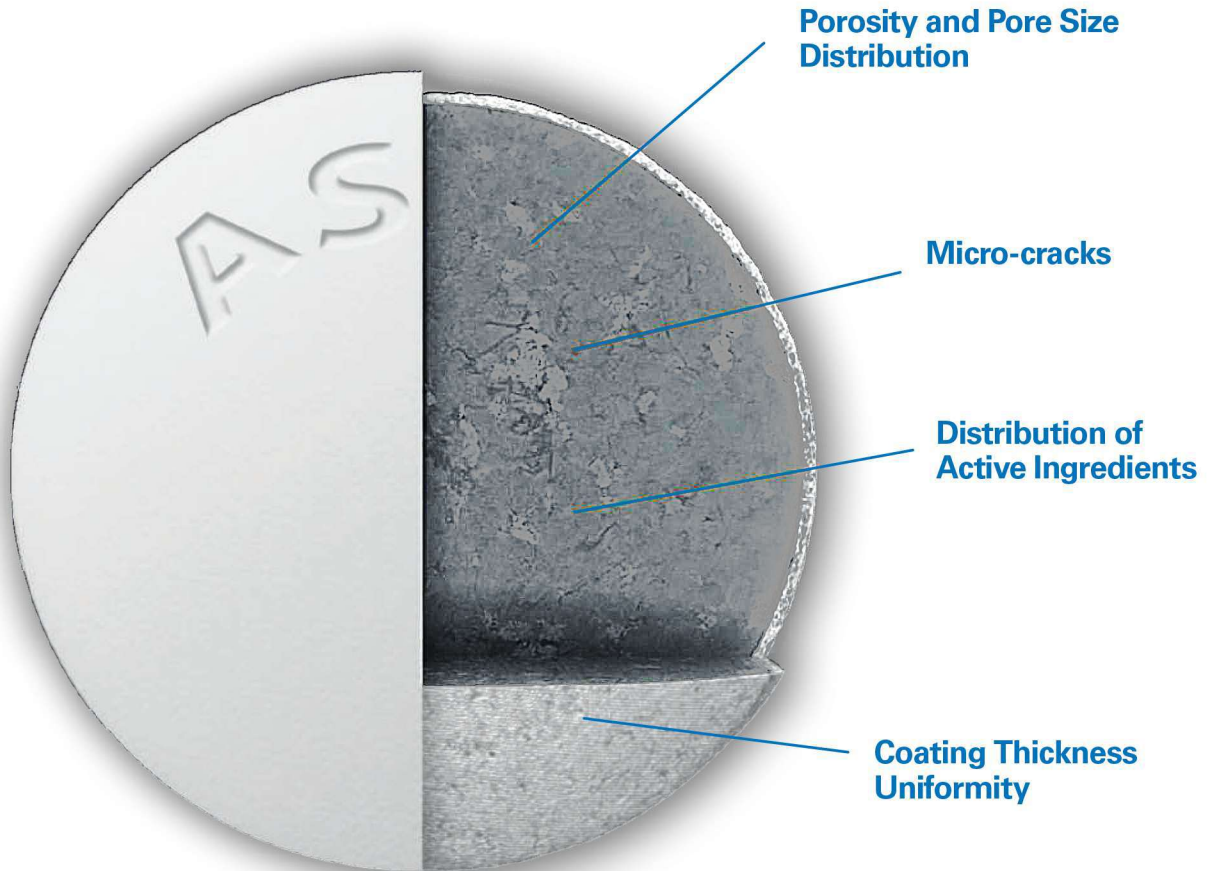
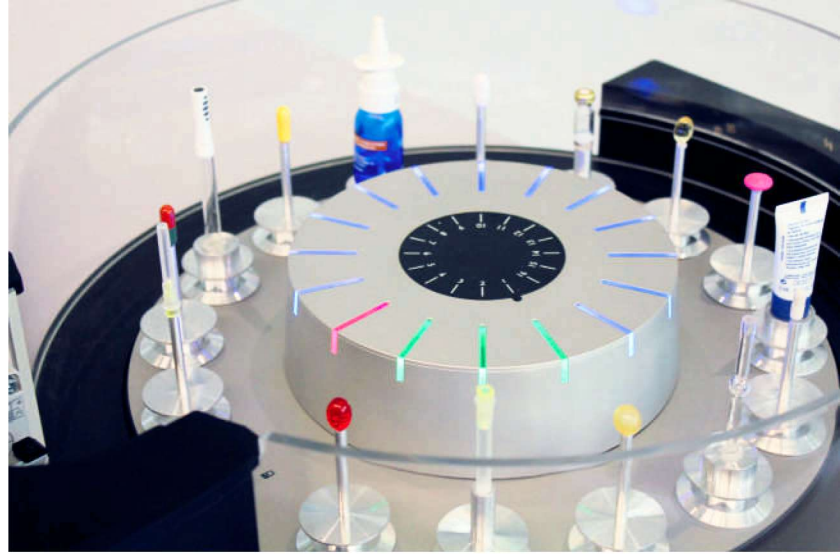




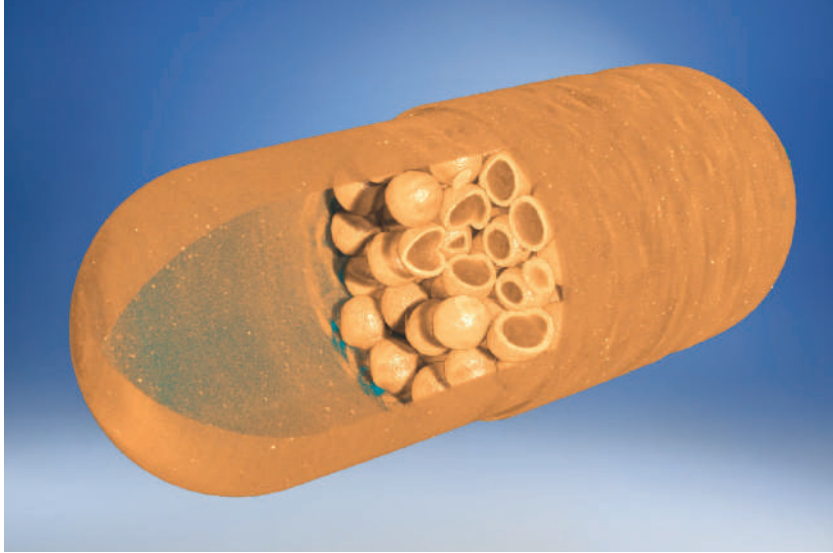
# $\mu$ CT for the Pharmaceutical Industries

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

# Find out What's Inside



Pharmaceutical tablet (Aspirin)  
SKYSCAN 1272 – Voxel size 3  $\mu\text{m}$



# Nondestructive Testing at Your Fingertips

X-ray micro-computed tomography ( $\mu$ CT) is one of the most powerful methods for getting 3D insights into products and devices. It is nondestructive, requiring minimal to no sample preparation, eliminating the tedious task of embedding, coating, or thin slicing.

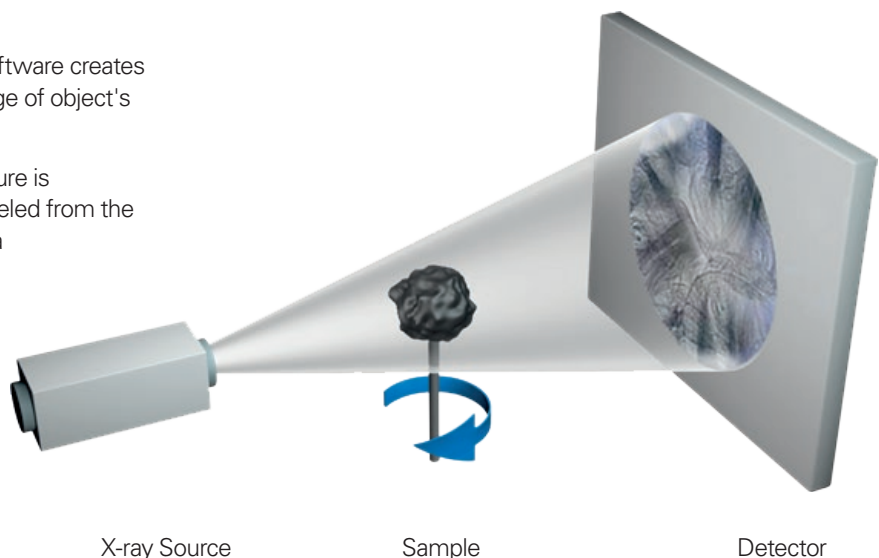
Bruker microCT, the pioneer of high-resolution  $\mu$ CT, has advanced this technology, from the R&D center to product development and

quality control, with unparalleled speed and ease-of-use, all 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-CT™ scanning, allow high-throughput data collection with a touch of your finger.

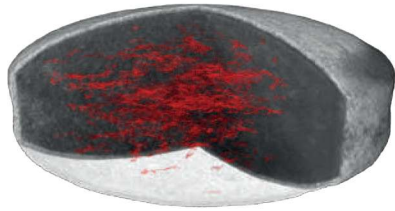
## How it works

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



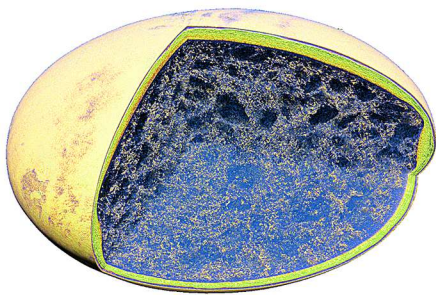
# Tablet Development & Ramp-up

## Pill Pores and Micro-cracks



Tablet with front corner virtually made transparent, visualizing internal cracks in red – SKYSCAN 1272 – Voxel size 3  $\mu\text{m}$

## Tablet Coatings



Coating analysis of a pharmaceutical tablet SKYSCAN 1272 – Voxel size 5  $\mu\text{m}$

## Save Time and Money

Development of a new product or process can be a time consuming and costly endeavor.  $\mu\text{CT}$  can accelerate time-to-market by providing immediate feedback on a product's internal structure, identifying discrepancies between the expected result and the actual outcome.  $\mu\text{CT}$  provides insight into key factors such as compressive force, vacuum strength, mixing ratio, and much more.

<b>Tablet Compaction Density</b>	Calculate percent porosity, pore size, and pore size distribution for whole tablets.
<b>Micro-cracking</b>	Identify stress induced micro-cracks in tablets and bilayer products.
<b>Distribution of Active Ingredients</b>	Determine total volume and percent volume of active ingredients.
<b>In-situ Testing of Compression</b>	Perform in-situ compression for dynamic testing of mechanical properties.
<b>Coating Thickness</b>	Assess coating thickness uniformity.

# Packaging and Sealing

## Vial Top



Volume render of a glass vial with rubber seal and aluminum cap SKYSCAN 1275 – Voxel size 10  $\mu\text{m}$

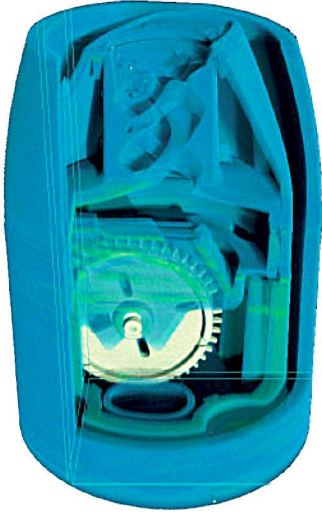
## Ensure Product Integrity

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.  $\mu\text{CT}$  can help recognize nonconforming packaging machines, discover supplier variation in components, and isolate problematic design issues.

<b>Seal Integrity</b>	Locate gaps in seal interfaces or other leakage pathways.
<b>Process Comparison</b>	Compare changes in sealing and closure processes for production optimization.
<b>Component Variation</b>	Measure dimensional variation of components from suppliers.

# Inspection

## Inhaler – Spray Nozzle



Inhaler head  
SKYSCAN 1275 – Voxel size 25  $\mu\text{m}$

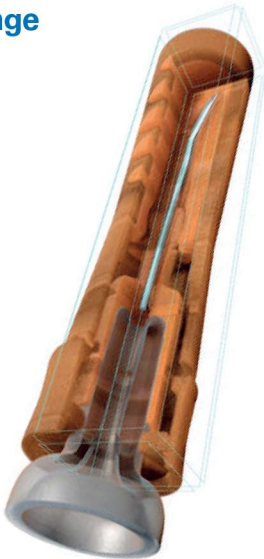
## Fast Nondestructive Inspection

When cutting your sample is not an option,  $\mu\text{CT}$  provides the solution. Designing and testing packaging assembly is a critical task to ensuring medicine can be delivered properly to the patient when it matters. 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  
SKYSCAN 1275 – Voxel size 10  $\mu\text{m}$

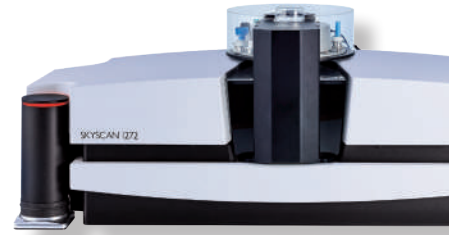
## Looking Without Cutting

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  $\mu\text{CT}$  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 microCT Advantage

Bruker microCT's development of the SKYSCAN  $\mu$ CT 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, SKYSCAN  $\mu$ CT scanners 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 dimensional measurement 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 pixel reconstruction in a single slice
- SKYSCAN 1275: 96mm x 120mm field of view in a desktop unit
- Seamless imaging stitching

## Exceptional Speed

Scan in as little as 3 minutes. Bruker microCT has reinvented the workflow of  $\mu$ CT 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-CT™
- World's fastest, patented (licensed) reconstruction algorithm InstaRecon®

## 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 indicate "Scanning", "Pending", or "Done" for each sample changer position
- Load new samples while live scanning is being performed
- SKYSCAN 1272: Genius Mode smart parameter selection

## Maintenance Free, Desktop $\mu$ CTs

in this and many other places starting every word from capital letter looks inappropriate. Bruker microCT'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 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.

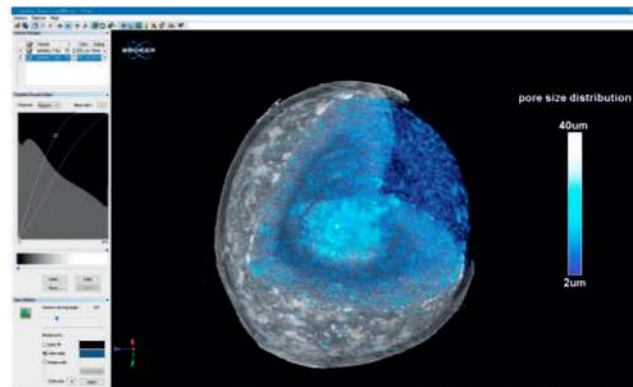
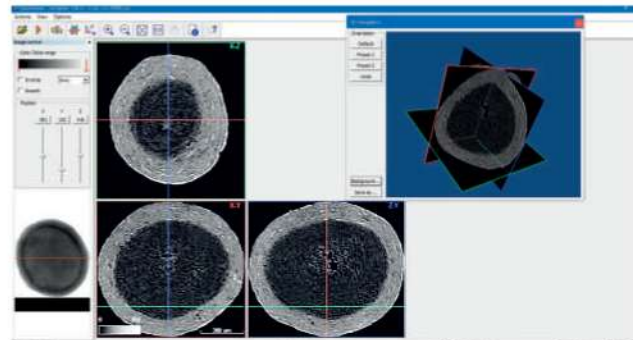
## CTAN – 2D/3D Image Analysis and Processing

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.

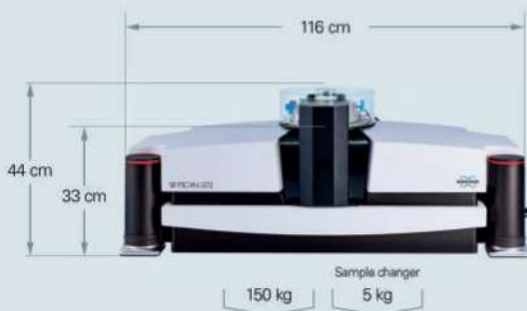
All software is Windows 10 based and GLP compliant.



# Welcome to the BRUKER Family

## Specifications SKYSCAN 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, 14-bit cooled CCD fiber-optically coupled to scintillator
<b>Maximum object size</b>	75 mm in diameter using offset scan (27 mm in fast single scan)
<b>Detail detectability</b>	0.35 µm (16 Mp) or 0.45 µm (11 Mp) at highest resolution
<b>Reconstruction</b>	Hierarchical (InstaRecon <sup>®</sup> ) and multithreaded CPU/GPU 3D reconstruction)
<b>Optional stages</b>	Cooling, heating, compression/ tension
<b>Radiation safety</b>	< 1 µSv/h



SKYSCAN 1272 High-Resolution Desktop µCT  
with optional sample changer

## 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>Reconstruction</b>	GPU-accelerated reconstruction
<b>Optional stages</b>	Micro-positioning, cooling, heating, compression/tension
<b>Radiation safety</b>	< 1 µSv/h



SKYSCAN 1275 High-speed Desktop µCT  
with optional sample changer

Bruker microCT is continually improving its products and reserves the right to change specifications without notice.  
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