Achilles EXPII
Affordable and convenient fracture risk assessment using quantitative ultrasound

Healthy aging. Strong bones. It’s vital.
gehealthcare.com
Osteoporosis is a disease of global relevance and affects millions of women worldwide. Osteoporosis is estimated to affect 200 million women worldwide – approximately one-tenth of women aged 60, one-fifth of women aged 70, two-fifths of women aged 80 and two-thirds of women aged 90.

Worldwide, osteoporosis causes more than 8.9 million fractures annually, resulting in an osteoporotic fracture every 3 seconds.¹

Osteoporosis affects 200 million women worldwide.

Quick and affordable way for initial osteoporosis assessment

GE Healthcare offers Achilles EXPII – a quick, convenient and affordable product for initial assessment of osteoporosis and fracture risk.

Based on the Quantitative Ultrasound (QUS) technology, Achilles EXPII helps you protect the vitality of your patients by making accurate fracture risk assessment both comfortable and convenient.

Achilles EXPII can be used as an effective initial Osteoporosis assessment tool before proceeding for a DXA scan. The exam is quick and comfortable for your patients, and its user-friendly design makes it easy for your staff to operate, with no formal certification required.

Osteoporosis fracture risk

Relative risk = 2.0/S.D.
Quantitative Ultrasound (QUS) offers you portable and accurate technology for measuring bone properties at the calcaneus (heel bone) without the use of ionizing radiation. QUS helps you accurately predict fracture risk for post-menopausal women.

QUS technology is based on ultrasound waves that easily pass through fluid and human tissues, and undergo attenuation based on the density of the calcaneus bone. Analysis of this attenuation can be used to generate empirical measurement.

Quantitative ultrasound can be used to measure a variety of parameters that pertain to bone density by measuring values related to the velocity and attenuation of ultrasound waves as they pass through bone.

Awareness and education can lead to strength and vitality.
How Achilles EXPII Works

The Achilles EXPII bone ultrasonometers use high frequency sound waves (ultrasound) to evaluate bone status in the heel, the os calcis. Achilles EXPII measurements are performed with the person seated, with one foot placed on the Footplate. The heel is surrounded by warm water encapsulated between inflated membranes. Water is the optimum medium for the transmission of ultrasound. A transducer on one side of the heel converts an electrical signal into a sound wave, which passes through the water and the person’s heel. A transducer at a fixed distance on the opposite side of the heel receives the sound wave and converts it to an electrical signal that is analyzed. The Achilles EXPII measure the speed of sound (SOS) and the frequency-dependent attenuation of the sound waves (broadband ultrasound attenuation or BUA), and combines them to form a clinical measure called the Stiffness Index.

Ultrasonometry provides a measurement of physical properties of bone. Two of the most commonly used ultrasound measures are the velocity (speed of sound; SOS in m/sec) and frequency attenuation (broadband ultrasound attenuation; BUA in dB/MHz) of a sound wave as it travels through a bone.2-6

The ultrasound characteristics of trabecular bone usually correlate well (r>0.8) with bone density in vitro,7-19 but the ultrasound characteristics may provide incremental information about bone strength not provided by density alone.

To express the ultrasound results, the Achilles combines the SOS and BUA values to calculate a clinical measure called the Stiffness Index.
Stiffness Index

The Achilles ultrasonometer measures ultrasound variables of the os calcis to provide a clinical measure called Stiffness Index – indicating risk of osteoporotic fracture in postmenopausal women comparable to bone mineral density (BMD) as measured by X-ray absorptiometry at the spine or hip.

Stiffness index results expressed as t-scores are used to assist the physicians in the diagnosis of osteoporosis in the same way as are t-scores or obtained by X-ray absorptiometry. Either the stiffness index t-score or X-ray absorptiometry t-score can be utilized by a physician, in conjunction with other clinical risk factors, to provide a comprehensive skeletal assessment.

The stiffness index has a precision error in older women comparable to that of x-ray absorptiometry, which makes it suitable for monitoring bone changes.

The Stiffness Index combines BUA and SOS into a single clinical measure that has a lower precision error than either variable alone. BUA and SOS vary in opposite directions with temperature. The linear combination of BUA and SOS cancel measurement variations as the temperature of the heel and water equilibrate. This provides decreased precision error, and faster measurements.

The Stiffness Index is constructed by “normalizing” BUA and SOS through subtracting the lowest observable values (50 dB/MHz and 1380 m/sec) from each and then scaling the resultant values. The Stiffness Index is the sum of the scaled and normalized BUA and SOS values. The resultant formula is:

\[
\text{Stiffness Index} = (0.67 \times \text{BUA} + 0.28 \times \text{SOS}) - 420.
\]

Note that normalized and scaled BUA and SOS values contribute about equally to the resulting Stiffness Index over the adult age range.

<table>
<thead>
<tr>
<th>Unadjusted</th>
<th>Normalized and Scaled</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUA</td>
<td>SOS</td>
</tr>
<tr>
<td>Age 20</td>
<td>125</td>
</tr>
<tr>
<td>Age 60</td>
<td>108</td>
</tr>
<tr>
<td>Osteoporotic</td>
<td>95</td>
</tr>
</tbody>
</table>

The International Society for Clinical Densitometry (ISCD)\(^2\) has confirmed that peripheral bone density measurements have value for assessing fracture risk and identifying individuals who should be considered for a DXA measurement. Of the available techniques quantitative ultrasound (QUS) is one of the best methods for assessing fracture risk in men and postmenopausal women.

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(1) Calf Support  
(2) Handle  
(3) (Inflated) Membrane (applied part)  
(4) Membrane Retainer Ring  
(5) Footplate (applied part)  
(6) LCD Display with Touch Panel  
(7) Stylus, for Touch Panel  
(8) USB-Host (Thumb Drive, External Printer)  
(9) USB-Slave (PC Software Option)  
(10) Internal Printer Door with Thermal Paper Slot  
(11) Fuse Box  
(12) Power Switch  
(13) Power Cable Jack  
(14) Water Management Tray
High negative predictive value

QUS technology offers high negative predictive value – 97 percent for 50 to 59-year-old Caucasian women – making Achilles EXPII especially useful for discriminating between those not at risk for fracture and those in need of further evaluation by central DXA.²⁰,²¹

“Quantitative ultrasound technology is inexpensive, portable, convenient and ionizing radiation free.”
The benefits of Achilles are supported by a range of features

CERTAINTY
• Proven in 11 prospective clinical studies\textsuperscript{10}
• High negative predictive value
• Dynamic signal-strength compensation allows measurement over a wide range of bone densities
• Bi-directional measurement helps ensure a consistent reading
• Controlled measurement of site temperature for greater accuracy than other QUS systems
• Results expressed as Stiffness Index – a composite of Speed of Sound (SOS) and Broadband Ultrasound Attenuation (BUA) – which compensates for the effect of heel width and temperature

COMFORT
• No messy gels
• Warm, water-filled membranes hug the heel
• Built-in leg support
• Large, easy-to-read color display tilts towards the patient
• No ionizing radiation
• Quick exam – just a few minutes from shoe off to shoe on

CONVENIENCE
• No special rooms
• Durable and easily portable
• Light-weight, compact design
• Generates full-sized and full-color reports
• On-board memory stores up to 2,000 patient records – no need to carry a computer
• Customizable measurement workflows allow you to select which patient data to collect and report
• Achilles EXPII can be operated through PC or laptop through OsteReportN (Optional purchase) software

For hospitals and physicians performing osteoporosis public health and education, the portable Achilles can be used as part of a skeletal health education program.

For hospitals and clinics needing risk stratification to determine which patients need follow-up with central DXA, the Achilles closely matches the prevalence of DXA-defined osteoporosis.

For clinics offering osteoporosis treatment to their patients, Achilles is an effective solution with proven, long-term precision monitoring.
Comparison of Achilles and competitive ultrasonometers to DXA for osteoporosis testing

Among these ultrasonometers, Achilles most closely matches DXA findings based on the percentage of 60-year-old women it determines to have osteoporosis, as defined by a DXA T-score < -2.5 at the femoral neck.

Estimated osteoporosis prevalence (%)

- Sahara
- QUI
- Central DXA (femoral neck BMD)
- Achilles
- Omnisense (phalanges SOS)
- IGEA DBM sonic ADSOS

Osteoporotic fracture risk assessment as discriminating as DXA at the hip and spine

The osteoporotic fracture risk assessment provided by Achilles closely matches prevalence as defined by central DXA (see chart below). Yet it’s fast and affordable.

Its high negative predictive value – 97 percent for 50 to 59-year-old Caucasian women – makes Achilles especially useful for discriminating between those not at risk for fracture and those in need of further evaluation by central DXA.

Additionally, Achilles has proven long-term precision, making it useful for monitoring bone changes.

Clinical confidence is based on many features:
- Dynamic signal strength compensation allows measurement over a wide range of bone density
- Bi-directional measurement ensures a consistent reading
- Measurement site temperature is controlled for more accuracy
- Results expressed as Stiffness Index – a composite of Speed of Sound (SOS) and Broadband Ultrasound Attenuation (BUA) – compensate for the effect of heel width and temperature

Certainty

The Achilles EXPIII, the latest edition to the family of proven portable GE Achilles ultrasonometers, offers rugged durability, dynamic signal strength, and customizable workflow features

Compared to previous generation Achilles units, the EXPIII offers:
- Longer lasting membranes (~3,000 - 5,000 scans per set vs. ~200 – 500 scans per set)
- Faster heel scan time (10 seconds vs. 60 seconds in previous model)
- Larger, easy-to-read color display
- External printer support via USB
- External USB data storage capability
- An on-board patient database that holds 2,000 patients.
- Faster internal printer speed (15 seconds vs. 60 seconds in previous models)
- Customizable measurement workflow
Comfort

A quick and comfortable exam is the first step toward vitality.

With Achilles, the patient experience is pleasant. The exam is quick: just a few minutes from shoes off to shoes on. The patient is seated. No messy gels are needed. Its ultrasound technology emits no ionizing radiation.

Inflated membranes hug the heel.

Convenience

Efficient, customizable workflow.

Your staff will appreciate the simplicity of Achilles. It’s easy for technicians to learn and to use, and it requires no special rooms, no formal certification, and no licensing. Results are concise and easy to interpret.

Along with rugged durability, Achilles boasts plenty of technical features. A large, easy-to-read color display tilts back and forth. Reports print out in full color and full size. The on-board memory stores up to 2,000 patient records. And customizable measurement workflows allow you to select which data to collect and report:

- Prevalence data
- Clinical risk factors
- Patient identification data
Portable
Convenient, light-weight, compact design

Operating Achilles EXPII is quick and easy
Achilles EXPII is easy to operate and the entire scan just takes 1-2 minutes.

Ease of use
• Fixed transducers
  – No imprecise caliper mechanism
• Temperature controlled water
  – Now self-contained
  – Water-path ultrasound provides the most accurate and most precise results
• Position the heel and measure
  – Simple slide heel between the membranes
OsteoReportN

Achilles OsteoReportN is an external PC application option that enhances the functionality of the Achilles with:

- Patient database
- Customizable reporting
- Remote operation
- DICOM® compatibility

OsteoReportN plots measurement results over time to visualize trends in your patient’s fracture risk and automatically recalculates clinical results if patient data is updated.

Easy to understand educational material can be printed with the results to help you explain the results and next steps for your patient.

You can conveniently operate the Achilles EXPII unit directly from your PC. Also, OsteoReportN is DICOM compatible.

Achilles OsteoReportN application requires a PC computer with the following minimum requirements:

- PC with 2Ghz CPU or higher
- 512MB of RAM or higher
- 8 Gigabyte of available space on hard drive or higher
- Windows® XP (SP3) 32 bit or Windows 7 64 bit
- Keyboard and Microsoft® Mouse or compatible pointing device
- Super VGA (1024 x 768) or hi-resolution video adapter & monitor
- CD ROM
- Windows-compatible color printer capability
- USB 2.0 Port
- USB Cable

Achilles OsteoReport application also requires:
An Achilles EXPII running firmware version 1.50 or higher
Achilles EXPII results

- Easy-to-read LCD display
- Tiltable/reversible for operator convenience
- View waveforms and results

Achilles EXPII Results

Results

| T Score:  | -1.6 |
| Z Score:  | -1.1 |

Stiffness Index: 75
ID: 100330181255
BUA: 61.4
SOS: 1621.8
% Age Matched: 81.4
% Young Adult: 74.8

General Electric Company GE Medical System

Name: Scuri, Fernando
Age/Birthdate: 51 years, 1969.08.08
Sex: Female
HEEL: Left

ID: 110501125455
Doctor: David Roe
Test Date: 2011.05.03

Stiffness Index: 81
% Young Adult: 81
% Age Matched: 89
T Score: -1.2
Z Score: -0.6
BUA: 71.1
SOS: 1620.8

Clinical Risk Factors:
Ever HRT, Ever Smoke, Failed Chair Test,

Comments: Medium Risk of Osteoporotic Fracture

Follow Up: None, 6 Months, 12 Months, 18 Months, 24 Months

GE Healthcare Achilles Serial Number 60019 Software Version 1.10A
## Achilles comparison table

<table>
<thead>
<tr>
<th>Product name</th>
<th>Achilles EXPII</th>
<th>Previous Model – Achilles Express*</th>
<th>Previous Model – Achilles InSight*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanning site</td>
<td>Heel</td>
<td>Heel</td>
<td>Heel</td>
</tr>
<tr>
<td>Scanning method</td>
<td>QUS with SmartDry coupling</td>
<td>QUS with SmartDry coupling</td>
<td>QUS with SmartDry coupling</td>
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<tr>
<td>Membrane life (# of measurements)</td>
<td>~3000</td>
<td>~200</td>
<td>~200</td>
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<tr>
<td>Membrane color</td>
<td>White/thicker – not interchangeable with AE &amp; A</td>
<td>Tan/thin</td>
<td>Tan/thin</td>
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<tr>
<td>Heel scan time (seconds)</td>
<td>10</td>
<td>60</td>
<td>15</td>
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<tr>
<td>QA test duration (seconds)</td>
<td>30</td>
<td>60</td>
<td>30</td>
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<tr>
<td>Foot positioning</td>
<td>Graduated foot plate (without toe peg)</td>
<td>Foot plate (with toe peg)</td>
<td>Graduated foot plate (with toe peg)</td>
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<tr>
<td>Heel coupling method</td>
<td>Alcohol</td>
<td>Alcohol</td>
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<tr>
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<td>2% CV</td>
<td>2% CV</td>
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<td>6.5&quot; color LCD VGA (640 x 480 pixels)</td>
<td>5.5&quot; B&amp;W LCD (320 x 240 pixels)</td>
<td>5.5&quot; color LCD (320 x 240 pixels)</td>
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<td>Touch panel response time</td>
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<td>58 mm thermal</td>
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<td>Patient data input fields</td>
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<td>Shims/smaller feet</td>
<td>1 raised shim (Identical to Express)</td>
<td>1 raised shim</td>
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<tr>
<td>Water replacement period</td>
<td>4½ months</td>
<td>4½ months</td>
<td>4½ months</td>
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<tr>
<td>- Light use</td>
<td>2 weeks</td>
<td>2 weeks</td>
<td>2 weeks</td>
</tr>
<tr>
<td>- Heavy use</td>
<td>(&gt;50 measurements/day)</td>
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<td></td>
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<tr>
<td>Data storage/ internal memory/ # of patients</td>
<td>2000</td>
<td>100</td>
<td>300</td>
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<tr>
<td>Data storage – External USB</td>
<td>USB 2.0 thumb drive</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Database/reporting application</td>
<td>---</td>
<td>OsteoReport</td>
<td>OsteoReport</td>
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<td>Weight</td>
<td>11.5 kg (25.4 lbs)</td>
<td>11.5 kg (25.4 lbs)</td>
<td>11.5 kg (25.4 lbs)</td>
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<tr>
<td>Physical dimensions</td>
<td>275 mm x 305 mm x 550 mm</td>
<td>281 mm x 305 mm x 560 mm</td>
<td>281 mm x 305 mm x 560 mm</td>
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<tr>
<td>- 11&quot; H x 12&quot; W x 22&quot; D</td>
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<td>Measurement workflow</td>
<td>Customizable</td>
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<td>Not customizable</td>
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<tr>
<td>Color</td>
<td>White over dark gray</td>
<td>Beige over gray</td>
<td>Beige over gray</td>
</tr>
</tbody>
</table>

*This model is no longer being offered by GE Healthcare*
Specifications (nominal)

Reference populations:

<table>
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<tr>
<th></th>
<th>AF</th>
<th>AM</th>
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<tr>
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<tr>
<td>Mercosurian</td>
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<tr>
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<tr>
<td>USA</td>
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<td></td>
<td></td>
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</tr>
</tbody>
</table>

Specifications:

Dimensions | 275 mm x 305 mm x 550 mm (11” H x 12” W x 22” D)
Weight      | 11.5 kg (25.4 lbs.)
Display     | 6.5” Color LCD VGA (640 x 480) with graphical display
            | Tilts and inverts for optimal viewing
            | Brightness ≥ 400cd/m²
Printer     | Internal 58 mm thermal printer with graphical output
            | Print report ≤ 15 seconds
            | Specific external printer support for A4 size paper
USB port    | USB2.0
            | USB Host x 2, USB Slave x 1
Battery     | CR2032 +3V
            | Inside device, customer does not required to replace it
Power Consumption | 650VA without peripherals
Transducers | Quarter wave-matched broadband elements
            | Center frequency = 0.5 MHz
            | Single element transmission and reception
Output power of Ultrasound | p < 1 MPa
            | lob < 20 mW/cm²
            | Ispta < 100 mW/cm²
Coupling System | Smart Dry™
            | Fluid-coupled, through-transmission ultrasound
            | Fully automated and self-contained
            | Heated coupling fluid 33°C (92°F)
            | 70% Isopropyl Alcohol or Ethanol
            | Replaceable TPE (Thermoplastic elastomer) Membranes
            | Pressure < 3 psi
Analysis    | Real-time, point-by-point analog/digital conversion
            | Smart detection algorithm, Discrete Fourier Transform
            | Simultaneous Stiffness/SOS/BUA determination
Results     | Stiffness Index with WHO classification
            | T-Score with % Young Adult
            | Z-Score with % Age-Matched
In Vivo Precision and Accuracy | < 2.0% CV (ambient temperatures between 15°C and 33°C)
Scan Throughput | 10 seconds Signal Acquisition
Warm up     | ≤ 15 minutes from 4°C
Expected Service Life | 6 years

Electrical Requirements:

Voltage | 100-240V AC @50/60 Hz
Power Capacity | ≥ 650VA
THD (Total Harmonic distortion) | < 5% per IEEE 519-1992 standard for power quality and total harmonic distortion

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Environmental Requirements:

Operating ambient | Temperature: 15°C ~ 35°C,
            | Humidity: 30 ~ 90%RH (non-condense),
Storage/Transport ambient | Temperature*: -20°C ~ 70°C,
            | Humidity: 30 ~ 95%RH (non-condense)
Static | Static-free environment
Dust, fumes, and debris | Clean, well ventilated environment, free from dust, smoke, and other airborne contaminants
External cleaning agents | Clean, well ventilated environment, free from dust, smoke, and other airborne contaminants
Temperature*: Pump shall be no more than half full of water when the temperature is below 0°C

Dimensions:

[Image of device dimensions]
References:

1. International Osteoporosis Foundation.