TEST RESULTS
Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The mg/dL measurement is a US version, while mmol/L is used in many countries around the world. The analyzer is preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see the analyzer User Guide.

QUALITY CONTROL
Please refer to the analyzer User Guide for the proper procedure and materials to be used to perform Quality Control tests. Quality Control tests are used to ensure that the system (analyzer, strips, and MEMo Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility's quality control requirements.

EXPECTED VALUES
Blood cholesterol levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise.
The expected or reference ranges recommended are as follows from the US National Cholesterol Education Program (NCEP) 2001 Guidelines:[7]
Cholesterol (Total) Expected Values
• Below 200 mg/dL (5.18 mmol/L) – desirable
• 200-239 mg/dL (5.18-6.20 mmol/L) – borderline to high
• 240 mg/dL (6.21 mmol/L) and above – high
A healthcare professional will discuss values that are specifically appropriate for each patient. At least two measurements of cholesterol on separate occasions should be made before a medical decision is made, since a single reading may not be representative of a patient's usual cholesterol concentration. An elevated cholesterol level is only one risk factor for heart disease. There are many others. A cholesterol level less than 200 mg/dL is desirable. ALWAYS CONSULT A HEALTHCARE PROFESSIONAL BEFORE MAKING ANY CHANGES IN TREATMENT PLANS OR MEDICATION.

MEASURING RANGE
The cholesterol test system will detect cholesterol levels from 100-400 mg/dL (2.59-10.36 mmol/L) and will display a number value for results in this range. If the display reads "LOW" or "<___" (less than measuring range), the cholesterol level is below 100 mg/dL (2.59 mmol/L). Results above 400 mg/dL (10.36 mmol/L) will read "HIGH" or ">___" (greater than measuring range). If a "LOW", "HIGH", "<" or ">" result is displayed, always test again.

LIMITATIONS OF THE PROCEDURE
1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and Heparin do not interfere with the test. Fingerstick whole blood is the specimen of choice.
2. NEONATAL USE: This product has not been tested using neonatal blood. Until testing is done this test system should not be used on neonatal blood samples.
3. METABOLITES: Reducing substances such as Vitamin C may falsely decrease the test result.
4. HEMATOCRIT: Hematocrit values above 50% or lower than 30% may incorrectly lower the cholesterol result.
5. Bilirubin up to 20 mg/dL and hemoglobin up to 200 mg/dL do not interfere.

PERFORMANCE CHARACTERISTICS
1. ACCURACY: A clinical study was performed by healthcare professionals who measured cholesterol levels on fresh capillary blood specimens from 125 persons. The results below show that the Cholesterol Test Strips compare well to a reference cholesterol method that is correlated to the "Abell-Kendall Method". The performance of the Cholesterol Test Strips have been determined by a network laboratory (Cholesterol Reference Method Laboratory Network) to meet both accuracy and precision requirements recommended by the NCEP. This certification is issued through the Centers for Disease Control.
   PTS PANELS Cholesterol vs. Reference Method
   Number of patients = 125
   slope = 1.01
   y-intercept = -1.83
   r = 0.91

Two hundred three (203) persons stuck their own finger and tested their cholesterol. In these studies 4.4%, or 9 patients obtained false negative (incorrectly low results). About 23% of the patients obtained results that were incorrectly high (false positives).

2. PRECISION: Twenty replicates of various levels of whole blood were tested for cholesterol. The following results were obtained:

No. of Samples	20	20	20	20
Mean Cholesterol Conc. (mg/dL)	105	154	230	262
Std. Deviation (mg/dL)	2.54	3.72	6.61	7.67
Coefficient of Variation (%)	2.42	2.41	2.88	2.92

This means that the variation between strips is less than 3%.

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1711	PTS PANELS Cholesterol Test Strips – 25 Tests
1712	PTS PANELS Cholesterol Test Strips – 6 Tests
1790	PTS PANELS Cholesterol Test Strips – 3 Tests
730/1709	CardioChek Analyzer
1708	CardioChek P•A Analyzer
0721	PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2

CLIA INFORMATION (US only)
Complexity Categorization: Waived

REFERENCES

1. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor,. W.B. Saunders Company, Philadelphia, 1991.
3. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
4. NCCLS Tentative Guideline EP7-T. Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
5. National Cholesterol Education Program. Report of expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. National Heart, Lung and Blood Institute, NIH, Bethesda, MD, Arch. Int. Med., 148:36-69 (1988).
6. NCCLS. User evaluation of precision performance of clinical chemistry devices: tentative guidelines. 1984:2(1):1-48.EP5-T.
7. National Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001.

CUSTOMER SERVICE
Customer Service is available to answer questions regarding the CardioChek brand analyzers and PTS Panels Test Strips. Outside Customer Service hours, please contact your healthcare professional.

(877) 870-5610 (8 a.m. – 5 p.m. EST, M-F toll-free inside the USA)
(317) 870-5610, FAX 1 (317) 870-5608
E-mail inforequest@cardiochek.com

The CardioChek brand analyzers and PTS PANELS Test Strips are manufactured in the US by Polymer Technology Systems, Inc., Indianapolis, IN 46268.

CE 0197

AUTHORIZED EUROPEAN REPRESENTATIVE
per IVDD 98/79/EC
MDSS GmbH
D-30163 Hannover
Germany

Explanation of Symbols

	Use By/ Expiration date	REF	Catalog number
LOT	Batch Code/ Lot number		Consult instructions for use
IVD	For in vitro diagnostic use		Manufacturer
CE 0197	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.		Store at/Temperature limitation