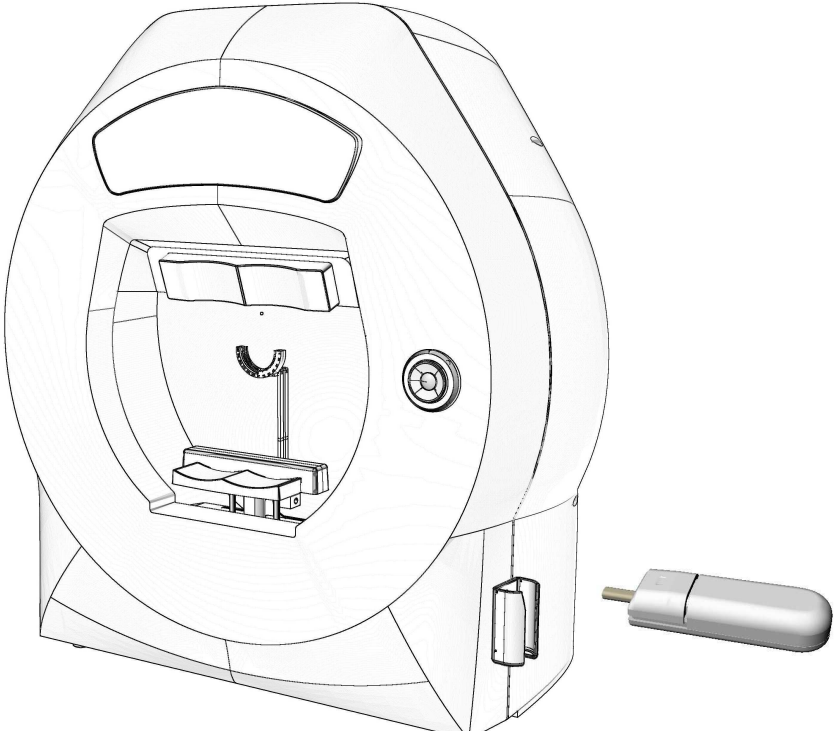


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	<b>AP-300 AUTOMATED PERIMETER</b> <b>SP-53.02</b>	Released: 2015-10-23

<b>Device name:</b>	AUTOMATED PERIMETER AP-300
<b>Models:</b>	AP-300; AP-3000 TOMEY; PERIMAT Rodenstock
<b>Manufacturer:</b>	FREY S.J. 05-502 Piaseczno ul. Wołodjowskiego 38 POLAND Tel: +48 22 397-86-09 E-mail: <a href="mailto:freymedical.eu">freymedical.eu</a> <a href="http://www.freymedical.eu">www.freymedical.eu</a>

<b>Drawing/Picture of the device:</b>	
---------------------------------------	---

<b>Product type:</b>	<input checked="" type="checkbox"/> Medical device
<b>Intended purpose:</b>	Examination of a retinal sensitivity to the light, in the visual field test for detection of a stimulus on a specified background.

#### PRODUCT CHARACTERISTICS

<input type="checkbox"/> disposable product	<input type="checkbox"/> disposable product	<input checked="" type="checkbox"/>	active product
<input checked="" type="checkbox"/> reusable product	<input type="checkbox"/> reusable product	<input type="checkbox"/>	non-active product
<input type="checkbox"/> product to multiple sterilization	<input type="checkbox"/> product to multiple sterilization	<input checked="" type="checkbox"/>	device with measurement function
<input type="checkbox"/> recyclable	<input type="checkbox"/> recyclable	<input checked="" type="checkbox"/>	accessories supplied with the device
<input type="checkbox"/> supervision of medical waste required	<input type="checkbox"/> supervision of medical waste required	<input type="checkbox"/>	accessories supplied separately
<input type="checkbox"/> leaflet required	<input type="checkbox"/> leaflet required	<input type="checkbox"/>	operating with combination with other device
<input checked="" type="checkbox"/> user manual required	<input type="checkbox"/> user manual required	<input type="checkbox"/>	product has an expiration date
<input type="checkbox"/> invasive device	<input checked="" type="checkbox"/> invasive device	<input type="checkbox"/>	product intended to be fully absorbed
<input type="checkbox"/> surgically invasive device	<input type="checkbox"/> surgically invasive device	<input type="checkbox"/>	the device contains a medicinal substance
<input type="checkbox"/> implantable device	<input type="checkbox"/> implantable device	<input type="checkbox"/>	the product contains animal tissue
<input type="checkbox"/> product for in vitro diagnostic	<input type="checkbox"/> product for in vitro diagnostic		

<b>EC Directive</b>	93/42/EEC
<b>Rule</b>	12

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<b>Class of the medical device:</b>	Class I Medical Device with measuring function. Justification: 1) Device is an active product. 2) Device is not invasive. 3) Patient contact time with the device is temporary (<60 min). 4) Device is used to determine the threshold sensitivity of the retina			
<b>UMDNS code</b>				
<b>TECHNICAL DATA</b>				
<b>1. Operating conditions</b>				
Ambient temperature:	+10° to +40° C			
Relative humidity:	30 to 85 %			
Atmospheric pressure:	700 to 1060 hPa			
Expecting lifetime:	10 years			
Operating mode:	<input type="checkbox"/> intermittent  <input checked="" type="checkbox"/> continuous			
<b>2. Technical data</b>				
Dimensions H/W/D	566 x 633 x 396 mm			
Weight	30kg			
Voltage	110-230 VAC 50/60 Hz			
Power consumption	Max 95W			
Fuses	2 x T 800mA			
Software	AP Perimeter – main application of the device; database management system Firebird (software to be installed on a computer)			
Measurement bowl	Part hemispherical Radius 300mm, integrated with diffusing surface. Materials: plastics (ABS), white			
Visual field extent	100°			
	Full 50°	164 points		
	Glaucoma 22°/50°	104 points		
	Central 30°	120 points		
	Central 22°	96 points		
	Wide 22°/30°	128 points		
	Peripheral 30° do 50°	72 points		
	Macula 10°	48 points		
	Driving 50°/80°	192 points		
Stimulus source	Front projection LED			
Stimulus color	White	Green	Blue	Red
Stimulus size	Goldmann size I (0,11°) Goldmann size II (0,22°) Goldmann size III (0,43°) Goldmann size IV (0,9°) Goldmann size V (1,8°)			
Stimulus intensity	0.03 asb to 10000 asb in 15 3dB or 36 1dB steps			
Exposure time	Adjustable: 0.1 to 9.9s			
Response time	Adjustable: 0.1 to 9.9s			
Inter test delay	Adjustable: 0.1 to 9.9s			
Background illumination	10asb (3.2 cd/m2), 31.5asb (10cd/m2), 315asb(100cd/m2), automatic control			
Fixation control method	Heijl-Krakau – blind spot method CCD camera			
Fixation monitor	Central: green; Other: red			
Test lens diameter	38 mm			
Patient chin rest	Electrically adjustable up/down and right/left			

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	material: plastics (ABS)
PC	Internal
Housing	Housing made of plastic (BAYDUR), color grey; elements of the housing (bottom plate) of aluminum.
<b>3. Accessories and supplies</b>	
Patient response button	54-16070.01; material: ABS
Operation Manual	54-11905.01
Warranty card	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
<b>INSTRUCTIONS / LABELING</b>	
Manufacturing Instruction	--
Service Manual	53-36818.rr; 53-36819.rr; 53-36826.rr; 53-36927.rr
Packing Instruction	53-76584.rr
Labelling	Device labels: 53-19084.rr; 53-19083.rr; 53-19080.rr; 53-19079.rr; 53-19078.rr Box labels: 53-12087.rr; 53-12091.rr; 53-12078.rr; 53-12076.rr

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QUALITY REQUIREMENTS										
Subject of control	Sampling				Method of control				Records	Proceedings in case of deviations
	Where?	Who?	Sample size	Frequency	What (parameter)?	Who?	How (method/standard)?	Requirements		
Component - housing	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Appearance	Devices assembler	Visual inspection	Plastic (PP) housing, grey, with no visible damage, scratches	Quality Control checklist	According to Procedure PR-03.YY 'Proceedings in case of quality deviations'.
Component - Measurement bowl	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Number, size and arrangement of holes	Devices assembler	Using templates 024/ 025;	Holes comply with templates.	Quality Control checklist	According to Procedure PR-03.YY
	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Appearance	Devices assembler	Visual inspection	Diffusion surface in white, with no visible flaws, damage and dirt	Quality Control checklist	
Component - Control Boards	Production - assembly	Devices assembler	Each piece	Each piece, before calibration	Microcontroller programming	Devices assembler	Verification using 009 flash programmer software	Microcontroller is programming properly, no error messages appear.	Quality Control checklist.	According to Procedure PR-03.YY
	Production - assembly	Devices assembler	Each piece	Each piece, before calibration	Controlling of stimulus and fixation LEDs	Devices assembler	Visual inspection	All LEDs appear during test	Quality Control checklist	
	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Backlight controlling; transmission of an image from the camera; chin-rest controlling	Devices assembler	Visual inspection	Backlight is working properly - brightens and darkens; Picture from CCD kamera is transmitted to a PC;	Quality Control checklist	
Component - Stimulus disc	Production - assembly	Devices assembler	Each piece	Each piece, before calibration	Geometry and cleanliness	Devices assembler	Visual inspection	- Disc filters and holes edges clean for all sizes and colors of stimulus; - Regular round shape of holes, sizes in accordance to specifications	Quality Control checklist	According to Procedure PR-03.YY

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QUALITY REQUIREMENTS										
Subject of control	Sampling				Method of control				Records	Proceedings in case of deviations
	Where?	Who?	Sample size	Frequency	What (parameter)?	Who?	How (method/standard)?	Requirements		
Componenet - Projection module (complete)	Production - assembly	Devices assembler	Each piece	Each piece, before calibration	Appearance; lighting	Devices assembler	Visual inspection	No flaws or damage on the lens of a LED. - Color temperature of the LEDs in accordance with the specification	Quality Control checklist	According to Procedure PR-03.YY
	Production - assembly	Devices assembler	Each piece	Each piece, before calibration	Mechanism of module  LED calibrated properly - lits with proper luminance.	Devices assembler	Visual inspection  Using the measuring instrument 001 (002), according to the calibration manual	- mechanism of projection unit running smoothly, without any popping noises or creak - movement limit detectors are working properly  - LED brightness comply with the requirements contained in the Calibration manual.		
Component - Chin rest	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Appearance; moving up – down and left – right; home procedure	Devices assembler	Visual inspection	- mechanism runs smoothly in both axes, - movement limit detectors are working properly - no scratches, blemishes and mechanical damage.	Quality Control checklist	According to Procedure PR-03.YY
Component – Forehead support	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Appearance; moving left – right; home procedure	Devices assembler	Visual inspection	- mechanism runs smoothly left - right - movement limit detectors are working properly - no scratches, blemishes etc.	Quality Control checklist	According to Procedure PR-03.YY

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QUALITY REQUIREMENTS										
Subject of control	Sampling				Method of control				Records	Proceedings in case of deviations
	Where?	Who?	Sample size	Frequency	What (parameter) ?	Who?	How (method/standard)?	Requirements		
Component CCD Camera	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Picture quality	Devices assembler	Visual inspection	Camera picture with the correct focus, lack of blemishes and defects on the sensor or lens.	Quality Control checklist	According to Procedure PR-03.YY
Component - Housing	Production - assembly	Devices assembler	Each piece	Each piece, before using for assembly	Appearance	Devices assembler	Visual inspection	Plastic (PP) housing, grey, with no visible damage, scratches	Quality Control checklist	According to Procedure PR-03.YY

Finished product	Production - assembly	Quality inspector	Each piece	Each device, before approving for release	Functional test with AP Perimeter software (LED test and patient's exam performed)	Devices assembler	According to Manufacturing instruction.	All functions of the Perimeter area working properly: - stimulus LED - fixation LED - backlight - chin rest moving - patient response button - CCD camera; - digital eye tracking - test static perimetry exam - test kinetic perimetry exam	Quality Control checklist	According to Procedure PR-03.YY
	Production - assembly	Quality inspector	Each piece	Each device, before approving for release	Electrical Safety Test	Devices assembler	According to Manufacturing instruction. <b>Electrical Safety Test example attached.</b>	Device is successfully passing a test using tester 005 (SECUTEST SIII)	Quality Control checklist	According to Procedure PR-03.YY
	Production - assembly	Quality inspector	Each piece	Each device, before approving for release	Cleanliness and appearance	Devices assembler	Visual inspection	Device clean, without blemishes and dirt	Quality Control checklist	According to Procedure PR-03.YY
	Production - packing	Quality inspector	Each piece	Each device, before approving for release	Labeling and packing.	Devices assembler	Visual inspection	Device properly labeled (name plate, serial number); accessories	Quality Control checklist	According to Procedure PR-03.YY

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							attached to the device, device properly packaged, labeled with box labels - in accordance with packing instruction.		
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<b>STANDARDS</b>	
Harmonized: EN 60601-1:2006 + A11:2011 + A1:2013 EN 60601-1-2:2007 EN 62304:2006/AC:2008 EN ISO 10993-1:2009 EN ISO 14971:2012 EN 980:2008 Other: EN ISO 12866:1999/AC:2000	
<b>REGULATORY</b>	
Essentials Requirements compliance checklist	53-53011.02
Risk Analysis	53-53012.03
Clinical evaluation	OK-01.02
Declaration of Conformity (template)	F-31.01
EC Certificate of Conformity	1443-MDD-15/2015

#### 4. Attachements

- Electrical Safety Test report - example

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*Electrical Safety Test report (example); test performed for each unit before release.*

Date ;25.08.11  
 ID-No. ;PHDA0034  
 Regulation ;EN 60601  
 Type ;AP-250  
 Protective class ; I  
 Applied part ; (B)

Visual control ;[ ] ;00

Safety measurement	; measured	; limit	; failed
		;NB ;SL	
Protective earth resistance	; +0.067 Ohm	; <0.100 Ohm	; [ ]
Insulation resistance	; >+310.0 MOhm	; >2.000 MOhm	; [ ]
Test voltage	; +0521 V	; +0500 V	
High voltage test	; +01.53 kV	; +01.50 kV	; 0
Earth leakage current	; +0.015 mA	; <0.500 mA	; [ ]
Earth leakage current SFC	; +0.032 mA	; <1.000 mA	; [ ]
Housing leakage current	; +000.0 µA	; <0.100 mA	; [ ]
Housing leakage current SFC	; +000.0 µA	; <0.500 mA	; [ ] [ ]
Patient leakage current AC	; +000.0 µA	; <0.100 mA	; [ ]
Patient leakage current AC SFC	; +000.4 µA	; <0.500 mA	; [ ] [ ]
Patient leakage current DC	; +000.0 µA	; <10.00 µA	; [ ]
Patient leakage current DC SFC	; +000.0 µA	; <050.0 µA	; [ ]
Residual current	; +0.014 mA	; <03.50 mA	; [ ]
Nominal voltage	; +253.0 V		

Function test  
 Current I max ; +00.15 A  
 Power P max ; +0026 W  
 Voltage U min ; +228.1 V

Tester ;Secutest SIII A00 D00  
 Sr.-No. ;OC 426600 0001

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