

## Mechanical Testing of Medical Gloves with ASTM D412 and ISO 37

No. MT-2303

### ■ Introduction

Single use gloves are essential personal protective equipment in the medical, chemical, and food industry to prevent exposure to harmful contaminants and substances. They are made of a variety of polymers such as nitrile, latex, and polyvinyl chloride. There are many test standards that dictate testing the mechanical properties of these gloves to ensure they have sufficient strength, elongation, and tear resistance to withstand the forces of use without failing and risking unwanted exposure.

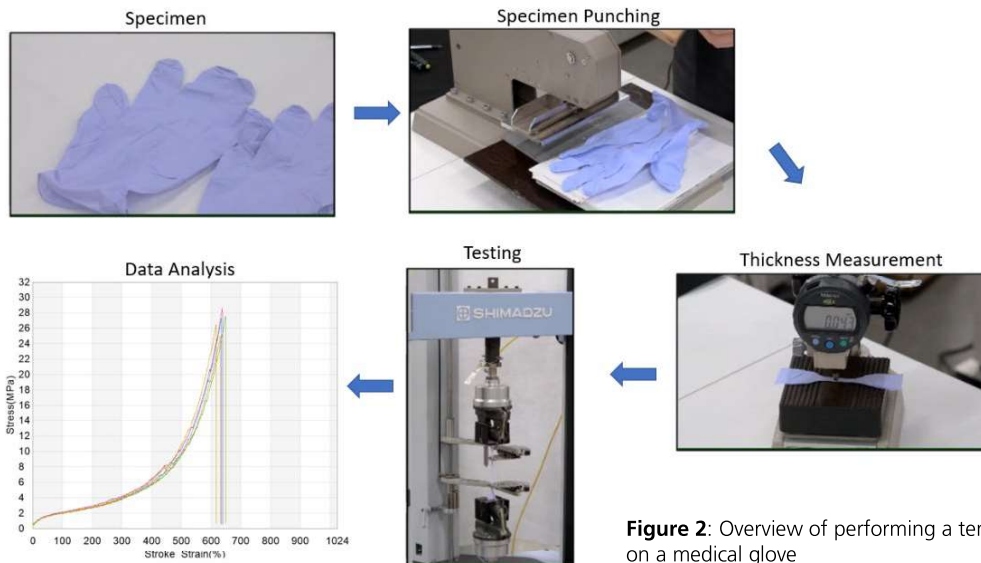
### ■ Standards Relating to Mechanical Strength of Medical Gloves

The two main standards defining mechanical test procedures are ASTM D412 and ISO 37, which both specify preparing either a dumbbell or o-ring specimen of rubber and performing tensile tests. Though very similar, the standards are not identical. They provide different options regarding specimen dimensions, test speed, and sample preparation. Both methods can be performed with a Shimadzu Universal Testing Machine.



**Figure 1:** Shimadzu AGS-X Precision Universal Testing Machine with a DSES-1000 long-travel contact extensometer and TRVIEW-X non-contact extensometer

Strength Test Standards	Related Standards
ASTM D412	<ul style="list-style-type: none"> <li>• ASTM D3577 for rubber surgical gloves</li> <li>• ASTM D3478 for rubber examination gloves</li> <li>• ASTM D5250 for PVC gloves</li> <li>• ASTM D6319 for nitrile examination gloves</li> </ul>
ISO 37	<ul style="list-style-type: none"> <li>• ISO 10282 for single-use rubber surgical gloves</li> <li>• ISO 11193-1, -2, and -3 for single use rubber and PVC gloves for dentistry and examination</li> <li>• ISO 23529 for rubber - general procedures for preparing and conditioning test piece for physical test methods</li> </ul>



**Figure 2:** Overview of performing a tensile test on a medical glove

■ **Measurement Systems and Conditions**

*Extensometer:* Due to the high elongation and thinness of the sample, a specialized extensometer is required.

Shimadzu’s non-contact TRViewX Video Extensometer (with 500 or 800 mm field-of-view) and a DSES-1000 long-travel contact extensometer can both be used. Both options have variable gauge length in the middle of the parallel part of the test piece using an adhesive gauge marker.

*Grips:* Pneumatic flat grips with rubber-coated or flat grips are recommended to prevent the samples from slipping out of the grip faces as they thin, but other forms of mechanical self-tightening grips such as pantograph or roller grips can also be used.

*Test Frame:* Shimadzu’s AGS-X and AGX-V are both suitable instruments for performing medical glove testing. A dual column system with the ability to achieve the high elongations and a suitable low-force load cell to ensure accurate measurement results is suggested.

Measurement Example

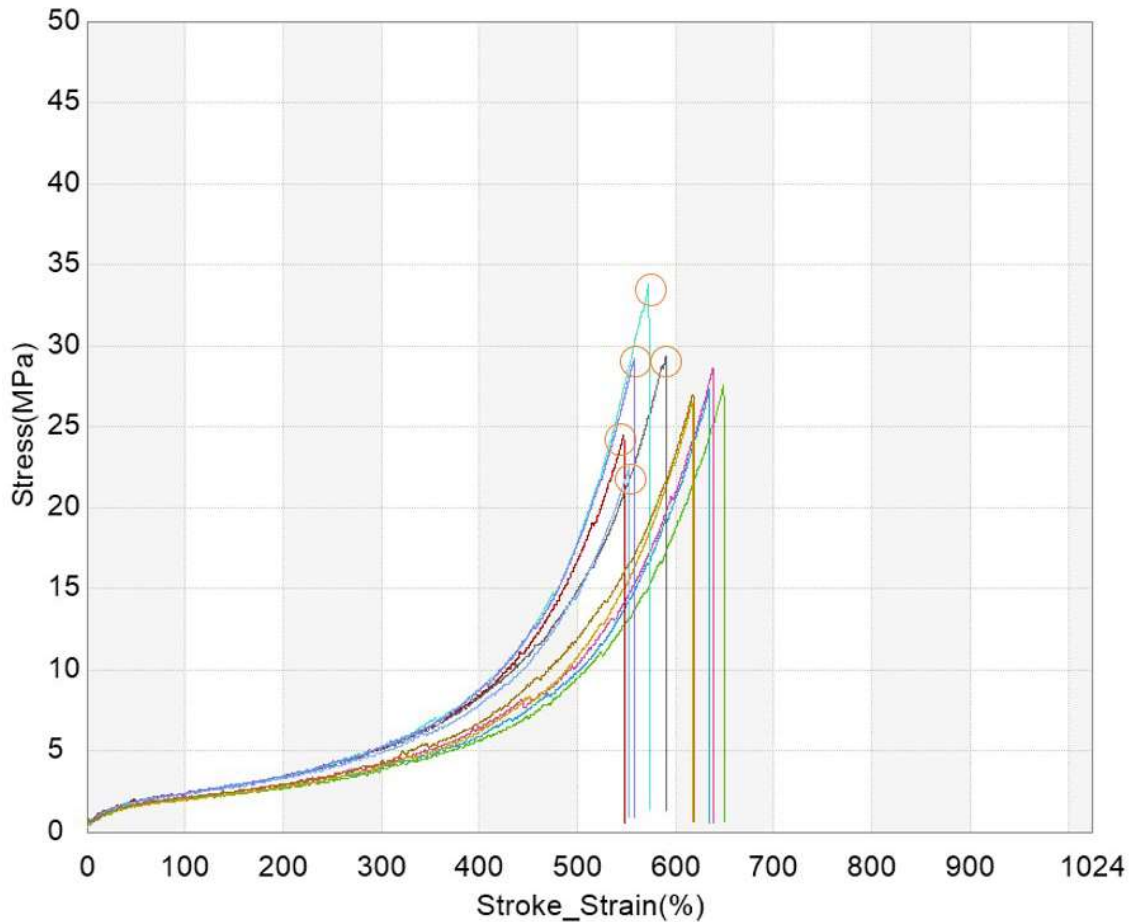


Figure 3: Tensile Test Results from 2 Batches of Nitrile Rubber Gloves

Table 1: Specification of Test System and Conditions

<b>Instrument</b>	AGS-X 100 N
<b>Grip</b>	Pneumatic Flat Grips
<b>Extensometer</b>	DSES-1000 with 1 inch (25.4 mm) gauge block
<b>Software</b>	TrapeziumX-V
<b>Test Speed</b>	500 mm/min
<b>Data Processing</b>	Max Stress, Break Elongation, Stress at Given Elongation, Elongation at Given Strain, Yield Point
<b>Specimen Materials</b>	Nitrile Rubber
<b>Specimen Thickness</b>	3.5 mil (9 mm)

Five specimens of ASTM D412 compliant dumbbell specimens were prepared from gloves made from two different batches of nitrile rubber: Batch 1 was freshly prepared, and Batch 2 was older and had been stored improperly. Samples were punched out of the gloves with a sample ASTM D412 sample die. Thicknesses were measured with a thickness dial gauge. Figure 3 shows the measurement results on a stress-strain curve, with red circles around the break points of Batch 2 samples. The samples tested from Batch 2 show noticeably lower elongation at break and appear to have more variability in strength results.

**Table 2:** Test Results

Specimen	Strength (MPa)	Elongation at Break (%)
Batch 1 Average	27.37	558.2
Batch 2 Average	27.87	618.3

#### ■ Data Management

Manufacturing quality assurance testing of rubber gloves creates a large amount of data results. Shimadzu's testing machine software, LabSolutions AG, is compatible with a stand-alone or network LabSolutions data integrity package that enables database storage, user management, operation logs, and electronic signatures to manage project data and conform to FDA 21 CFR Part II data integrity requirements more easily.

#### ■ Conclusions

In conclusion, Shimadzu precision universal test machines provide excellent results when testing the tensile properties of medical glove materials. Several accessories are available for convenient and accurate measurement of sample elongation and tensile strength.



**SHIMADZU Corporation**  
www.shimadzu.com/an/

**SHIMADZU SCIENTIFIC INSTRUMENTS**  
7102 Riverwood Drive, Columbia, MD 21046, USA  
Phone: 800-477-1227/410-381-1227, Fax: 410-381-1222  
URL: www.ShimadzuMaterialScience.com

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