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1 Summary of 510(k) owners administrative data

COMPANY NAME AND ADDRESS:	Entomed AB Bariumgatan 29 213 64 Malmö Sweden
CONTACT PERSON:	Charlotte Mattisson
EMAIL:	charlotte.mattisson@entomed.se
TELEPHONE NUMBER:	+ 46 (40) - 210090
FAX:	+ 46 (40) - 210092
TRADE NAME OF DEVICE:	Entomed SA201/202 Screening Audiometer and Entomed SA203/204 Diagnostic Audiometer
COMMON NAME:	Audiometer
CLASSIFICATION:	Class II Medical Device, Reg no 874.1050, Product Code EWO
PREDICATE DEVICE:	Interacoustic Diagnostic Audiometer AD229b and GSI 61 Clinical Audiometer
DATE SUMMARY PREPARED:	July 10 2009

2 Entomed AB

Entomed is a Swedish specialist company within the ENT (Ear-Nose-Throat) sector, founded 1986, with home production of audiometers, and an extensive agency business for Welch Allyn and diagnostical instruments from Grason-Stadler (GSI), Maico, and Oriola.
Up to year 2007 Entomed products were sold and distributed by GSI under the brand name GSI 66, GSI 67 and GSI 68. Since 2008 the products are sold directly from Entomed through a worldwide distributor network, under the brand names SA201™ ,SA202™, SA 203™ and SA204™.
The SA20X series audiometer presented in this 510(k) submission is a new modernized generation of the well reputed product line. The new generation is digital and RoHS compatible.

3 Description of the device

The SA 201/202/203/204 audiometers are electroacoustic devices that produces controlled levels of test tones and signals.

The SA201/202 are IEC 60645 Type 4 Pure Tone Audiometers and the SA203/204 Diagnostic Audiometers are IEC 60645 Type 3 Audiometers.

The SA201/202 are manual pure tone air conduction, screening audiometers. SA202 has the additional capability to perform automatic pure tone audiometry.

The SA203/204 are both automatic air and bone conduction audiometers with synchronized masking possibility in order to avoid overhearing to the not tested ear. The SA 204 has the additional capability of using speech-testing. Both can be operated manually if required.

All models can be used for determination of hearing thresholds and assist to diagnose hearing loss.

All models, 201/202/203/204 have a built-in microphone for easier communication with the test person. Furthermore they all have outputs for TDH39, Sennheiser HDA200 and EARtone 5A insert ear phones. SA203/204 have outputs for B71 Bone Conductor and Free-field system (optional).

All models should be operated by people with education/training within the field of audiometry such as Audiologists, Hearing Aid dispensers, Health Care and School nurses with appropriate training in audiology and Ear Nose Throat specialists.

The performance characteristics for the SA 201/202/203/204 are such that they meet or exceed the following standards:

Standard	Name	SA201	SA202	SA203	SA204
IEC 60645-1 (1992)	Audiometers Part1; Pure Tone Audiometers	x	x	x	x
IEC 60645-2(1993)	Audiometers Part 2; Equipment for Speech Audiometry	NA	NA	NA	x
ISO 389:1991	Calibration of Air Conduction Audiometers	x	x	x	x
ISO 389-2	Calibration of Insert Phones	x	x	x	x
ISO 389-3	Calibration of Bone Vibrators	NA	NA	x	x
ISO 389-4	Calibration of Narrow Band Masking Noise	NA	NA	x	x
ISO 389-7	Calibration of Free Field Audiometers	NA	NA	x	x
IEC 60601-1 2nd edition 1988	Medical Electrical Equipment Part1: General Requirements for Safety	x	x	x	x
IEC 60601-1-2 3rd edition 2007	Medical Electrical Equipment Part1-2: General Requirements for Basic Safety and Essential Performance-Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	x	x	x	x
ISO 8253-1	Audiometric Test Methods Part1; Basic Pure Tone Air and Bone Conduction Threshold Audiometry	x	x	x	x
ISO 8253-2	Audiometric Test Methods Part 2; Sound Field Audiometry with Pure Tone and Narrow Band Test Signals	NA	NA	x	x
ISO 8253-3	Audiometric Test Methods Part 3; Speech Audiometry	NA	NA	NA	x

NA = Not Applicable

4 Indication for use.

The Entomed SA 201/202/203/204 series of audiometers are screening and diagnostic audiometers used to determine hearing thresholds and assist to diagnose hearing loss.

The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to understand the basic principles of the test method when explained by the operator.

5 Summary of Performance Comparison between SA 204 and Interacoustic AD 229b (predicate) and GSI 61 (predicate)

The predicates selected for the SE discussion in this 510(k) are the Interacoustic Diagnostic Audiometer AD229b and GSI 61 Clinical Audiometer.
The technical features of the SA204 are very similar to the Interacoustic AD 229b. However, the technical design using two separate, identical channels differs between the SA204 and the Interacoustic AD 229. The SA204 has 2 identical channels. By adding another predicate to the SE discussion that also has 2 identical channels, the GSI 61, it is shown that the technical solution to use two identical channels is well known and accepted.

Similarities between the predicates are presented in Tables 1a-1d and differences between the predicates are presented in Tables 2a – 2d.

Table 1a Similarities between SA204 and Interacoustic AD229b and GSI 61

Comparison Parameter	**SA204**	**Interacoustic AD229b**	**GSI 61**
Intended use	*"The Entomed SA 201/202/203/204 series of audiometers are screening (201/202) and diagnostic (203/204) audiometers used to determine hearing thresholds and assist to diagnose hearing loss The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to be able to understand the basic principles of the test method when explained by the operator"*	*"The Interacoustic Model AD229 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. Because of its master hearing aid capability this device is also indicated for simulating a hearing aid during audiometric testing thus it may help in the selection and adjustment of a patient's hearing aid"*. (statement obtained from 510(k) summary from 510(k) application k982249)	Determine hearing thresholds and assist to diagnose hearing loss. It can also be used in the selection and adjustment of a patient's hearing aid.
Air Conduction Pure Tone - Frequency Range and Format	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Pulsed (2.5 pulses/sec), Frequency Modulation (Warble: ± 5 % triangular 10 Hz at 8 kHz, 8 Hz at 6 kHz and 5 Hz at 125 Hz – 4 kHz)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Multiple Pulses (250-5000 msec. on/off'), Frequency Modulation (Warble: ± 5 % , 5Hz true sine wave)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz). *Format*: Steady, Pulsed (Tone pulsed 200 msec ON, 200 msec OFF), Frequency Modulation (Tone modulated ± 5 % of centre frequency at a rate of 5 Hz)
Bone Conduction – Frequency Range	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Narrow Band Noise Range	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Speech Noise Range	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Synchronous Masking	Locks the noise attenuator to the tone attenuator	Locks channel 2 attenuator to channel 1 attenuator	Locks the noise attenuator to the tone attenuator
Speech Channel L and R	*Microphone*: Input for live speech testing and communications *IN1 and IN2*: Inputs for recorded speech material from external stereo CD/tape player	*Microphone*: Input for live speech testing and communications *Channel 1 and Channel 2*: Inputs for 2 channels for prerecorded material *Speech Noise*: Narrow Band noise or White noise	*Microphone*: Input for live speech testing and communications *External A and External B*: Accepts recorded speech material from external stereo tape cassette or CD player *Speech Noise*: White noise

	Speech Noise: White noise filtered to a low and middle frequency band, simulating the average spectrum of conversational speech		
Communication Operator/Test subject	Talk Forward, Talk back and Monitor / Live Speech monitor headset	Talk Forward, Talk back and Monitor / Live Speech monitor headset	Talk Forward, Talk back and Monitor / Live Speech monitor headset
Transducers	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH50P, EARTone 3A, Single Insert Phone (470 Ω) Sennheiser HDA 200, Radioear B71 bone vibrator
Tone Presentation	Manual Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation
Patient signal	Test subject response switch push button	Reed switch push button	Subject response hand switch
Store Function:	Internal Memory for AC L/R and BC L/R	Internal Memory for AC L/R and BC L/R and full speech curve	No internal memory for either AC L/R, BC L/R or speech curve
Test: Auto Threshold	Patient controlled Hughson Westlake procedure according to ISO 8253-1	Patient controlled Hughson Westlake procedure according to ISO 8253-1 or OSHA procedure with automatic re-check (US edition only)	No auto threshold function available

Table 1b. Similarities between SA203 and Interacoustic AD 229b and GSI 61

Comparison Parameter	SA203	Interacoustic AD229b	GSI 61
Intended use	*"The Entomed SA 201/202/203/204 series of audiometers are screening (201/202) and diagnostic (203/204) audiometers used to determine hearing thresholds and assist to diagnose hearing loss The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to be able to understand the basic principles of the test method when explained by the operator"*	*"The Interacoustic Model AD229 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. Because of its master hearing aid capability this device is also indicated for simulating a hearing aid during audiometric testing thus it may help in the selection and adjustment of a patient's hearing aid".*	Determine hearing thresholds and assist to diagnose hearing loss. It can also be used in the selection and adjustment of a patient's hearing aid.
Air Conduction Pure Tone - Frequency Range and Format	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Pulsed (2.5 pulses/sec), Frequency Modulation (Warble: ± 5 % triangular 10 Hz at 8 kHz, 8 Hz at 6 kHz and 5 Hz at 125 Hz – 4 kHz)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Multiple Pulses (250-5000 msec. on/off), Frequency Modulation (Warble: ± 5 % , 5Hz true sine wave)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz). *Format*: Steady, Pulsed (Tone pulsed 200 msec ON, 200 msec OFF), Frequency Modulation (Tone modulated ± 5 % of centre frequency at a rate of 5 Hz)
Bone Conduction – Frequency Range	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Narrow Band Noise Range	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Speech Noise Range	Speech Noise not available	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Synchronous Masking	Locks the noise attenuator to the tone attenuator	Locks channel 2 attenuator to channel 1 attenuator	Locks the noise attenuator to the tone attenuator
Speech Channel L and R	Speech Channels L and R are not available	*Microphone*: Input for live speech testing and communications *Channel 1 and Channel 2*: Inputs for 2 channels for prerecorded	*Microphone*: Input for live speech testing and communications *External A and External B*: Accepts recorded speech material

		material *Speech Noise*: Narrow Band noise or White noise	from external stereo tape cassette or CD player *Speech Noise*: White noise
Communication Operator/Test subject	Talk Forward	Talk Forward, Talk back and Monitor / Live Speech monitor headset	Talk Forward, Talk back and Monitor / Live Speech monitor headset
Transducers	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH50P, EARTone 3A, Single Insert Phone (470 Ω) Sennheiser HDA 200, Radioear B71 bone vibrator
Tone Presentation	Manual Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation
Patient signal	Test subject response switch push button	Reed switch push button	Subject response hand switch
Store Function:	Internal Memory for AC L/R and BC L/R	Internal Memory for AC L/R and BC L/R and full speech curve	No internal memory for either AC L/R, BC L/R or speech curve
Test: Auto Threshold	Patient controlled Hughson Westlake procedure according to ISO 8253-1	Patient controlled Hughson Westlake procedure according to ISO 8253-1 or OSHA procedure with automatic re-check (US edition only)	No auto threshold function available

Table 1c. Similarities between SA202 and Interacoustic AD 229b and GSI 61

Comparison Parameter	**SA202**	**Interacoustic AD229b**	**GSI 61**
Intended use	*"The Entomed SA 201/202/203/204 series of audiometers are screening (201/202) and diagnostic (203/204) audiometers used to determine hearing thresholds and assist to diagnose hearing loss The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to be able to understand the basic principles of the test method when explained by the operator"*	*"The Interacoustic Model AD229 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. Because of its master hearing aid capability this device is also indicated for simulating a hearing aid during audiometric testing thus it may help in the selection and adjustment of a patient's hearing aid".*	Determine hearing thresholds and assist to diagnose hearing loss. It can also be used in the selection and adjustment of a patient's hearing aid.
Air Conduction Pure Tone - Frequency Range and Format	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Pulsed (2.5 pulses/sec), Frequency Modulation (Warble: ± 5 % triangular 10 Hz at 8 kHz, 8 Hz at 6 kHz and 5 Hz at 125 Hz – 4 kHz)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Multiple Pulses (250-5000 msec. on/off), Frequency Modulation (Warble: ± 5 % , 5Hz true sine wave)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz). *Format*: Steady, Pulsed (Tone pulsed 200 msec ON, 200 msec OFF), Frequency Modulation (Tone modulated ± 5 % of centre frequency at a rate of 5 Hz)
Bone Conduction – Frequency Range	Bone conduction not available	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Narrow Band Noise Range	Narrow Band Noise not available	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Speech Noise Range	Speech Noise not available	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Synchronous Masking	Synchronous Masking not available	Locks channel 2 attenuator to channel 1 attenuator	Locks the noise attenuator to the tone attenuator
Speech Channel L and R	Speech Channel L and R not available	*Microphone*: Input for live speech testing and communications *Channel 1 and Channel 2*: Inputs for 2 channels for prerecorded	*Microphone*: Input for live speech testing and communications *External A and External B*: Accepts recorded speech material

		material *Speech Noise*: Narrow Band noise or White noise	from external stereo tape cassette or CD player *Speech Noise*: White noise
Communication Operator/Test subject	Talk Forward	Talk Forward, Talk back and Monitor / Live Speech monitor headset	Talk Forward, Talk back and Monitor / Live Speech monitor headset
Transducers	TDH39, EARTone 5A, Sennheiser HDA 200	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH50P, EARTone 3A, Single Insert Phone (470 Ω) Sennheiser HDA 200, Radioear B71 bone vibrator
Tone Presentation	Manual Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation
Patient signal	Test subject response switch push button	Reed switch push button	Subject response hand switch
Store Function:	Internal Memory for AC L/R	Internal Memory for AC L/R and BC L/R and full speech curve	No internal memory for either AC L/R, BC L/R or speech curve
Test: Auto Threshold	Patient controlled Hughson Westlake procedure according to ISO 8253-1	Patient controlled Hughson Westlake procedure according to ISO 8253-1 or OSHA procedure with automatic re-check (US edition only)	No auto threshold function available

Table 1d. Similarities between SA201 and Interacoustic AD 229b and GSI 61

Comparison Parameter	**SA201**	**Interacoustic AD229b**	**GSI 61**
Intended use	*"The Entomed SA 201/202/203/204 series of audiometers are screening (201/202) and diagnostic (203/204) audiometers used to determine hearing thresholds and assist to diagnose hearing loss The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to be able to understand the basic principles of the test method when explained by the operator"*	*"The Interacoustic Model AD229 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. Because of its master hearing aid capability this device is also indicated for simulating a hearing aid during audiometric testing thus it may help in the selection and adjustment of a patient's hearing aid".*	Determine hearing thresholds and assist to diagnose hearing loss. It can also be used in the selection and adjustment of a patient´s hearing aid.
Air Conduction Pure Tone - Frequency Range and Format	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Pulsed (2.5 pulses/sec), Frequency Modulation (Warble: ± 5 % triangular 10 Hz at 8 kHz, 8 Hz at 6 kHz and 5 Hz at 125 Hz – 4 kHz)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz *Format*: Steady, Multiple Pulses (250-5000 msec. on/off), Frequency Modulation (Warble: ± 5 % , 5Hz true sine wave)	*Range*: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz). *Format*: Steady, Pulsed (Tone pulsed 200 msec ON, 200 msec OFF), Frequency Modulation (Tone modulated ± 5 % of centre frequency at a rate of 5 Hz)
Bone Conduction – Frequency Range	Bone conduction not available	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Narrow Band Noise Range	Narrow Band Noise not available	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Speech Noise Range	Speech Noise not available	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000 Hz (High frequency as "Optional accessories" 8000 Hz to 20 000 Hz)
Synchronous Masking	Synchronous Masking not available	Locks channel 2 attenuator to channel 1 attenuator	Locks the noise attenuator to the tone attenuator
Speech Channel L and R	Speech Channel L and R not available	*Microphone*: Input for live speech testing and communications *Channel 1 and Channel 2*: Inputs for 2 channels for prerecorded	*Microphone*: Input for live speech testing and communications *External A and External B*: Accepts recorded speech material

		material *Speech Noise*: Narrow Band noise or White noise	from external stereo tape cassette or CD player *Speech Noise*: White noise
Communication Operator/Test subject	Talk Forward	Talk Forward, Talk back and Monitor / Live Speech monitor headset	Talk Forward, Talk back and Monitor / Live Speech monitor headset
Transducers	TDH39, EARTone 5A, Sennheiser HDA 200	TDH39, EARTone 5A, Sennheiser HDA 200, Radioear B71 bone vibrator	TDH50P, EARTone 3A, Single Insert Phone (470 Ω) Sennheiser HDA 200, Radioear B71 bone vibrator
Tone Presentation	Manual Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation	Manual or Reverse Single Pulse Multiple Pulses Frequency Modulation
Patient signal	Test subject response switch push button	Reed switch push button	Subject response hand switch
Store Function:	Internal Memory for one AC L/R audiogram	Internal Memory for AC L/R and BC L/R and full speech curve	No internal memory for either AC L/R, BC L/R or speech curve
Test: Auto Threshold	Auto threshold not available	Patient controlled Hughson Westlake procedure according to ISO 8253-1 or OSHA procedure with automatic re-check (US edition only)	No auto threshold function available

Table 2a Differences between SA204 and Interacoustic AD229b and GSI 61

Comparison Parameter	**SA204**	**Interacoustic AD229b**	**GSI 61**
Masking -White Noise -Routing of masking	White Noise and Routing of masking not available	White Noise available. Routing of masking not available	White Noise and Routing of Masking available
Frequency Selection	Any frequency can be deselected	125, 250, 750, 1500 Hz or 8kHz can be deselected	No frequency can be deselected
Tone Presentation -Reverse Tone	Not Available	Available	Available
Routing possibilities	No routing possibilities	No routing possibilities	Routing possibilities available
High Frequency	Not Available	Not Available	Available at 9, 10, 11.2, 12.5, 14, 16, 18, 20 kHz
Digital Signal Generator	Yes	No	No
CF Card and Calibration Card	Yes	No	No
Display audiograms on Front Display	No	No	Yes
Compatible Windows Software	AudiMax II	OtoAccess™ Database and diagnostic modules software PrintView, Interacoustics database and diagnostic modules, NOAH	Audi-Link Audiometer driver for NOAH
Internal Memory for full speech curve	Not Available	Available	Available
Tests -SISI -ALT -ABLB -Stenger -Stenger Speech -High Frequency	SISI, ALT, ABLB, Stenger, Stenger Speech and High Frequency are not available	SISI, ALT and High Frequency are not available. ABLB, Stenger and Stenger Speech are available.	SISI, ALT and High Frequency are available. ABLB, Stenger and Stenger Speech are not available.
2 identical channels	Yes	No	Yes
Dimensions (LxWxH)	37.6x26.4x7.3 cm	36x26x10 cm	50x39x32 cm
Weight	1.25 kg	1.8 kg	8.7 kg
Power Supply	External, 100-240 V	External, 100-115 V or 230 V	Internal Power Supply
Power Consumption	15 W	40 W	90 W
Attenuator Controls	1 HL rotary control for test signal intensity and 1 HL rotary control for masking intensity	1 HL rotary control for channel 1 and 1 HL rotary control for channel 2	- 2 independent HL rotary controls for test signal and masking intensity -push buttons that allows intensity step size of 1, 2 or 5 dB

Table 2b Differences between SA203 and Interacoustic AD229b and GSI 61

Comparison Parameter	**SA203**	**Interacoustic AD229b**	**GSI 61**
Masking -White Noise -Routing of masking	White Noise and Routing of masking not available	White Noise available. Routing of masking not available	White Noise and Routing of Masking available
Frequency Selection	Any frequency can be deselected	125, 250, 750, 1500 Hz or 8kHz can be deselected	No frequency can be deselected
Tone Presentation -Reverse Tone	Not Available	Available	Available
Routing possibilities	No routing possibilities	No routing possibilities	Routing possibilities available
High Frequency	Not Available	Not Available	Available at 9, 10, 11.2, 12.5, 14, 16, 18, 20 kHz
Digital Signal Generator	Yes	No	No
CF Card and Calibration Card	Yes	No	No
Display audiograms on Front Display	No	No	Yes
Compatible Windows Software	AudiMax II	OtoAccess™ Database and diagnostic modules software PrintView, Interacoustics database and diagnostic modules, NOAH	Audi-Link Audiometer driver for NOAH
Internal Memory for full speech curve	Not Available	Available	Available
Tests -SISI -ALT -ABLB -Stenger -Stenger Speech -High Frequency	SISI, ALT, ABLB, Stenger, Stenger Speech and High Frequency are not available	SISI, ALT and High Frequency are not available. ABLB, Stenger and Stenger Speech are available.	SISI, ALT and High Frequency are available. ABLB, Stenger and Stenger Speech are not available.
2 identical channels	Yes	No	Yes
Dimensions (LxWxH)	37.6x26.4x7.3 cm	36x26x10 cm	50x39x32 cm
Weight	1.15 kg	1.8 kg	8.7 kg
Power Supply	External, 100-240 V	External, 100-115 V or 230 V	Internal Power Supply
Power Consumption	15 W	40 W	90 W
Attenuator Controls	1 HL rotary control for test signal intensity and 1 HL rotary control for masking intensity	1 HL rotary control for channel 1 and 1 HL rotary control for channel 2	- 2 independent HL rotary controls for test signal and masking intensity -push buttons that allows intensity step size of 1, 2 or 5 dB

Table 2c Differences between SA202 and Interacoustic AD229b and GSI 61

Comparison Parameter	**SA202**	**Interacoustic AD229b**	**GSI 61**
Masking -White Noise -Routing of masking	White Noise and Routing of masking not available	White Noise available. Routing of masking not available	White Noise and Routing of Masking available
Frequency Selection	Any frequency can be deselected	125, 250, 750, 1500 Hz or 8kHz can be deselected	No frequency can be deselected
Tone Presentation -Reverse Tone	Not Available	Available	Available
Routing possibilities	No routing possibilities	No routing possibilities	Routing possibilities available
High Frequency	Not Available	Not Available	Available at 9, 10, 11.2, 12.5, 14, 16, 18, 20 kHz
Digital Signal Generator	Yes	No	No
CF Card and Calibration Card	Yes	No	No
Display audiograms on Front Display	No	No	Yes
Compatible Windows Software	AudiMax II	OtoAccess™ Database and diagnostic modules software PrintView, Interacoustics database and diagnostic modules, NOAH	Audi-Link Audiometer driver for NOAH
Internal Memory for full speech curve	Not Available	Available	Available
Tests -SISI -ALT -ABLB -Stenger -Stenger Speech -High Frequency	SISI, ALT, ABLB, Stenger, Stenger Speech and High Frequency are not available	SISI, ALT and High Frequency are not available. ABLB, Stenger and Stenger Speech are available.	SISI, ALT and High Frequency are available. ABLB, Stenger and Stenger Speech are not available.
2 identical channels	Yes	No	Yes
Dimensions (LxWxH)	37.6x26.4x7.3 cm	36x26x10 cm	50x39x32 cm
Weight	1.15 kg	1.8 kg	8.7 kg
Power Supply	External, 100-240 V	External, 100-115 V or 230 V	Internal Power Supply
Power Consumption	15 W	40 W	90 W
Attenuator Controls	1 HL rotary control for test signal intensity and 1 HL rotary control for masking intensity	1 HL rotary control for channel 1 and 1 HL rotary control for channel 2	- 2 independent HL rotary controls for test signal and masking intensity -push buttons that allows intensity step size of 1, 2 or 5 dB

Table 2d Differences between SA201 and Interacoustic AD229b and GSI 61

Comparison Parameter	SA201	Interacoustic AD229b	GSI 61
Masking -White Noise -Routing of masking	White Noise and Routing of masking not available	White Noise available. Routing of masking not available	White Noise and Routing of Masking available
Frequency Selection	Any frequency can be deselected	125, 250, 750, 1500 Hz or 8kHz can be deselected	No frequency can be deselected
Tone Presentation -Reverse Tone	Not Available	Available	Available
Routing possibilities	No routing possibilities	No routing possibilities	Routing possibilities available
High Frequency	Not Available	Not Available	Available at 9, 10, 11.2, 12.5, 14, 16, 18, 20 kHz
Digital Signal Generator	Yes	No	No
CF Card and Calibration Card	Yes	No	No
Display audiograms on Front Display	No	No	Yes
Compatible Windows Software	AudiMax II	OtoAccess™ Database and diagnostic modules software PrintView, Interacoustics database and diagnostic modules, NOAH	Audi-Link Audiometer driver for NOAH
Internal Memory for full speech curve	Not Available	Available	Available
Tests -SISI -ALT -ABLB -Stenger -Stenger Speech -High Frequency	SISI, ALT, ABLB, Stenger, Stenger Speech and High Frequency are not available	SISI, ALT and High Frequency are not available. ABLB, Stenger and Stenger Speech are available.	SISI, ALT and High Frequency are available. ABLB, Stenger and Stenger Speech are not available.
2 identical channels	Yes	No	Yes
Dimensions (LxWxH)	37.6x26.4x7.3 cm	36x26x10 cm	50x39x32 cm
Weight	1.15 kg	1.8 kg	8.7 kg
Power Supply	External, 100-240 V	External, 100-115 V or 230 V	Internal Power Supply
Power Consumption	15 W	40 W	90 W
Attenuator Controls	1 HL rotary control for test signal intensity and 1 HL rotary control for masking intensity	1 HL rotary control for channel 1 and 1 HL rotary control for channel 2	- 2 independent HL rotary controls for test signal and masking intensity -push buttons that allows intensity step size of 1, 2 or 5 dB

6 Technical Design Differences between the SA204 and Predicates

6.1 Digital Signal Processor

The tone generator within the SA204 is a Digital Signal Processor. This might be different to the GSI 61 and the AD229b. Most audiometers operate by using an analog tone generator.
This may be a new way to produce a tone, at a certain frequency, within the field of audiometry. However the digital technique has been used within other competence areas for several years hence it is well-known and accepted (for example within computers, mp3-players, video-game consoles). Generating the frequency digitally is a modern way to produce a signal. The frequencies and SPL levels produced are such that they meet the demands of those described in the standard IEC 60645-1 and 60645-2.

6.2 CF Card and Calibration Card

The SA 201/202/203/204 uses a concept where part of the software necessary for operating the audiometer and calibrating the audiometer is stored on separate memory cards that can be attached and removed from the main board. These cards are here referred to as the Calibration CF Card and the CF Card. CF stands for Compact Flash. The CF Card contains the CPU and memory.

Traditionally EPROM has been used for control and storage of software version, set-up data, calibration data etc. Technically it is much more difficult to manipulate software on a CF Card than on an EPROM and hence the risks for unauthorized changes decreases when using the CF Cards.
Furthermore, by using one CF Card for calibration and another for operation of the audiometer, and restricting the access to the Calibration CF Card, the risk for calibration data being faulty/changed/altered is minimized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Entomed AB
c/o Charlotte Mattisson, Ph.D.
Quality Assurance and Regulatory Affairs
Bariumgatan 29
SE-213 64 Malmö
Sweden

OCT - 2 2009

Re: K092111
Trade/Device Name: Entomed SA201/202 Screening Audiometer and SA203/204 Diagnostic Audiometer
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: II
Product Code: EWO
Dated: July 10, 2009
Received: July 14, 2009

Dear Dr. Mattisson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092111

Indication for Use

510(k) Number (if known):

Device Name: Entomed SA201/202 Screening Audiometer and SA203/204 Diagnostic Audiometer

Indication For Use:

The Entomed SA 201/202/203/204 series of audiometers are screening and diagnostic audiometers used to determine hearing thresholds and assist to diagnose hearing loss.

The audiometer can be used on the majority of adults and children (from 4 years of age and upwards). The test person has to be able to understand the basic principles of the test method when explained by the operator.

Prescription Use ___x___ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K092111