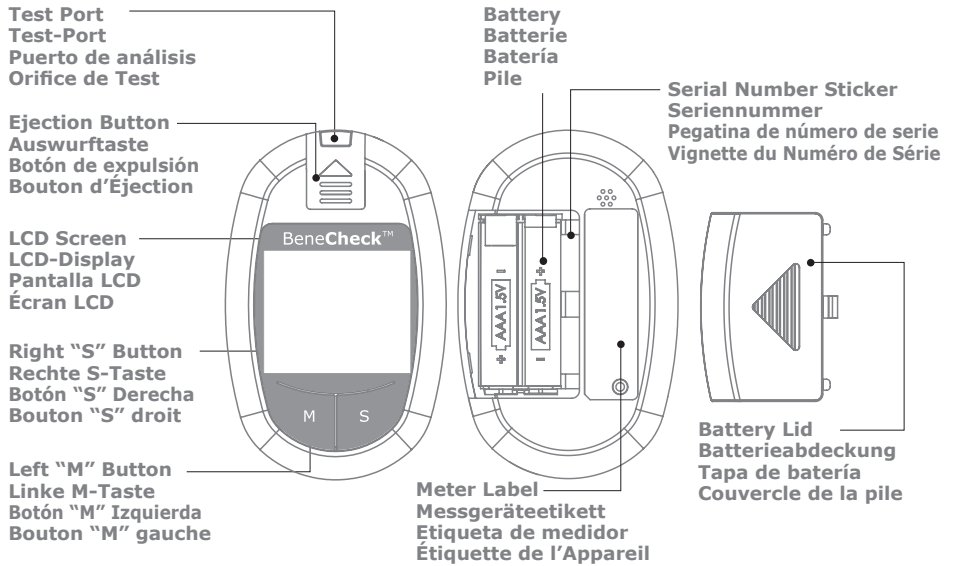
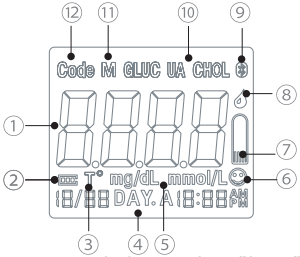
BeneCheck Meter Kit Meter (Front Side & Back Side) / **BeneCheck Messgerät** Messgerät (Vorderseite & Rückseite) / **Kit Medidor BeneCheck** Medidor (Parte delantera y parte trasera) / **Kit de l'Appareil BeneCheck** Appareil (Face Avant et Face Arrière)



LCD Screen Display: Information and test result display
LCD-Displayanzeige: Anzeige von Informationen und Testergebnissen
Visualización de pantalla LCD: Visualización de información y resultados de prueba
Affichage de l'Écran LCD: Affichage de l'information et du résultat de test



Alert Tones: • Normal Alert: a short "beep"
• Warning Alert: 3 short "beeps"
• Turning On/ Off: a long "beep"

Alarmtöne: • Normaler Alarm: ein kurzer "Piep"
• Warnalarm: 3 kurze "Piepser"
• An-/Ausschalten: ein langer "Piep"

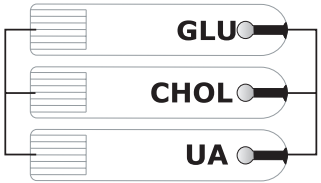
Tonos de alerta: • Alerta normal: un pitido corto
• Alerta de advertencia: 3 pitidos cortos
• Encender/ Apagar: un pitido largo

Tonalités d'Alerte : • Alerte Normale: un "bip" court
• Alerte de Mise en Garde: 3 "bips" courts
• Marche/ Arrêt: un "bip" long

① Result Area / Messergebnisse/ Zona de resultado/ Zone du Résultat
② Low Battery / Schwache Batterie / Batería baja / Batterie Faible
③ Temperature Icon / Temperatursymbol / Icono de temperatura / Icône de Température
④ Average (GLU) / Durchschnitt (GLU) / Media (GLU) / Moyenne (GLU)
⑤ Unit Icon / Einheitssymbol / Icono de unidad / Icône d'Unité
⑥ System Check, Data upload successful / Systemüberprüfung, Daten-Upload war erfolgreich / Control del sistema, Subida de datos correcta / Vérification du Système, Téléchargement des données réussi
⑦ Strip Loading Icon / Streifenbeladungssymbol / Icono de tira cargando / Icône de Chargement de la Bandelette
⑧ Blood Loading Icon / Blutentnahmesymbol / Icono de sangre cargando / Icône de Chargement du San
⑨ Bluetooth on / Bluetooth an / Bluetooth activado / Bluetooth activé
⑩ Test Mode Icon / Testmodussymbol / Icono de modo de prueba / Icône de Mode de Test
⑪ Memory Mode Icon /Speichermodussymbol / Icono de modo de memoria / Icône de Mode Mémoire
⑫ Code Number Icon / Codenummersymbol / Icono de código numérico / Icône de Numéro de Code

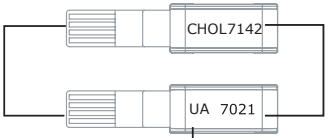
Test Strip / Teststreifen / Tira reactiva / Bandelette de Test:
GLU (GDH-FAD)- Glucose / Glucose / Glucosa / Glucose
CHOL- Total Cholesterol / Gesamtcholesterin / Colesterol Total / Cholestérol Total
UA- Uric Acid / Harnsäure / Ácido úrico / Acide urique

Electronic Contact Bars
Elektronische Kontaktleisten
Rodillos de contacto electrónicos
Barres de Contact Electroniques



Sample Inlet
Probeneinlass
Entrada de muestra
Entrée de l'échantillon

Code Strip: Contact Bar
Code-Streifen: Kontaktleiste
Código de tira: Rodillo de contacto
Bandelette de Code: Barre de Contact



Code
Code
Código
Code

Test Mode
Testmodus
Modo de prueba
Mode de Test

Labelling and Information / Etikettierung und Informationen / Etiquetado e información/ Etiquetage et Information

• Use by • Verwenden bis
• Fecha de caducidad • Utiliser avant

• Manufactured by • Hersteller
• Fabricado por • Fabriqué par

• Do not re-use • Nicht wiederverwenden
• No reutilizar • Ne pas réutiliser

• Keep dry • Trocken halten
• Mantener seco • Garder au sec

• Keep away from sunlight
• Vom Sonnenlicht fernhalten
• Mantener alejado de la luz solar
• Conserver à l'abri de la lumière

• Read instructions • Anweisungen lesen
• Leer instrucciones • Lire les instructions

• Caution, consult accompanying documents
• Vorsicht, Begleitdokumente lesen
• Cuidado, consulte los documentos adjuntos
• Attention, consulter les documents joints

• EU Representative • EU Repräsentant
• Representante UE • Représenté dans l'UE

• Comply with WEEE Directive 2012/19/EU
• Entspricht der WEEE Richtlinie 2012/19/EU
• Eento con la Directiva WEEE 2012/09/EU
• Conforme à la Directive DEEE 2012/19/EU

• *In-vitro* diagnostic • *In-Vitro*-Diagnostik
• Diagnóstico *in vitro* • Diagnostic *In-vitro*

• Lot number • Chargennummer
• Número de lote • Numéro de lot

• Date of Manufacture • Herstellungsdatum
• Fecha de fabricación • Date de fabrication

• Serial number • Seriennummer
• Número de serie • Numéro de série'

• Operation temperature limitation
• Temperaturbegrenzung Arbeitsbereich
• Límite de temperatura de funcionamiento
• Température de Fonctionnement Limitée

• Storage & Transportation Condition
• Temperaturbegrenzung Lagerung und Transport
• Condiciones de almacenamiento y transporte
• Condition de Transport et de Stockage

• Storage & Transportation Relative Humidity
• Lagerung & Transport Relative Luftfeuchtigkeit
• Humedad relativa de almacenamiento y transporte
• Humidité Relative pour le Transport et le Stockage

• CE certification • CE Zertifikat
• Certificado CE • Certification CE

EN

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Chapter 1 Introduction

Introduction

Please read carefully before using meter kit, and consult healthcare professional before making any important medical decision. Please contact your local customer service for further assistance with the product.

Normal Environmental Conditions

This meter designed under the following conditions:

- Indoor use
- Overvoltage category II
- Pollution degree 2

Electromagnetic Compatibility

This meter meets the electromagnetic compatibility, emission, and immunity, and the requirements of IEC 61326-2-6, ISO 18113-5 and IEC 61010-1.

Intended Use

- *In vitro* diagnostic use only.
- Do not inhale or swallow
- Measuring blood glucose in fresh capillary whole blood from fingertip, palm, or forearm/ venous blood /arterial blood.
- Measuring total cholesterol/ uric acid in fresh capillary whole blood from fingertip.
- The meter can be used by laypersons or healthcare professionals.

Principles of the Examination Method

- Electrochemical biosensor technology.

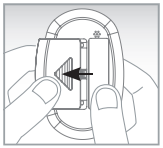
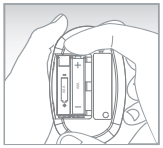
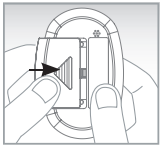
The meter is plasma-calibrated by reference instruments, which are traceable to the following standard reference materials and methods.

Test	Standard	Method
Glucose	NIST SRM 917	Glucose Dehydrogenase
Total Cholesterol	NIST SRM 911	Abell / Kendall
Uric Acid	NIST SRM 913	Uricase / UV

Chapter 2 Setting the Meter

2.1 Installing/ Replacing the Batteries

This meter uses AAA battery * 2. Please remove the plastic tab under the battery before using. **Note:** Dispose the batteries according to your local environmental regulations.

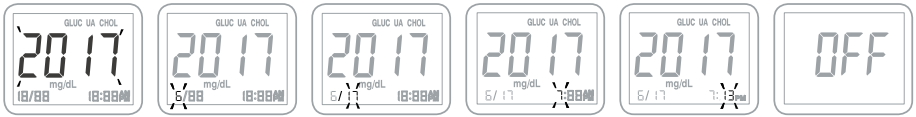
1  2  3 

2.2 Set the Date and Time

Press "S" Button (3 secs) → One "Beep" Sound → Setting Mode → Turn Off Automatically after Setting

- Setting order: Year/ Month/ Date/ Hour/ Minute
- Press "M" button to advance one unit, "S" button to enter next setting.

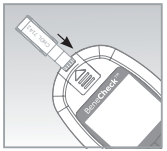
Note: Correct setting is important while managing your health records.

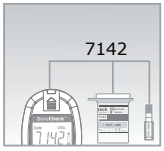


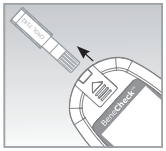
2.3 Code the Meter (Total Cholesterol/ Uric Acid)

- Code your meter when you first use it or open a new vial of strips.
- Make sure the meter is off before you insert the code strip.

• Make sure the codes on screen, code strip, and strip vial label are the same.

1 

2 

3 

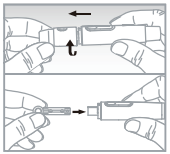
Note: With Auto Strip Recognition function, once you code your meter, the meter will switch to the test mode automatically when you insert a strip.

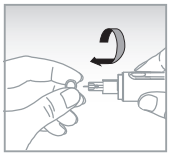
Chapter 3 How to Perform a Test

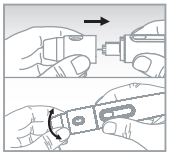
Materials you need to perform a test:
BeneCheck Meter/ BeneCheck Test Strip/ Lancing Device/ Lancets/ Tissue or Cotton Ball with 75% Ethanol or Disinfection Wipes

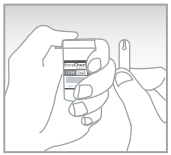
3.1 Perform the Test

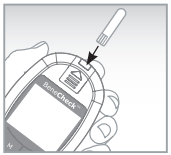
• Wash and clean your hands with disinfection wipes, and make sure your hands are dry before testing.

1 
Insert lancet firmly.

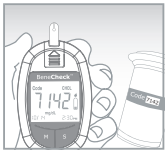
2 
Remove and save the protective cap.

3 
Recap lancing device and adjust penetration depth.

4 
Take a strip and close the vial immediately.

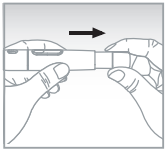
5 
Insert the strip.

6



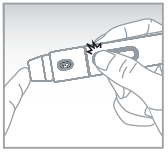
Make sure the code number is correct.

7



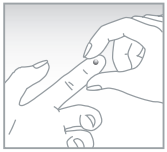
Pull the sliding barrel till it clicks.

8



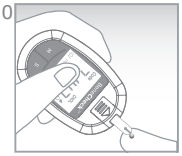
Press the release button to sample.

9

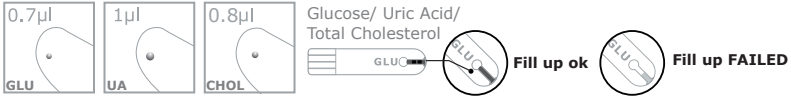


Wipe off first drop of blood and start sampling.

10



Touch the blood sample with strip.



Note: Insufficient fill up of blood sample could lead to inaccurate or failed test result. Do not refill the test strip.

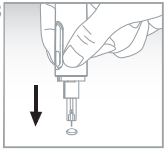
11

Result will show after countdown. Then eject the used strip to biohazard container.

12

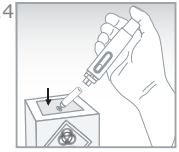
The meter will turn off automatically.

13



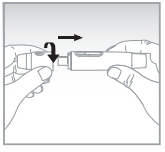
Pierce used lancet into protective cap.

14



Discard used lancet to biohazard container.

15



Recap lancing device and storage.

Note: Please refer to Lancing Device Instructions for detail procedure.

Note:
- Please finish the test within 3 minutes or the meter will turn off automatically.
- The meter will not turn on if you insert the wrong end or wrong side of strip.
- Marked open date on new open strip vial, do not use expired strip.
- Dropping, bumping or other violent impact will damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning:
- Please follow local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other material that has been in contact with blood should be treated as potential biohazards.
- If user has infectious disease, the used test materials could be sources of infection.
- Lancets cannot be reused.
- Always use certified lancets to ensure safety.
- Keep the system away from children and pets.

3.2 Alternate Site Testing (AST)

You can test your glucose from fingertip, palm or forearm. Taking blood from palm or forearm could reduce the pain, but the glucose level changes faster. These differences may cause wrong medical decision.

Note: Please consult healthcare professional before AST sampling.

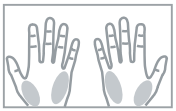
Suitable timing to acquire blood sample from alternate sites:
- Routinely before meal.
- Prior or 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.

DO NOT test from alternate sites:

- During or less than 2 hours after meal/ short-acting or rapid-acting insulin analogue/ exercise.
- When you think your glucose level is low or unaware of your low blood glucose condition.
- When you are examined for hypoglycemia or hyperglycemia.
- Your AST test result does not match your health condition.
- When you are ill, or you are operating machinery or driving a car.

Palm sampling

- No visible veins.
- Away from deep palm prints.



Forearm sampling

- Away from bones, visible veins and hair.

Sampling from an Alternative Site:

1. Repeat the steps 1-7 in Chapter 3.1.(Replace the lacing device tip with adjustable AST tip.)
2. Hold the lancing device against sampling site, and press the release button.
   Keep holding the lancing device against sampling site until sufficient sample formed.
3. Then repeat steps 10-15 in Chapter 3.1.

Note:

- Sampling from fingertip if your AST test result does not match your health condition.
- Repeat puncturing the same spot may cause soreness and calluses.
- Do not squeeze the site excessively. It may take longer for sufficient blood sample to form.
- Do not use smeared blood sample, please acquire new blood sample.
- If you continue failing in getting enough blood samples, please try to get lancets in lower gauge or sample from fingertip instead.

Chapter 4 Meter Memory Function

- Glucose - 360 results, capable in counting 7-, 14-, 21- and 28- days average
- Total Cholesterol - 50 results
- Uric Acid - 50 results

The latest test result will replace the oldest when the records exceed maximum memory capacity. The memories start record from M1 to M360 or M1 to M50, include test results and control solution test results.

Note: The control results are not included in the average.

Directions for Checking Memories:

No Test Strip in the Meter → Press "M" Button (3 secs) → A Short "Beep" → Enter the Memory Mode → Full Display on Screen → Press "M" Button to Switch Mode (GLUC/ CHOL/ UA) → Press "S" Button to Confirm → Press "S" Button for Next Test Record/ Press "M" Button for Previous Record → Press "M" Button (3 secs) to Turn Off

- In GLU memory mode, it will display 7-, 14-, 21-, 28- days average first.
- Once you enter one memory mode, you cannot switch. You need to turn off the meter (Press "M" button for 3 seconds) and enter the memory mode again.

Memory Records are shown as follows:

7-, 14-, 21-, 28-days average

Test Record

Control Record

Chapter 5 Control Solution Test

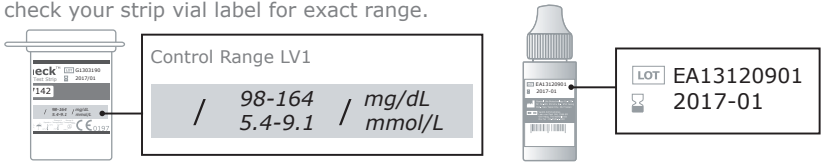
Control solution is used to check the performance of the kit.

The meter kit should be check:

- When the meter and strip do not work properly.
- When the test result is unusual or inconsistent.

Control solution range is shown as follow:

Please check your strip vial label for exact range.



Perform a Control Test:

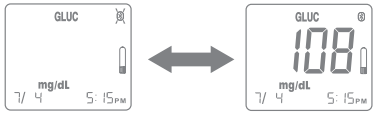
Insert an Unused Strip → Make Sure the Code Number is Correct (Total Cholesterol/ Uric Acid) → Press "M" Button (3 secs) → Enter Control Solution Mode (Shown CL on Screen) → Shake the Control Solution Well → Discard First Three Drops → Put One Drop onto a Clean Surface → Touch the Control Solution with Strip Sample Inlet → Test Result Display after Count Down → Compare the Result with the Range Listed on Test Strip Vial

Note:

- Do not reuse the test strip.
- Marked open date on new open control solution.
- Do not use the meter if the control test is out of range.
- If the control test keeps result wrongly, please contact an authorized distributor.
- Control solutions are not included. Please contact an authorized distributor for purchasing.

Chapter 6 Transmission Function

The meter provides Bluetooth transmission function. It can transmit test results to connected device wirelessly via Bluetooth.



The screen show " " means Bluetooth transmission function is working.

- The meter with Bluetooth 4.0 can apply to IOS, Android 2.3.3 and above.
- The meter complies with IEC 60601-1-2 and the relevant EMC (electromagnetic compatibility) and RF (radio transmission) requirements regulated by US Federal Communications Commission. The purpose of these requirements is to ensure that meter does not affect or being affected by other devices during operation.
- The meter and the transmission function may be interfered while other device is operating nearby. Ex: mobile phone, wireless internet, etc.
- If the transmission has been interfered. Please keep the meter away from the source of interference or turn off the interfering device.
- Please make sure the meter and the receiving device are placed within a reasonable distance (less than five meters) during transmission via Bluetooth.
- Please do not share the meter with other people if you are using Bluetooth transmission function. The test results from other people will also transmit to the receiving device, and it will influence your test record.
- The Bluetooth transmission function may not work on certain types of mobile phone due to the compatibility of Android systems.
- Frequency range: 2402 – 2480MHz. RF power: 3 dBm @ room temperature Typical.

Chapter 7 Care and Maintenance

7.1 Storing Your Meter and Strip

Meter:

- Avoid bump or violent behavior.
- Do not use in extremely dry environment. It may cause static discharges.
- Do not use under electromagnetic radiation, ex: electrical equipment.
- Do not disassemble the meter for any reason.
- No modification of this equipment is allowed.
- Keep meter clean by wiping the exterior appearance with tissues or lint-free cloth.
- Do not expose the meter under lint, dust, sunlight, heat or humid environment.

Strip:

- Do not store in high humidity environment, or expose directly to sunlight.
- Do not freeze or refrigerate the meter and strips.
- Keep your hand dry and clean while handing the strips and performing the test.
- Do not bend, cut or fold the strips.

7.2 Cleaning and Caring for Your Meter

Please use soft cloth slightly damp with one of the following solution to clean meter surface.

- 75% alcohol
- Super Sani-Cloth disposable wipes
- Mild dishwashing liquid with water
- 10% household bleach solution and 90% water

Note:

- Do not allow any other wet cloth or liquid.
- Do not allow any liquid run in or around the test port and battery cover.
- Make sure the meter is completely dry before use.
- Protection impairment if used in a manner not specified by the manufacturer.

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
	• Problem with code strip. • Problem with test strip. • Insert strip improperly.	Repeat the coding procedure (Chapter 2.3) and insert the strip again. If the problem persists, please contact local distributor for service.
	• Low battery.	Replace with new battery.
	• Problem with code strip or meter. • Insert code strip improperly.	Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.
	• Incorrect meter operating temperature.	Repeat the test after meter return to operating temperature. If the problem persists, please contact local distributor for service.
	• Used strip. • Damped strip.	Follow Chapter 3.1 and repeat the test with a new strip. If the problem persists, please contact local distributor for service.

	• Test incomplete due to removing the strip during measuring.	Follow Chapter 3.1 and repeat the test with a new strip. Do not remove the strip before the test is completed.
	• Improper code strip.	Repeat the coding procedure (Chapter 2.3). If the problem persists, please contact local distributor for service.
	• Sample volume not enough.	Repeat the test with a new strip, and make sure the sample volume is enough. If the problem persists, please contact local distributor for service.
	• Test result is higher than the range listed on Chapter 9.	Follow Chapter 3.1 and repeat the test with the same strip. If the problem persists, please contact local distributor for service.
	• Test result is lower than the range listed on Chapter 9.	Follow Chapter 3.1 and repeat the test with the same strip. If the problem persists, please contact local distributor for service.

Chapter 9 Specification

Test Sample	Fresh Capillary Whole Blood
Measuring Time	GLU:5 seconds; CHOL: 26 seconds; UA: 15 seconds
Measuring Range	GLU: 20-600 mg/dL (1.1-33.3 mmol/L); CHOL: 100-400 mg/dL (2.59-10.35 mmol/L); UA: 3-20 mg/dL (0.18-1.19 mmol/L)
Sample Volume	GLU: 0.7 μL; CHOL: 0.8 μL; UA: 1 μL
Storage & Transportation Condition	4-30˚C (39-86˚F)
Operation Temperature	10-40˚C (50-104˚F)
Storage & Transportation Relative Humidity	10-90%
Memory	460 Test Results (GLU: 360 ; CHOL: 50 ; UA: 50)
Battery Type	AAA battery * 2
Battery Life	Approximately 1,000 tests
Dimensions	95*60*20mm
Weight	71g (with battery)
Altitude	10,000 feet (3048 m)
Expected Service Life	5 years
Transmission Function	Bluetooth 4.0

Note:

- Please refer to the strip insert for accuracy, precision, limitation, and other important information.

Contents of the Kit (please check the meter outer box for exact detail)
- BeneCheck Supreme Multi-Monitoring Meter (BX-M00D) (with AAA battery * 2)
- User's Manual
- Quick Guide
- Pouch
- Lancing Device

Optional (not included in the standard kit package, please contact your local distributor for ordering)
- BeneCheck Supreme Glucose Test Strips (BK-SG1)(with Insert)
- BeneCheck Supreme Total Cholesterol Test Strips (BK-SC2)(with code card & Insert)
- BeneCheck Supreme Uric Acid Test Strips (BK-SU1)(with code card & Insert)
- BeneCheck III Glucose Control Solution
- BeneCheck II Total Cholesterol Control Solution
- BeneCheck Uric Acid Control Solution
- Lancets (Please refer to package for manufacture information.)

Note: After purchasing, if the contents are damaged, please contact authorized distributor immediately.

Electromagnetic Compatibility

This meter meets the electrostatic discharge immunity testing was basic standard IEC6100-4-2. In addition, the meter meets the electromagnetic emissions requirements as per EN61326. The purpose of these requirements is to ensure that meter does not affect or being affected by other devices during operation.

Warning:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. The BeneCheck Multi-Monitoring Meter may provide a description or list of equipment with which the BeneCheck Multi-Monitoring Meter has been tested in a stacked or adjacent configuration.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BeneCheck Multi-Monitoring Meter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC Statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.