3Shape company profile

3Shape is a Danish company specialized in the development of integrated 3D solutions for industrial and healthcare applications. We market our solutions worldwide.

Areas of expertise

**3D scanning:** 3Shape has developed 3D scanners for the creation of accurate and functional 3D models from real objects, such as ear impressions. Our 3D scanners offer superior performance in terms of scanning speed, accuracy, and ease of use.

**3D processing:** 3Shape offers extensive software packages for the processing of 3D models. With these processing packages, our users can for example transform simple 3D ear impression models into fully functional hearing aid shells ready to be manufactured automatically on computer-controlled equipment. Other applications of our processing software include statistical analysis, measurements and quality control.

**3D databases:** our database tools allow the users to organize and easily retrieve 3D models online. 3D models can be categorized, e.g. by size or shape, and stored with their measures, statistical analyses, and processing history.

**System integration software:** 3Shape delivers software to integrate our solution modules into seamless production systems that interface with third-party production equipment, ERP systems and other CAD/CAM software.

All our solutions run on standard Windows™-based PCs and offer an intuitive user interface. These solutions can be used by anyone with basic computer literacy.

Underlying our solutions is a unique combination of advanced algorithms and hardware design. 3Shape has several international patents pending on its technology and applications.

3Shape's outstanding development team has a strong expertise in image analysis, computer graphics, advanced mathematics and process reengineering. Our expanding team currently counts 15 developers, five of which hold PhDs in image analysis and mathematical modeling.

Example of application: customized hearing aids production

By combining the above areas of expertise, 3Shape has developed an integrated 3D production system for hearing aid manufacturers. The system enables our customers to 3D scan individual ear impressions, transform the 3D models into functional hearing aid shells and create these customized shells on 3D printing equipment. Tangible benefits from implementing the system range from savings in manufacturing costs to improvements in product quality.
3Shape Ear Impression 3D Scanner

3Shape's 3D scanner is the point of entry of the automated hearing aid production system. It creates accurate digital 3D copies of the patient's ear impression in a few minutes. The 3D models can be used directly in 3Shape's modeling software, ShellDesigner™. The modeled shells are manufactured on 3D printers.

Our scanning system runs on standard Windows™-based PCs (included with the system) and requires no specific technical expertise to be operated.

Technology

The scanning of an ear impression is performed using an optical scanning system, whereby laser planes are projected onto the impression. Four high-resolution digital cameras acquire images of the lines created on the impression. 3Shape's unique image processing software tracks the corresponding lines in each image with subpixel precision.

Complete geometry in one scan

Unique features of the scanner guarantee superior scan results. In particular the scanner is able to capture the full geometry of a full concha ear impression in one scanning session. This eliminates the painstaking process of stitching different scans together or obtaining scans with occluded areas.

- State-of-the-art projective geometry and a novel calibration of our multiple lasers and cameras ensure consistently high levels of precision
- Rotation and translation: to ensure maximum exposure of the ear impression's geometry to the cameras and lasers, the impression is placed on a rotation plate (360 degree rotation) and moves along a linear axis (translation). Moreover, the system analyses the impression during the scanning process to make sure that the object is moved optimally to cover hidden areas
Accurate and compressed output
The initial output of the scanning process is a point cloud of approximately 200,000 points, depending on the impression. 3Shape's unique surface creation software module then automatically optimizes this data and creates a 3D polygonal model. The final surface is reduced to approximately 25,000 triangles. It is an accurate replica of the full original impression in a compressed format, which makes it easy to manipulate and transfer.

User-friendliness
The "one-button" scanning software offers superior user-friendliness and can easily be operated by a non-expert user with a minimum of training. To perform a 3D scan, the user merely needs to place the impression in the scanner and press one button in the scanning software. No settings need to be adjusted. The system handles all operations automatically.

Specifications
<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision</td>
<td>10 - 100 microns</td>
</tr>
<tr>
<td>Total scanning and surface creation time</td>
<td>1-3 minutes</td>
</tr>
<tr>
<td>Points scanned</td>
<td>app. 200,000</td>
</tr>
<tr>
<td>Final 3D model</td>
<td>app. 25,000 triangles</td>
</tr>
<tr>
<td>Scan output format</td>
<td>STL polygonal model</td>
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<tr>
<td>Cameras</td>
<td>4</td>
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<tr>
<td>Lasers</td>
<td>2 x Non-Gaussian line generators</td>
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<tr>
<td>Processing hardware</td>
<td>1.7 Ghz Pentium 4, 380 Mb ram</td>
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<tr>
<td>Miscellaneous hardware</td>
<td>Cables, calibration object (all included)</td>
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<tr>
<td>Interface</td>
<td>Standard TCP/IP based network</td>
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<tr>
<td>Object movement</td>
<td>Rotation and translation</td>
</tr>
<tr>
<td>Operating voltage</td>
<td>110/220 V</td>
</tr>
<tr>
<td>Ear impression color requirements</td>
<td>All non-transparent colors</td>
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</table>
Integrated hearing aid production system

In order to achieve optimal efficiency and automation of its hearing aid production system, 3Shape offers software to integrate all system modules. The software package is essential to handle the computer-aided manufacturing process and the large amount of data generated.

The integration software ensures seamless data exchange between all system modules. It provides tools to organize and monitor the hearing aid production flow. Full interface with third-party equipment such as 3D printers and milling machines is also provided.

Our system integration software takes the hearing aid or earmold manufacturers’ existing process and infrastructure into account to provide a solution that can be most rapidly and effectively implemented.

The main features of 3Shape's system integration software are presented overleaf.

Overview of the hearing aid production system supplied by 3Shape

At the beginning of the process, an operator types in all the details of the order into the system or imports these data from the ERP system. All data will be automatically available at any step of the production process. The operator creates an accurate 3D copy of the patient's ear impression by inserting it into 3Shape's 3D scanner and simply pressing one button in the 3D scanning software.

After a few minutes, an accurate 3D digital replica of the ear impression is available on screen. With 3Shape's modeling software, ShellDesigner™, the operator transforms the 3D ear impression into a finished 3D shell which includes all the hearing aid's features, such as ventilation channel, sound in- and output.

The 3D shells are automatically produced by a 3D printer (not supplied by 3Shape) with which the system fully interfaces. Existing faceplates can be integrated into the process. A milling path is automatically generated by ShellDesigner™ and sent to a CNC machine (not supplied by 3Shape) that mills the faceplate so it accurately fits the modeled shell. Alternatively, module holders can directly be 3D printed as an integrated part of the shell. Detailed instructions for mounting the components into the shell are provided by the system.

The main benefits of implementing the system compared to current production methods are:

- Improved comfort
- Fewer returns and remakes
- Easy replacement
- Consistent quality
- Smaller hearing aids
- Reduced production costs
Main features of the system integration software

3Shape's system integration software ensures a smooth handling and monitoring of the following tasks in the hearing aid production system:

- Registration of orders and product configuration in an order form adapted to the manufacturer’s ordering system. Alternatively, it is possible to import the order data directly from the manufacturer's ERP system
- Creation of unique production identification number for each hearing aid shell to ensure easy access, retrieval, identification, and flow control
- Organization and monitoring of the production flow and status of all hearing aids in production
- 3D scanning of the ear impressions and automatic export of completed 3D scanning files to database
- Retrieval of correct 3D scanning files and configuration parameters (ventilation channel and shell thickness, electronics, faceplate and components references) for modeling and automatic import of the necessary 3D files into the modeling software
- 3D modeling of the hearing aid shell and correct database handling of product configuration parameters if components are changed during the modeling
- Retrieval and arrangement of 3D hearing aid models from database to perform 3D printing of one or more shells at the same time
- Automatic retrieval of 3D milling files from database to perform faceplate milling
- Automatic retrieval of correct electronics and components references for hearing aid mounting and registration of components' serial number
- Automatic XML file creation and export of production information to back-end systems
- Call center module to retrieve status on individual hearing aids in the production process. The operator can instantly retrieve the status of any hearing aid in the system based on customers' requests
ShellDesigner™

ShellDesigner™ is an advanced software package used to transform 3D ear impressions created by a 3Shape 3D scanner into 3D models of shells for ITE, ITC or CIC hearing aids in a few simple steps. The output of the software is a shell ready to be 3D manufactured.

ShellDesigner™ is characterized by its ease of use, flexibility, and processing speed.

ShellDesigner™ features

- Intuitive interface - fully graphical Windows™-based interface customized for hearing aid modeling. The user is guided through all the steps of the production process
- User-friendliness - only basic computer knowledge is required to use the software
- Automation - most features are automated or assisted by the system
- Ease of use - possibility to move back and forth in the shell design process. The software modifies the 3D model accordingly in real-time
- Flexibility - ShellDesigner™ can incorporate all hearing aid components and can model any size of shells, from CIC to full concha. As the whole ear impression is modeled, the user has the possibility to adjust the size and appearance of the instrument to suit the patient’s ear optimally
- Productivity - the modeling process can be completed in a few minutes. This allows for reductions in labor costs compared to current production methods
- Real-time processing - all modeling operations are performed on screen in real time. Results are assessed immediately
- Full simulation - all hearing aid components, such as transducer, receiver, volume control and battery compartment are incorporated in the modeling process to obtain the most realistic results
- Automatic on-screen placement of components - assisted by collision control tools
- Easy manipulation and visualization - using Spaceball™ motion control device
- Display options - the hearing aid can be visualized alone, with electronic components, and/or inside the patient's ear
- Simultaneous modeling - possibility to model the left and right ear simultaneously for better aesthetic assessment
- Workflow template saved with the 3D models - to ease later reference and production of new shells for the same the patient

ShellDesigner™ workflow overview (see examples overleaf)

- Step 1. Import of a 3D scanned ear impression, all configuration parameters, and CAD models of components
- Step 2. Initial 3D shaping. The ear impression's surface is smoothed and artefacts are removed
- Step 3. Placement of components. Optimal positioning of the electronic components in the shell
- Step 4. Shell creation. Rounding of the shell’s top and creation of a ventilation channel and sound exit. A unique shell identifier is also placed in the shell
- Step 5. Virtual faceplate. If traditional faceplates are used, milling paths for a CNC machine are generated to ensure a perfect fit of the faceplate with the shell
- Step 6. Verification of the finalized shell’s fit with the patient’s ear assisted by graphical reports
ShellDesigner™ workflow overview

Initial 3D shaping
- Raw ear impression model (3D scanner output)
- Easy removal of impression artefacts and thread marks
- Impression ready for modeling

Positioning the components
- Real-time shelling of the impression
- Local modification of surface
- Component placement with real-time collision detection

Shell creation
- Optional positioning of the volume control
- Positioning the sound exit
- Creation of the ventilation channel

Virtual faceplate and different shell sizes
- Full concha shell with faceplate and 1D tag
- CIC shell with faceplate and electronic components
- ITE shell with faceplate and 1D tag

Fit control
- Instant analysis of the deviations between original impression and final shell
- Preview of the shell in the patient’s ear in skin color
- Finished shell in the patient’s ear

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