All software is Windows 10 based and GLP compliant.

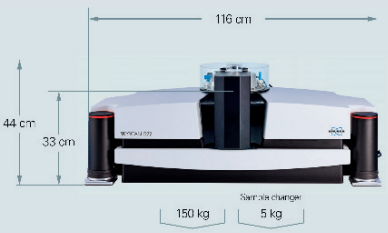
Welcome to the BRUKER Family

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



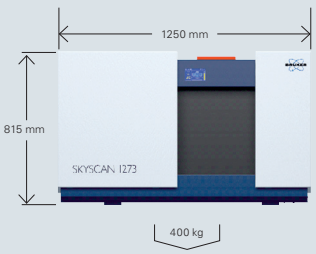
SKYSCAN 1275
High-speed Desktop XRM with optional sample changer

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



SKYSCAN 1272
High-Resolution Desktop XRM with optional sample changer

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



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-EXS016 © 2021 Bruker AXS.

Bruker
info.bmct@bruker.com

Worldwide offices
bruker.com/baxs-offices

Online information
bruker.com/microCT

www.bruker.com