



K963079

CANON U.S.A., INC.
ONE CANON PLAZA
LAKE SUCCESS, NY 11042-1198
TELEPHONE: (516) 328-5000
GENERAL FAX TELEPHONE
(516) 328-5069

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510(k) Summary

- 1. Date Prepared:** July 23, 1996
- 2. Applicant's Name:** Canon USA, Inc.
One Canon Plaza
Lake Success, NY 11042
U.S.A.

Mr. Glenn Impal / Mr. Ken Shadoff
Phone: (516) 328-5600
Fax: (516) 328-5169
- 3. Model Name:** Canon TX-10 Tonometer
86HKX, Tonometer, AC Powered
Document Control Number: ?
- 4. Predicate Model:** Canon T-2 Tonometer
86HKX, Tonometer, AC Powered
Document Control Number: K943939
- 5. Device Description:** The TX-10 is a tonometer designed using a non-contact measurement system. Air puff gently measures the intraocular pressure with the help of an auto-alignment system. Features quick and easy measurement that does not require any special skills.
- 6. Intended Use:** The TX-10 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.
- 7. Summary of Technological Characteristics:** See the attached comparison chart.
- 8. Assessment of Performance Data:** See Attachment 1

Comparison in the measurement accuracy among Canon TX-10 and Canon T-2

	TX-10	T-2	ISO Specifications (proposed)
Regression Slope	0.996	0.907	0.95 to 1.05
Regression Y intercept	0.462mmHg	1.08mmHg	-1.0 to +1.0
Standard Deviation of Difference, Sd	1.56mmHg	2.12mmHg	2.5mmHg
Coefficient of Correlation	0.926	0.858	Unspecified

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ATTACHMENT
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CANON TONOMETERS COMPARISON CHART

MODEL		CANON NON CONTACT TONOMETER T-2	CANON TONOMETER TX-10
Specifi- cation	Measuring Range Setting	0~30/0~60mmHg (Automatic)	Same as T-2
	Alignment Method	One bright dot with alignment level display	Auto Mode Monitor and auto fine alignment
			Manual Mode Monitor with two dots
	Increment	1 mmHg	Same as T-2
	Measuring Time	3 millisecond (0.003 second)	Same as T-2
	Fixation Target	LED (green)	Same as T-2
	Chin Rest	Manual	Power assisted (driving at controller)
Safety Mechanism		Mechanical Stopper	Software Controlled Stopper
Printout Format		R/L, date, time, avarage, ID, 3 or 10 data for each eye	Same as T-2
Display		5" (inch) B/W CRT	4" (inch) Color LCD
Dimentions (width x depth x height) mm		286 x 445 x 472	Body 299 x 340 x 177
			Controller 170 x 183 x 177
Weight (kg)		22.0	Body 16.0
			Controller 1.5