

microCOUNT* LITE LIQUID SCINTILLATION COUNTER



(shown with optional printer)

OPERATING INSTRUCTIONS

Distributed by
Ballard Medical Products,
a wholly-owned subsidiary of:

Kimberly-Clark*

12050 Lone Peak Parkway
Draper, UT 84020 USA

801-572-6800 Fax:801-572-6869

Customer Service 1-800-528-5591

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INTRODUCTION

INTENDED USE

The microCOUNT* LITE Liquid Scintillation Counter was designed specifically for counting of PYtest* test ¹⁴C samples for the detection of the *Helicobacter pylori* (*H.pylori*) bacteria. For accurate results the instrument must be calibrated for each type of sample to be counted. Standards for PYtest* test (¹⁴C Urea Breath Test) are included with the microCOUNT* LITE counter. The microCOUNT* LITE counter is intended for use in areas without sources of penetrating radiation present, such as a physician's office or clinic. The microCOUNT* LITE counter can be used in areas with near-background radiation levels that do not vary. Kimberly-Clark has another microCOUNT* model (Reorder No 60491) which is intended for use in environments such as a nuclear medicine lab where sources of radiation may be present, or background radiation may vary.

GENERAL DESCRIPTION

The microCOUNT* LITE counter is a single-sample liquid scintillation counter. The unit is portable, weighing approximately 25 pounds. A constant efficiency calculated by the internal standard method is used since the efficiency of breath samples does not change significantly from sample to sample. The instrument is designed to be very easy to use, incorporating a Daily Quality Control (QC) program to ensure proper operation. The Liquid Crystal display (LCD) provides instructions to the operator, providing prompts during QC and counting procedures. Results are normally reported in disintegrations per minute (DPM).

The counter is equipped with a serial data port (RS-232) located on the rear of the unit. This port is designed to allow calibration and sample results to be sent to an external recording device such as a computer via the microWARE (Reorder No. 60493) computer interface or an optional printer (Reorder No. 60496).

GETTING STARTED

SYSTEM SET-UP

1. Remove the instrument from its package.
2. Place the instrument on a table or countertop.
3. Open the package which contains the power cord.
4. Remove the breath pump power cord and set aside with the breath pump.
5. Follow INSTRUCTIONS FOR EASY SETUP shown on front of instrument and are listed here along with some additional explanation shown in italics.
 - ☐ Plug power cable into the back of the instrument and into wall outlet
 - ☐ Push on/off switch on back of instrument to "ON" position.
 - ☐ (FIRST TIME ONLY) press "COUNT" button while instrument is turning on to load defaults and to change language and date/time. *It is best to hold down the count button while turning the power on.*
 - ☐ Follow instructions on screen.
Note: To set parameters, use the up and down arrows to change the value and COUNT to enter the value. After pressing the count the next parameter will appear on the screen. When the last parameter has been modified, the instrument will restart and the quality control procedure will be required.
6. If you have the optional microWARE software interface:
 - Turn off both the computer and the microCOUNT* LITE counter.
 - Plug the cable (provided) into the serial port of the microCOUNT* LITE counter located at the rear of the unit.

- Plug the other end of the cable into the serial port of the nearby IBM-compatible PC you will use to run microWARE. You may need to use the 9-pin to 25-pin converter included with microWARE to make sure it will connect to the instrument.
 - To set up the software, consult the microWARE user's guide.
7. If you have the optional printer:
 - Make sure both the printer and microCOUNT* LITE Liquid Scintillation Counter are turned off.
 - Plug the data cable (9-pin) into the serial port in the back of the counter.
 - If the cable is not already connected to the printer, plug the cable into the 25-pin connector located at the bottom of the printer.
 - If necessary, insert paper into the printer by lifting the top cover of the printer and dropping a roll of paper into the paper hopper. Thread the paper through the slot in the printer top cover and replace top cover.
 - Plug printer power cord into power point designated for the printer and located at the rear of the microCOUNT* LITE counter.
 - Turn printer on using power switch.
 - For more information on the printer, consult the printer user's guide.
 8. Perform the QC procedure by first sliding the sample tray (drawer) open. To slide the tray open, pull the chrome pull-ring to expose the white counting chamber. Caution: Slamming or yanking the sample tray can result in damage and void the warranty.
 9. Insert the background sample ("BKG" on top) from the Pytest* Standard Set into the counting chamber and push the sample tray in completely. Note that while the tray is open, "TRAY IS OPEN, CLOSE TRAY TO CONTINUE" will be displayed on the LCD.
 10. Press the COUNT button. "WAIT-DARK ADAPTING" will be displayed on the LCD while it is going through the 15-second dark adaptation procedure. When that period is over, the instrument will beep once to signal the initiation of counting.
 11. The instrument will count for 5 minutes. The sample activity in counts per minute (CPM) and the time remaining in the count will be updated frequently on the LCD.
 12. At the end of the 5-minute counting period, the instrument will beep 3 times. The background activity in CPM will be displayed and the user is prompted to insert the ¹⁴C Standard (vial from standard set with red circle and black "¹⁴C" on top)
 13. Swap the ¹⁴C standard for the background standard, close the sample tray and press count.
 14. The ¹⁴C standard will be counted for 5 minutes as was the background sample. At the end of the counting period, the instrument will display the results of the QC procedure (either QC OK or QC FAILED) including the background and efficiency values.

QUICK START BREATH SAMPLE ANALYSIS PROCEDURE

1. Make sure the microCOUNT* LITE counter has passed QC as described in the previous section. (Instrument does NOT have "QC NEEDED" displayed on the LCD.)
2. If QC has not been performed (indicated by "QC NEEDED" on LCD), do so as stated in the previous section.
3. Slide the sample tray out, insert the unknown sample (patient breath sample), and slide tray fully in.
4. Depress the COUNT button, wait for 5 minutes. Results will be displayed on the LCD panel (and on optional printer or PC) in disintegrations per minute (DPM).

DETAILED DESCRIPTION OF INSTRUMENT

INSTRUMENT SPECIFICATIONS

Efficiency and Background

Typical ^{14}C (Pytest* test breath sample geometry) efficiency: 40-60%

Typical background (with breath sample): 30-90 CPM

Electrical Requirements

Automatic switching 115VAC or 230VAC. Use a 200 volt-ampere (VA) Uninterruptible Power Supply (UPS) if there is any doubt about the quality of the wall voltage.

Dimensions

	Width	Height	Depth	Weight
MicroCOUNT*LITE Liquid Scintillation Counter	14.25 inches	6.5 inches	10 inches	25 lbs.

PRINCIPLES OF OPERATION

Units of radioactivity and counting efficiencies

Radiation is measured in units of activity or their derivatives. The units generally reported by instruments are counts per minute (CPM). This is the number of radiation events recorded by the instrument in one minute. This is not necessarily the number of events (decays) that actually occurred, but the number of events the instrument detected. The absolute number of radiation events that occur in a sample are referred to as disintegrations per minute (DPM). Some detectors are more efficient at detecting a given amount of radiation than others. By knowing the efficiency of the detection system, or the number of events detected by the instrument compared to the number that actually occurred, one can then convert CPM to DPM. To determine the efficiency of the detection system, a known amount of radioactivity (in DPM) is placed in front of the detector and the detector response is measured (in CPM). The ratio of CPM to DPM is then calculated and that ratio is the efficiency for that detector and that type of radiation source. Standardized reference sources are available to perform this type of an efficiency check.

During the daily QC procedure a representative background sample is counted and the Background CPM value is obtained and stored. When the ^{14}C standard is counted, the efficiency is calculated by dividing the number of CPM the microCOUNT* LITE counter obtains by the actual number of DPM in the sample. For instance, if the microCOUNT* LITE counter detects 10,000 CPM, and the standard is known to contain 20,000 DPM, then the counting efficiency for that sample configuration is $10,000/20,000 = 0.5$ or 50%. This value is obtained daily through the microCOUNT* LITE counter QC process and stored in memory. When counting unknown samples, the following formula is applied:

Equation 1. Calculation of disintegrations per minute (DPM)

$$DPM = \frac{(Sample_{CPM} - Background_{CPM})}{Efficiency}$$

Where:

*Sample*_{CPM} = CPM of unknown sample

*Background*_{CPM} = CPM of background sample counted in Daily QC procedure

Efficiency = efficiency of counter for breath test samples obtained during Daily QC procedure

For persons unfamiliar with radiation detection, the concepts of CPM, DPM, and efficiency can be rather confusing. The following is an attempt to describe these concepts.

Suppose you hold 10 marbles in your hand (10 DPM). Without your glasses, you see 6 marbles. Therefore, your counting efficiency is 6/10 or 60%. However, you know that your eyesight is not perfect and you use a correction factor (glasses) to be able to count or see all 10 marbles. So, with your glasses, you and a colleague who doesn't need glasses both see 10 marbles.

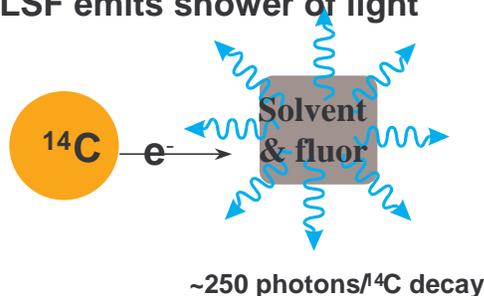
The microCOUNT* LITE Liquid Scintillation Counter typically "sees" 5/10 (50%) of the scintillation events in the Pytest* test sample. However, if we know that the efficiency is 50%, it can be accounted for. That's the purpose of the QC procedure, in which a sample of known activity and similar sample characteristics is counted and the efficiency is obtained. This efficiency is then applied to subsequent samples, such that if the instrument detects 4 CPM above background and the efficiency is 50%, then really there were 8 DPM in the sample. Feel free to work out the preceding example using Equation 1. The use of DPM versus CPM removes instrument and laboratory variability. Some instruments have higher counting efficiencies than others for a particular sample composition. Within reason, having a lower or higher efficiency than another instrument does not mean it performs any better than that instrument. As long as you know the counting efficiency of each, you will get the same result.

¹⁴C and the liquid scintillation counting process

Carbon-14 (C-14 or ¹⁴C) is a radionuclide commonly used for medical research and patient diagnosis. It has a half-life of 5760 years and emits one beta particle (energetic electron) per disintegration with a maximum energy of 165 keV. The most common system to detect the beta particles from ¹⁴C is the liquid scintillation counter (LSC). This method involves collecting the ¹⁴C on a medium such as the liquid converted from the breath expired during a ¹⁴C breath test or a filter paper wipe of a surface. The sample is then mixed with liquid scintillation fluid (LSF) in a glass or plastic scintillation vial. The beta particles emitted by the ¹⁴C interact with fluors in the fluid and produce light as shown in Figure 1.

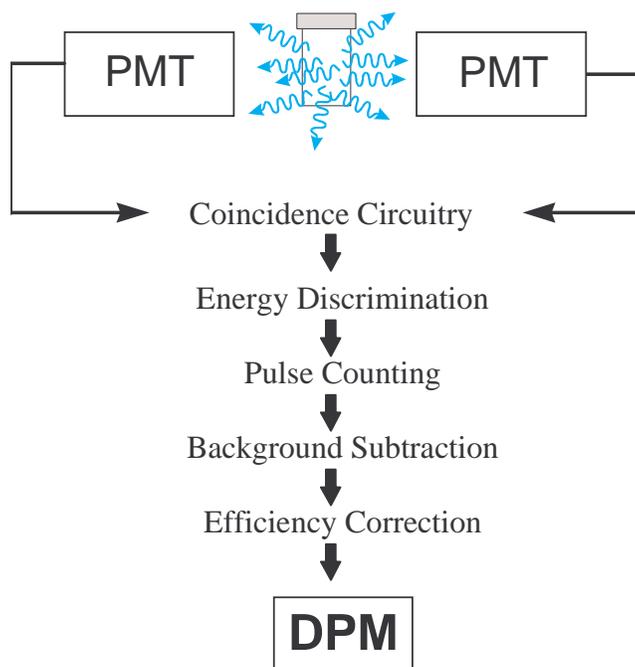
Figure 1: Interaction of ¹⁴C with LSF.

- **beta-particle (energetic electron) emitted from ¹⁴C in solution with LSF (solvent & fluors)**
- **beta-particle transfers energy to LSF**
- **Energetic LSF emits shower of light**



This light emitted from the LSF is measured and converted to electrical pulses by two light-sensitive detectors called photomultiplier tubes (PMTs). The pulses are counted by the instrument and the number of counts collected in a given period of time is directly proportional to the amount of radioactivity in the vial. The counting process is summarized in Figure 2.

Figure 2. Liquid scintillation counting process.



Liquid scintillation counting gives relatively high counting efficiencies unlike other types of radiation detection. Typical ^{14}C efficiencies using liquid scintillation counting are greater than 40%. When set up for unquenched samples, the microCOUNT* LITE Liquid Scintillation Counter can provide efficiencies greater than 80%. PYtest* test breath samples have significant quench, so the counting efficiency for them is less than the maximum. For most proportional flow or Geiger counters, maximum counting efficiencies are on the order of a few percent.

The microCOUNT* LITE counter is a single-sample liquid scintillation counter that is intended to count samples of a single configuration or “counting geometry.” This means that you would use it to count breath samples or radiation survey swipes but not 5 or 10 different sample types, all with different efficiencies.

The microCOUNT* LITE counter has a built-in QC program that stores a background level (in CPM) and an efficiency for a particular sample type. The system is designed so that the QC program must be run every day to ensure proper instrument operation. A standard set is included with the microCOUNT* LITE counter to perform this calibration. After counting the background and standard, the microCOUNT* LITE counter stores the background (in CPM) value and calculates the efficiency for the standard sample. Subsequent samples are then background-corrected and converted to DPM using the efficiency obtained through the daily QC program. The instrument is designed so that a constant efficiency will be applied since the efficiency of a given sample geometry will not vary significantly. Note that the default settings for the instrument utilize a 20,000 DPM standard. The PYtest* test standard set for use with the microCOUNT* LITE counter utilizes a 20,000 DPM standard, so no adjustment of the firmware is necessary. However, the instrument will allow use of a standard of activity other than 20,000 DPM, and **using a standard with a value other than 20,000 DPM can give an incorrect efficiency.** A standards set is included with the instrument for use in counting PYtest* test (^{14}C -urea) breath samples.

All results may be displayed through the display panel or an optional output device (printer or computer link). Data obtained with either device includes the sample DPM value, the time and date the measurement was taken along with other parameters such as background and efficiency.

YEAR-2000 (Y2K) COMPLIANCE

The microCOUNT* LITE Liquid Scintillation Counter is year-2000 compliant. The microCOUNT* LITE counter does not utilize dates in calculations. It does note when the date has changed so that the QC Needed message will come on and the QC procedure must be performed. To verify this, the microCOUNT* LITE counter clock was set at 12/31/1999, QC was performed, and a patient sample counted. The clock was then allowed to run until 01/01/2000. At that time the QC needed message came on as expected, and then QC was performed. The patient sample was then recounted in the microCOUNT* LITE counter and the results compared. As expected, the instrument performed equally well at both times.

Regarding the microWARE software, similar tests were performed with similar results. The microWARE does not use the date in any calculations, it only reports and records the date. The software is year-2000 compliant, however that is not to say that the computer running the software is year-2000 compliant. Kimberly-Clark makes no claims regarding the year-2000 compliance of host computers, only the microCOUNT* LITE counter, the microWARE and the optional printer.

PRECAUTIONS AND LIMITATIONS

1. Do not operate the microCOUNT* LITE counter in areas where penetrating radiation is higher than background (i.e. nuclear medicine departments, x-ray facilities, or near other sources of radiation). The microCOUNT* LITE counter is not designed to shield from these radiations, and they can interfere with results. We offer the original microCOUNT* (Reorder No. 60491) for facilities where radiation fields may be of concern. See the Troubleshooting section of this document or contact your Ballard representative for more information.
2. In order for the counter to operate, you must count a background and a standard containing a known amount of ^{14}C every 24 hours or when an instrument parameter is changed. The microCOUNT* LITE counter has an internal clock that is checked every time a sample count is initiated. The instrument will not operate if QC (Quality Control) has not been performed since midnight. The default activity for the standard is 20,000 DPM which matches the activity of the PYtest* Standard Set. Under normal use for the PYtest* test, no special modifications are necessary. A mismatch in instrument setup and standard activity may cause erroneous results. See the detailed instructions on instrument setup for more information. Standards are included with purchase of the instrument (but may be shipped separately).
3. Sample vials of the wrong size or shape, or standard vials with overhanging caps, may jam the sample tray or counting chamber. The counter is designed to receive a standard 20 mL scintillation vial with typical height dimensions of 58.5mm-63.0mm and a width of 26mm-28mm.
4. Static charges can build up on vials and cause errors in counting (erroneous high count rates). To avoid static buildup, especially in low-humidity environments, samples should be sprayed with an anti-static spray or wiped with a cloth containing anti-static materials.
5. The instrument is designed not to be sensitive to chemiluminescence, which is the product of chemical reactions that are perceived as radiation events. For counting PYtest* test samples, if a reading of 50-300 DPM is obtained initially, the sample should be re-counted to ensure chemiluminescence is not causing the result. Chemiluminescence will dissipate over fairly short period (minutes to hours). Once counts taken at least 30 minutes apart give similar results, chemiluminescence can be ruled out.
6. If the instrument is used in a manner other than described, the safety and performance of the instrument may be impaired. Kimberly-Clark takes no responsibility for use outside the parameters specified in this document.

HAZARDS

Electrical

The instrument should be operated from a supply source that incorporates a third-wire protective grounding conductor that conforms to local codes. Three- to two-wire isolation adapters should not be used. Without a third-wire earth ground, instrument operation may be unstable.

Radiation

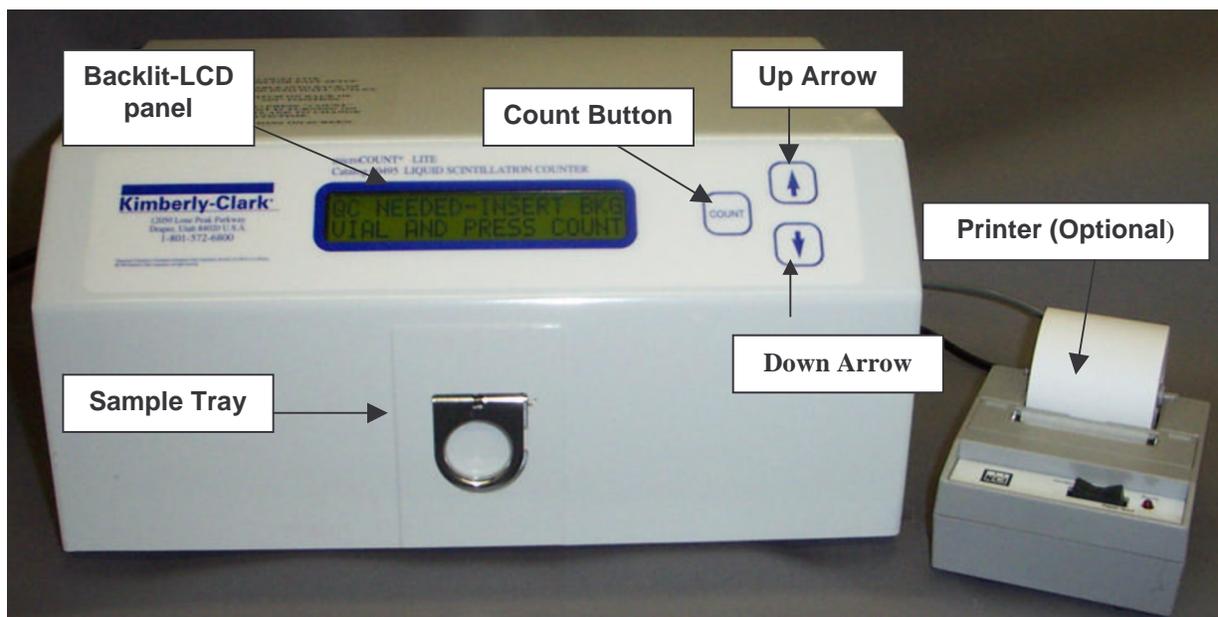
Although the level of radioactivity involved in liquid scintillation counting is minimal, there are hazards and correct procedures involved in the use of radioactive materials. Please contact your Radiation Health and Safety Officer for additional assistance.

If the instrument becomes contaminated with radioactive material, immediately contact your Radiation Health and Safety Officer and an Authorized Ballard Service Representative for assistance.

FRONT PANEL

The buttons, display and sample drawer on the front panel allow the user to perform various functions. They are described below and shown in Figure 3.

Figure 3. microCOUNT* LITE Liquid Scintillation Counter Front Panel.



Buttons

COUNT: This button initiates counting. To halt the counting cycle, depress the count button again. This prevents the user from interrupting the counting process early and getting a "quick" but possibly inaccurate result. When you interrupt a count, the "Ready" message will be displayed prompting the user to insert a vial and press the count button. Note that when the audio parameter is set to ON, that one beep signals the beginning of a count, and three beeps signal the end of the counting period.

UP ARROW/DOWN ARROW: These buttons allow the user to navigate through the menus during the setup procedure and change values. The Up Arrow increases a value while the Down Arrow decreases a value.

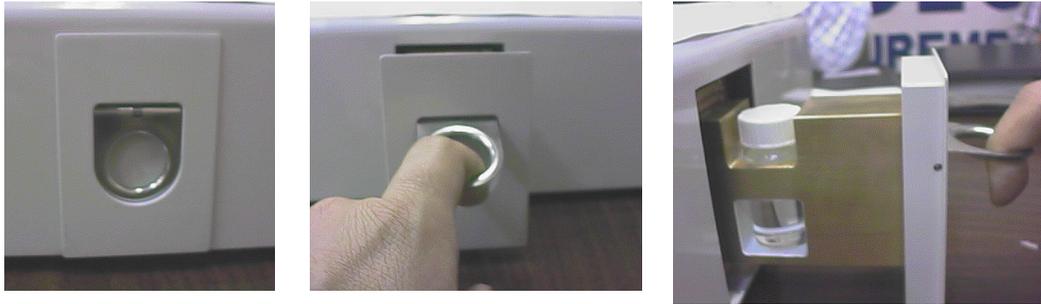
LCD Display

A liquid crystal display (LCD) is present on the front panel. The panel is backlit for low-light conditions and is capable of displaying 2 rows of 20 characters.

Sample Drawer

The sample drawer allows the user to change samples in the microCOUNT* LITE Liquid Scintillation Counter as shown in Figure 4.

Figure 4 . Sample drawer operation.



- p Caution** – Slamming or yanking the sample drawer can result in damage and void the warranty.

Notes on Operation

1. The efficiency and background values are or can be viewed on the LCD during most operations.
2. The unit will not count unless the sample chamber is fully closed, indicated by absence of “SAMPLE TRAY OPEN” message on LCD.
3. The unit needs to have QC performed every 24 hours (see procedure on page 14) or when a setup parameter is changed.
4. The unit may be left on continuously or turned off as desired. It does not have to be left on or off.
5. The display gives an estimate of the DPM (or CPM) until the counting time has been reached at which a final DPM result is displayed. The estimate is updated every few seconds.
6. Counting will not initiate until the dark adaptation period is over (normally 15 seconds). The instrument notifies the user via the LCD of this. Initiation of counting is identified by a single beep, and the termination of counting is identified by three beeps.
7. This instrument is not designed to be used in areas where radionuclides with penetrating emissions are used (i.e. nuclear medicine facilities, x-ray facilities, etc.). Kimberly-Clark offers the microCOUNT* Reorder No. 60491 for those facilities.

SYSTEM SETTINGS

The system settings are stored in memory and can be accessed by:

1. Turn system off (switch at right rear of unit).
2. Press and hold the up arrow.
3. Turn instrument power on while still holding the up arrow.

The following screens are used to change system parameters and are listed below in Table 1.

Table 1 . Setup screens and descriptions.

Parameter/text on LCD	Action/Description	Default
1. LANGUAGE ENGLISH UP/DOWN OR COUNT=OK	Pressing the up or down arrow advances the language parameter from English to Spanish. Press COUNT when you've selected the appropriate language.	ENGLISH
2A. DATE MONTH = 01 UP/DOWN OR COUNT=OK	Select the correct month by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	01
2B. DATE DAY = 02 UP/DOWN OR COUNT=OK	Select the correct DAY by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	02
2B. DATE YEAR = 99 UP/DOWN OR COUNT=OK	Select the correct YEAR by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	99
3A. TIME HOUR = 08 UP/DOWN OR COUNT=OK	Select the correct HOUR by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	08
3A. TIME MIN = 15 UP/DOWN OR COUNT=OK	Select the correct MINUTE by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	15
4. COUNTTIME = 300 SEC UP/DOWN OR COUNT=OK	Select the correct COUNTING TIME by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	300 SEC
5. DELAYTIME = 15 SEC UP/DOWN OR COUNT=OK	Select the correct DARK ADAPTATION PERIOD TIME by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	15 SEC
6. HV CH1 1100 VOLTS UP/DOWN OR COUNT=OK	Select the correct HIGH VOLTAGE FOR CHANNEL 1 by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value. The factory settings can be found in the Factory QC documentation shipped with the instrument	FACTORY SET. DOES NOT CHANGE WHEN DEFAULTS RE- LOADED
7. HV CH2 1100 VOLTS UP/DOWN OR COUNT=OK	Select the correct HIGH VOLTAGE FOR CHANNEL 2 by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value. The factory settings can be found in the Factory QC documentation shipped with the instrument	FACTORY SET. DOES NOT CHANGE WHEN DEFAULTS RE- LOADED
8. AUDIO ON (ON/OFF) UP/DOWN OR COUNT=OK	Turn the audio (beep) on or off by pressing the up or down arrow. For all menu items press count when you've selected the appropriate value.	ON
9. STANDARD 20000 DPM UP/DOWN OR COUNT=OK	Select the correct activity for the reference standard counted in the QC procedure by pressing the up (increase value) or down (decrease value) button. For all menu items press count when you've selected the appropriate value.	20,000 (Note: must remain same for use with Pytest* Standard Set)

After reaching the end of the menu, the text "COUNT = ACCEPT CHANGES UP/DOWN TO CONTINUE" is displayed. At this point if the user is finished, press the count button. If a mistake has been made or the user wishes to review the parameters, press up or down to go through the menu again. When finished, the instrument initializes again. QC will be required after entering the setup program.

Loading Default Settings

The default settings are listed in each section and can be loaded into memory by performing the following procedure:

- 1) Turn off the unit.
- 2) Turn the unit on while depressing the COUNT button until the words "LOADING DEFAULTS" appear on the display and a double-beep sounds.
- 3) The instrument will immediately go into SETUP MODE and require you to set the Language, Date, and Time. The other default values (listed in above table) will be loaded. The QC procedure must be performed after loading the default values.

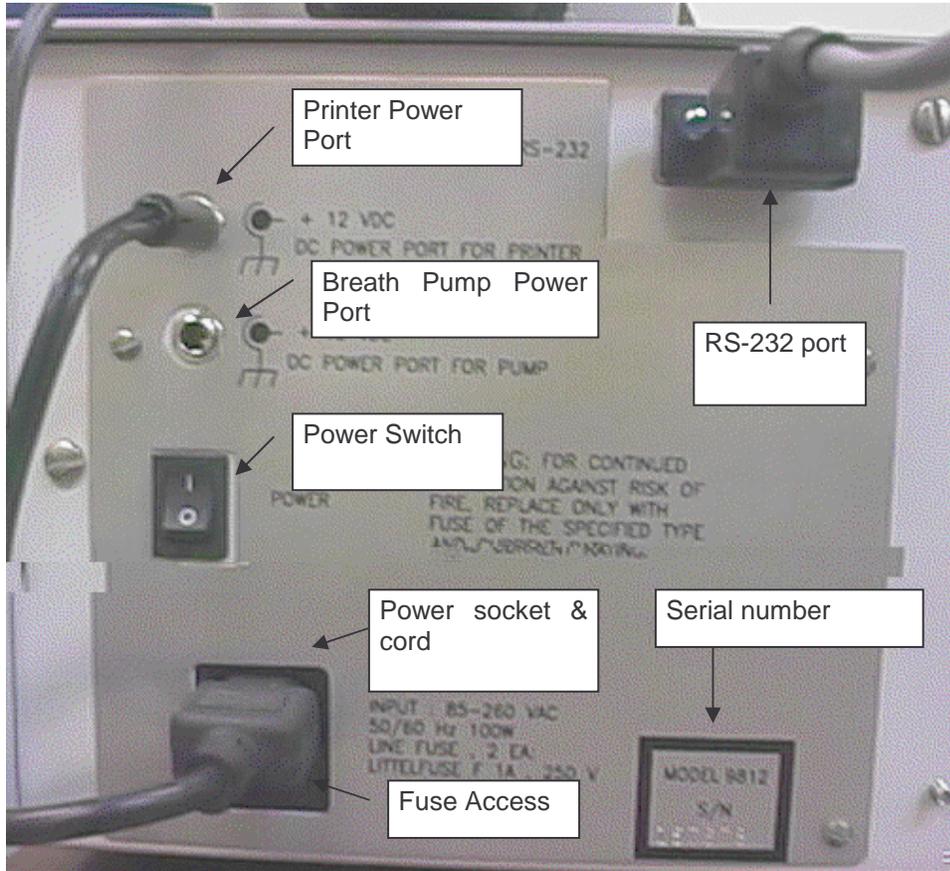
Repeat Mode

A special feature useful for instrument diagnostics is the repeat mode. At power-up, if the DOWN ARROW button is held down, the instrument will count the sample over and over again in the current counting mode until the instrument is turned off. The count button does not need to be pressed to initiate this sequence.

REAR PANEL

Note: All locations are described from the orientation of the user facing the rear of the panel. The rear panel and its connectors are shown in Figure 5.

Figure 5. Power and data connections on Rear Panel.



On/Off Power Switch

The Power switch for the microCOUNT* LITE Liquid Scintillation Counter is located at the lower left of the rear panel when facing the rear panel.

Power Cord

The power cord plugs into the microCOUNT* LITE counter near the power switch at the lower left of the rear panel. The cord is keyed to ensure correct orientation. Note: Make sure the power cord is fully plugged in and that the power cord is connected to a functioning power receptacle. If you have the cord plugged into a power strip, make sure the power strip is turned on. If no line voltage is present, the instrument will not operate, as evidenced by a blank LCD.

Line Fuses

There are two fuses located in the power receptacle. To check or change a fuse (Littlefuse F 1A, 250V), do the following:

- 1) Remove power cord from microCOUNT* LITE counter.
- 2) With screwdriver or similar tool, slide fuse access outward. The access panel is located immediately below the power receptacle.
- 3) Check fuses for continuity. Replace if necessary. Spare fuses are included with instrument.
- 4) Slide access drawer back into instrument until it clicks into place.
- 5) Secure power cord into receptacle.

RS-232 Serial Data Port

The data port located at the rear of the unit consists of a standard DB-9 nine-pin female connector. This port operates using the RS-232C specification at 9600 baud, 8 data bits, no parity, and 1 stop bit. RTS/CTS handshaking is also used. Data recording devices such as the optional printer and microWARE microCOUNT* LITE Liquid Scintillation Counter-to-PC software interface may be attached to this data port. The printer (Reorder No. 60496) is a compact, reliable dot-matrix printer optimized for use with the microCOUNT* LITE counter. Although it is possible to connect other serial (RS-232) devices to the microCOUNT* LITE counter, *parallel printers will not work when plugged into the data port of the microCOUNT* LITE counter*. Only devices listed in the Kimberly-Clark product catalog are supported. Consult the Catalog for other microCOUNT* LITE counter-related supplies and accessories.

Printer Power Port

The power cord for the optional printer should be inserted into the printer power port.

Breath Pump Power Port

The PYtest* test breath pump (Reorder # 60444) is shipped with a wall transformer (110VAC-12VDC). To reduce the number of outlets required to perform the PYtest* test, the power for the breath pump may be obtained from the microCOUNT* LITE counter. A power cord for the breath pump is included and typically taped to the top of the instrument. To power the pump, remove the wall transformer from the pump and place the power cord into the pump. The ends are keyed to reduce confusion. Insert the opposite end into the breath pump port of the microCOUNT* LITE counter.

Voltage Selection

The internal power supply of the instrument automatically accommodates any line voltage between 85V and 260V.

Serial Number

The serial number of the instrument is located on the lower right-hand side of the rear panel.

Battery

The internal battery, which maintains the time and date, can be accessed through a cover on the rear chassis. The battery, a Duracell DL2450 or equivalent, may require replacement if the instrument starts “forgetting” the date or time. The normal time frame for battery replacement is approximately 3 - 5 years.

DETAILED PROCEDURES FOR COUNTING SAMPLES

SAMPLE PREPARATION

The microCOUNT* LITE counter is suited for 20 mL liquid scintillation vials. Ten mL liquid scintillation fluid (LSF) should be added to each vial following transfer of breath through the breath collection fluid. Breath collection topics are discussed in the PYtest* test package insert and should be followed. The vials should be capped and shaken after adding LSF. There are many brands of LSF, some of which are chemically incompatible

with the breath collection fluid. A rule of thumb to use when testing an LSF is that if the sample does not turn clear or separates into two phases after several hours, that scintillant is likely incompatible with the breath collection fluid. We recommend using a biodegradable LSF for aqueous samples. It is important to note that the biodegradable cocktails have much lower flash points and are inherently safer than classical formulations. Contact Ballard Medical Products (1-800-528-5591) for information regarding supplies compatible with the PYtest* test ^{14}C -urea breath test for detection of *H.pylori*.

QUALITY CONTROL

Quality Control serves two purposes, the first of which is to verify that the counter is operating properly. The second purpose is to provide accurate background and efficiency values so that the conversion from counts per minute (CPM) to disintegrations per minute (DPM) can be made. The PYtest* Standards Sample Set (Kimberly-Clark Reorder No. 60456) which is included with the microCOUNT* LITE Liquid Scintillation Counter is utilized in the following procedure.

Quality Control must be performed when “QC Needed” is shown on the LCD. The instrument will not allow normal operation when QC is needed. The message comes on at midnight every day or when a system setting has been changed.

1. Insert the Background (BKG) sample vial of the standard set into the sample tray and close the sample drawer until “Tray is open” message is no longer displayed.
2. Press COUNT button. The display will count down until the dark adaptation period ends. A beep will sound, and the unit will begin counting with the time remaining displayed.
3. When preset (factory-set 5 minutes) time has been reached, result will be displayed in counts per minute (CPM). This value will be stored in non-volatile memory. The user is then prompted to insert the ^{14}C standard into the instrument.
4. Place the 20,000 DPM standard vial of the standard set (labeled ^{14}C) in counting chamber.
5. Press Count button. Counts will accumulate after the preset waiting time, and the counts per minute will be updated on the LCD along with the remaining counting time. When finished, the efficiency for that sample counting geometry is displayed and stored in non-volatile memory (i.e. 50 for 50%). If an optional output device (microWARE or the optional hardcopy printer) is attached, a “QC Passed” report will be printed.
6. The instrument is now ready for counting unknown samples if QC has passed.
7. If the quality control program fails, the display will read “FAIL” and if the optional hardcopy printer is attached, “QC FAILED” will be printed. If this is the case, check the samples (make sure the background sample and standard samples were counted in correct order) and repeat the previous steps. If repeated calibrations fail, consult the TROUBLESHOOTING section of the manual and/or contact Ballard at 1-800-528-5591.

BREATH SAMPLE COUNTING

1. If “QC Needed” message is displayed, perform Daily QC procedure using breath sample background and ^{14}C standards (Kimberly-Clark Reorder No. 60456).
2. Insert breath sample into counting chamber. Make sure sample chamber is fully closed as indicated by the absence of the “Tray is open” message.
3. Press the Count button. The counter will wait for the specified delay time, a beep will sound, and the unit will begin counting.
4. When finished counting, the unit will beep three times, and the results (in ^{14}C DPM) will be presented on the LCD display. If the optional hardcopy printer is attached, the result will be printed as well. Note that if the Audio ON/OFF button is set to OFF, the microCOUNT* LITE counter will not beep.

Chemiluminescence and repeat counting

Samples of “borderline” activity (50-300 DPM) should be counted again at a later time since chemical activity called chemiluminescence can temporarily produce false counts. The microCOUNT* LITE Liquid Scintillation Counter has been optimized to minimize the chemiluminescence associated with breath sample counting. However, if a sample falls in the range of 50-300 DPM, it is recommended to recount the sample at a later time (30 min or greater) to check the result. Decreasing activity indicates chemiluminescence, since the long half-life of ^{14}C provides essentially constant activity. Also note that only a small percentage of samples exhibit chemiluminescence, and this phenomenon may not be observed. Note that the PYtest* test samples are very stable - they will last for a long time due to the 5760 year half-life of ^{14}C .

MAINTENANCE AND TROUBLESHOOTING

Since the instrument is calibrated daily, no special maintenance is required. Should the efficiency or background change significantly, contact Ballard at 1-800-528-5591 . It is highly recommended that the daily QC results (as well as patient results) be recorded for future reference to solve any potential problems and also to ensure regulatory compliance with local, state and federal agencies.

Below are some solutions to problems encountered in using the microCOUNT* LITE counter.

DESCRIPTION OF PROBLEMS

After checking the power connections, the instrument is still dead.

Check the fuses located next to the point where the power cord is connected to the microCOUNT* LITE counter. The fuse panel is a spring-loaded door. The fuse is rated at 1 amp.

The instrument is giving wildly high results (hundreds of thousands of counts)

Make sure the sample tray cover is in place. If it is not in place, room light can get in the sample chamber and give erroneous results.

Instrument never stops counting or some parameters displayed as “65535.”

Sometimes, usually due to power supply problems, the internal memory can get scrambled. First correct any power supply related problems and then load the default settings (see page 11) to fix this problem.

Instrument says “QC NEEDED” often, more frequently than once every 24 hours.

The lithium battery that maintains the internal clock has run down and needs replacing. The replacement battery is a Duracell DL2450 or equivalent, which ordinarily has a 3 – 5 year lifetime. The battery and instructions for replacement can be obtained through Ballard at 1-800-528-5591.

Troubleshooting Data Sheet

Although not expected, occasionally users experience problems with the microCOUNT* LITE Liquid Scintillation Counter. The following sheet is designed to improve our ability to resolve problems quickly and efficiently. Please make a copy of this sheet and perform the steps listed below. Fill in the results for each step and fax the results to Ballard Technical Services at 801-572-6869. If you have not spoken with a Technical Support representative, one will contact you shortly after faxing the form back to Ballard.

Contact person: _____ Instrument Serial# _____

Voice number of Contact Person: _____ Fax# _____

1. Check the power connection going into the microCOUNT* LITE counter to ensure that power is going into the microCOUNT* LITE counter as described in the REAR PANEL section.
2. Once it is assured that the instrument is receiving power, reset the defaults for the instrument by powering the instrument down and then turn the instrument on while depressing the COUNT button. Then follow the prompts on the screen to set the language, date & time.
3. After defaults are loaded, perform the QC procedure. Enter results below:

QC RESULTS BKG: _____ CPM Efficiency: _____ % Pass/Fail _____

1. If the instrument fails to pass QC, turn the power off. Turn the instrument on while holding down both the up and down arrows. The "HV ROUTINE" message will be displayed and you will be prompted to put the ¹⁴C standard in the counting chamber and press count. When you do so, the instrument will go through a procedure that takes about 5 minutes to complete and is automatic. It changes the voltages of each detector and finds optimum settings. When "FINISHED" appears on the screen, write the following data below from the LCD display.

HV1 = _____ V HV2 = _____ V

2. Perform the QC procedure. Enter results below.

QC RESULTS BKG: _____ CPM Efficiency: _____ % Pass/Fail _____

Please fax this sheet to 801-572-6869. A technical support representative will contact you shortly to assist you.

Frequently Asked Questions

I use the microCOUNT* LITE Liquid Scintillation Counter in an area with gamma-emitting radiation sources. Will that affect the microCOUNT* LITE counter?

YES. The microCOUNT* LITE counter is not recommended for use in areas where sources of penetrating radiation are present such as nuclear medicine or x-ray facilities. Kimberly-Clark offers the microCOUNT* Reorder No. 60491 for use in those areas. Please consult your sales representative for further assistance.

My microCOUNT* LITE counter is acting erratically. Why is that?

This problem is not always easy to diagnose, but a good idea is that it might be a power-related problem. First check all power connections and see the power cord section of the manual describing the rear panel of the microCOUNT* LITE counter for more information.

How do I change the date and/or time?

Changing the date and time is described in the SYSTEM SETTINGS section (beginning on page 9).

Will the printer connected to my PC work with the microCOUNT* LITE Liquid Scintillation Counter?

Most likely NOT. Most PCs have parallel printers and the microCOUNT* LITE counter requires a serial printer. Kimberly-Clark only supports the printer that is described as a microCOUNT* LITE counter accessory. Please see the section entitled "RS-232 data port" for more information. If you wish to use a parallel printer connected to a PC, you may purchase the microWARE computer interface for the microCOUNT* LITE counter. It will allow for patient reporting and results to be printed on a standard printer.

How long will the microCOUNT* LITE counter last?

The microCOUNT* LITE counter is expected to operate as long as most liquid scintillation counters which typically last for 10-20 years, or longer.

Does the microCOUNT* LITE counter need annual service?

NO. It is calibrated daily which we believe is sufficient monitoring of the instrument. Service will only be needed if the instrument fails.

Can the microCOUNT* LITE counter be used for samples other than PYtest* test samples?

Yes, but you will have to prepare a standard set for that particular application. See the section titled "Counting Samples Other than PYtest* test Counting Geometry." Kimberly-Clark does not provide support for uses other than Pytest* test samples.

What's an acceptable range for the background and efficiency?

For the PYtest* test sample configuration, the efficiency is typically around 50%. Our internal QC procedure is to have the efficiency above 45% when it leaves the factory. However, an efficiency of 45% or lower is acceptable as long as it is constant, meaning that it really is 45% and it is staying that way. If the efficiency is dropping (i.e. more than a few percent per month), that would indicate a problem with the instrument.

The background value is typically around 30-80 CPM. However, the actual magnitude of the background may be outside the range stated here depending upon environmental factors such as altitude and other sources of radiation in the area. Most importantly, however, **the background should be relatively constant**. For example, if it fluctuates from 80 CPM one day to 30 CPM the next, that indicates a problem that needs to be corrected.

MICROCOUNT* LITE LIQUID SCINTILLATION COUNTER WARRANTY AND RETURN POLICY

The microCOUNT* LITE Liquid Scintillation Counter (the "Unit") has proven to be a durable instrument. However, any manufactured instrument may fail and need repair or replacement. The policy of Ballard Medical Products ("Ballard") for return and/or replacement of a Unit is set forth below:

WARRANTY

Ballard warrants that each Unit will be free of manufacturing defects for a period of one (1) year following Ballard's invoice date. Neglect or abuse of a Unit will void this warranty. In addition, this warranty excludes the replacement of photomultiplier tubes which are used for purposes other than those intended.

DISCLAIMER

THERE IS NO WARRANTY OF MERCHANTABILITY, FITNESS FOR USE, OR OTHER WARRANTIES BY BALLARD, EXPRESSED OR IMPLIED, BEYOND THOSE SET FORTH HEREIN. IN NO EVENT SHALL BALLARD BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES.

TECHNICAL SUPPORT AND INSTRUMENT REPAIR

If diagnostic assistance is required for a Unit, contact Ballard in the U.S.A. at 1-800-528-5591 for technical support. The technical support staff will work with you to try and resolve the problem. They will refer you to the troubleshooting section of this document and likely ask you a number of questions. They will also ask you to perform some counting tests (described in the troubleshooting section) to determine the cause of the problem and how to resolve it. If the problem cannot be resolved via telephone conversation, the Unit may need to be repaired.

If a Unit is in need of repair, you should ship the Unit, **as previously instructed by Ballard**, to (1) Ballard; or (2) the distributor who sold it to you; or (3) a local repair shop. If the Unit is still under warranty, the Unit will be repaired at Ballard's cost (including parts and labor), and Ballard will pay for shipping costs to and from the place of repair. Normal repair time is approximately two to four weeks.

If the Unit is no longer under warranty, you will still have the option of having the unit repaired by Ballard, at your cost (including shipping costs).

If the Unit being repaired is still under warranty, Ballard will provide a loaner Unit to you, at no cost, during the repair period. If the Unit is no longer under warranty, Ballard may be willing to provide a Unit on loan if you are willing to pay shipping costs for the Unit to travel from and back to Ballard. A loaned Unit must be promptly returned to Ballard **in the original shipping container** upon receipt of the repaired Unit.

Distributed By:

Ballard Medical Products, a wholly-owned subsidiary of Kimberly-Clark Corporation Draper, Utah 84020 USA
<http://www.kchealthcare.com> In USA Call 1-800-528-5591: International Call +801 572 6800