4Sight® – See it from every angle

A-Scan, B-Scan, UBM and Pachymeter in one platform

Your workflow should be as easy as possible, with as little steps as possible. We understand the daily demands of busy clinics like yours. The 4Sight console is designed to meet these needs by incorporating four different diagnostic probes into one seamless experience: A-Scan, B-Scan, UBM, and Pachymeter. Check out the benefits you'll receive from using the 4Sight below.

One solution for ophthalmic ultrasound imaging

- Proprietary signal processing
- High-quality imaging and testing at an affordable price
- Easy experience in switching between probes
- Choose whichever probe combination works for you
- Industry-leading clinical accuracy you can rely on
- Warranty and service programs
- We're available for live help and dependable support for as long as you have the 4Sight

Focused on your efficiency

- Single point of use technology for all ophthalmic diagnostic imaging
- Intuitive user interface for a rapid and smooth learning curve
- Easily transfer patient data between modalities to help decrease exam time
- Compatible with DICOM℠

(See reverse side for more info)

Keeler
Focused on you

keeler.co.uk • Clewer Hill Road, Windsor, SL4 4AA
United Kingdom • Phone: +44 1753 857177

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A Halma company

4Sight purchasing options

You can get the 4Sight with any mix of probes. When ordering, you will use the console part number shown below, and then choose your probes.

Console: #24-8000

Choose any one, two, three, or all four of the below probes to go with your 4Sight console.

- **A-Scan: #24-8000A**
- **B-Scan: #24-8000B**
- **Pachymeter: #24-8000P**
- **UBM: #24-8000U**

Questions? Call us at +44 1753 857177 and we'll be happy to assist you.

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04282022 REV A

EC Declaration of Conformity for Medical Device

Doc. No:	DOC-24-8000	Rev. No.:	02	Page 1 of 1	Effective Date:	05/09/2022

Manufacturer: Accutome, Inc.
(also trading as Accutome Ultrasound, Inc.)

Address: 3222 Phoenixville Pike
Malvern, PA 19355
Tel: 610-889-0200
Fax: 610-889-3233

Authorized Representative: Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (31) 70 345 8570
Fax: (31) 70 346 7299

General Applicable Directive:
- Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices
- (MDD 93/42/EEC), as amended by 2007/47/EC.
- Council Directive 2011/65/EU concerning Restriction of Hazardous Substances

Harmonized Standards:
- EN IEC 60601-1
- EN IEC 60601-1-2
- EN 60601-2-37
- EN ISO 10993
- EN ISO 14971
- IEC 1157
- EN IEC 62304

Device Name: 4Sight

Device Classification: IIa (MDD Annex IX Rule 10)

Route to Compliance: Annex VII coupled with Annex V

EC Certificate: No. CE 72349
Notified Body Number 2797

Description	Part Number
4Sight	**24-8000**

Probes:

Description	Part Number
A-Scan Probe	24-8000A
Pachymeter Probe	24-8000P
B-Scan Probe	24-8000B
UBM Probe	24-8000U

Accutome, Inc. hereby declares under our sole responsibility that the Accutome product meets the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

Signature: 

Date: 9 May 2022

Full Name: Claudia Hill

Position: Quality & Regulatory Manager

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Accutome, Inc.
DBA Keeler USA
3222 Phoenixville Pike
Malvern
Pennsylvania
19355
USA

Holds Certificate Number: FM 701460

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The distribution of ophthalmic knives. The distribution and service of ophthalmic instruments. The design, development, manufacture, distribution and service of ophthalmic ultrasound diagnostic devices and handheld applanation tonometers.

Previous certificate expires on 2023-02-04
Recertification audit ended 2023-01-04

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2003-02-13
Latest Revision Date: 2023-02-07

Effective Date: 2023-02-07
Expiry Date: 2026-02-04

...making excellence a habit.™