PROFILE®- 1

Bioluminometer Model 3560
1X and 10X

BACTERIAL MONITOR SYSTEM

OWNERS/USERS MANUAL

Model 3560 Instrument / PN: 89-117060
1000 Series
PROFILE SYSTEM / PN: 89-117012
Reagent Reorder / PN: 89-117015

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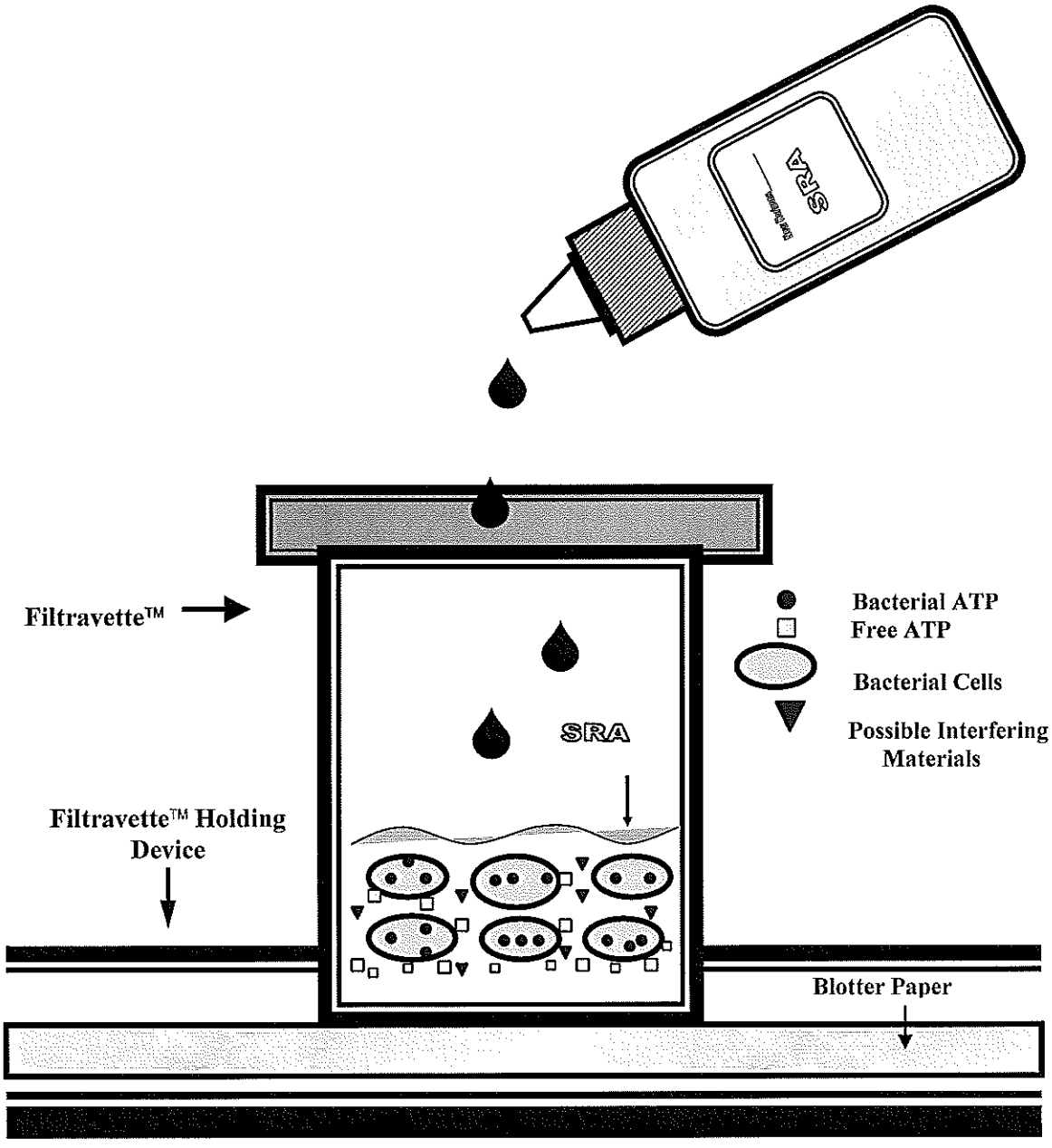
NHD's PROFILE-1 SYSTEM ...Sole Source for

the only rapid, portable ATP System proven to correlate to culture.

The PROFILE-1 System comes in a convenient carrying case with all necessary components for testing the sample. As supplied, the System has the capacity to perform 100 determinations. The patented Filtravette is a critical part of the System. The sample is placed in the Filtravette and reagents are introduced progressively.

- The only Field Test to detect viable spores. Proven to detect Biological Aerosols (vegetative bacterial cells or spores)
- Field Tested by the USDA in thousands of samples of beef, pork & poultry
- Field Tested by the US Military on spores and biowarfare agents
- Field Tested by the Canadian Food Inspection Agency and found to have 100% correlation in specificity and sensitivity to standard culture methods
- Correlates to Culture: USDA published data indicates results from the PROFILE System (a five minute assay, including sampling) correlate to aerobic plate counts (36 hour cultures) with r = ~0.92.
- Real Time Results: USDA field data indicates QC personnel identified a process deviation almost as soon as it was occurring, as opposed to after 24 to 48 hours.
- Correlation/Conversion Charts: USDA reports there is a 97% probability that value X (RLU: relative light units) indicates value Y (APC: aerobic place count).
- Field Tested Worldwide for Drinking Water by the University of Michigan.
- Detects Biological Aerosols (vegetative bacterial cells or spores).
- NHD's patented filtration system allows for discrimination of yeast/mold/fungi from bacterial ATP.
- Portable: fits into a lab coat pocket
- Field Use: runs off battery or cigarette lighter adapter.
- Differentiates Total ATP or Bacterial ATP results.
- Eliminates Potential False Positives: SRA reagent removes somatic/mammalian cells, etc that could cause false positive results.
- Eliminates Potential False Negatives: SRA reagent removes quenching agents/commercial sanitizers (table salt, heavy metals, chlorine, etc.) that could cause false negative results.
- Sensitivity: standard instrument is set at $10^4 - 10^5$; 10X units are also available, and sensitivity can be increased by use of a Cell Concentrator, sample size, and reagent concentration.
- Sampling: Liquid, powder, sponge, swab, etc.
- Sample Size Variables: With the use of the Cell Concentrator, large volumes of sample can be concentrated onto the Filtravette to increase sensitivity.
- NHD's Filtravette filtration system is patented.

The Addition of Somatic Releasing Agent Will Eliminate Free and Somatic ATP (Non-bacterial ATP) as well as any Other Interfering Materials Found in the Sample



NOTES AND CAUTIONS:

In order to assure optimum *PROFILE-1* system performance and to prevent damage to the Model 3560 Microluminometer, the following must be observed:

1. The reagents supplied with the *PROFILE-1* Bacteria Monitor System are formulated specifically for use with this system. **No substitutes are acceptable.**

2. Luciferin-luciferase (LL) should be kept refrigerated until it is ready to be reconstituted for use with the provided reconstitution fluid.

3. Reconstituted LL has a limited life and should not be left unrefrigerated for more than a total of 6 hours.

4. A disinfected work surface is required, as are good laboratory techniques.

5. It is recommended that clean, disposable non-powdered gloves be worn to prevent contamination of reagent and plastic surfaces.

6. Use a sterile pipette tip for each sample or reagent draw. To avoid contamination, only sterile pipette tips should ever enter a reagent bottle. To ensure sterility, do not install pipette tips until just before the pipetter is to be used. Exercise care when drawing samples from deep containers so that neither the pipetter unit nor the container become contaminated. And, do not immerse the pipette tip more than 2 cm (3/4 inch) below the top surface of liquids being drawn.

7. **CAUTION:** Immediately after completion of the test, remove the Filtravette in order to prevent damage to the instrument. Do not turn the Model 3560 Microluminometer on its side or flip upside down while Filtravette™ is in the slide drawer; the liquid sample may spill and contaminate the optical block and/or damage internal components.

8. When performing a surface test, use only a sterile Dacron swab.

9. Turn **ON/OFF** switch on back of instrument to OFF position when

10. **CAUTION:** Use only the AC adapter supplied with the Model 3560 Microluminometer.

11. Stressed (refrigerated or frozen) organisms have significantly reduced ATP. Check with manufacturer for protocol for measuring ATP in stressed organisms.

THE *PROFILE-1* SYSTEM

The *PROFILE-1* system has been developed to rapidly identify high levels of generic bacterial levels on food, water, environment and work surfaces. By following a simple procedure, a relative bacteria count may be determined in a matter of minutes. This is made possible by the high sensitivity design of the Model 3560 Microluminometer and the unique system chemistry which allows bacterial levels to be determined directly from freshly acquired samples. This easy-to-use system helps inspectors determine high bacterial counts on food, remove it from the line and process it for reinspection. It also helps sanitation inspectors determine high bacterial counts on equipment and work surfaces. Utilizing the PROFILE System, testing for water and spores can be performed in the field in a matter of minutes rather than days.

PROFILE-1 SYSTEM USE AND COMPONENTS

It is important to make sampling procedures, solution preparation and sample volumes consistent to assure that meaningful test results are obtained. It is recommended that food samples be obtained in accordance with the latest USDA defined procedures for use of this system. Spore samples must be heat-shocked to render them vegetative. Collection of consistent samples is therefore left to the responsibility of the user.

The *PROFILE-1* system comes in a convenient carrying case with all necessary components for testing of the standard sample. As supplied, the system has the capacity to perform 100 determinations. *PROFILE-1* 100 Determination Kits are available for the disposables. Each kit contains Filtravettes and reagents.

Items unique to the *PROFILE-1* system are shown in Figure 1.

The Filtravettes are a critical part of the system. The sample is placed in the Filtravettes and the reagents are introduced progressively. Pressure is applied from the top of the Filtravettes by using a positive pressure device. This forces interfering substances out of the Filtravette and into a thick blotter paper. (An optional vacuum manifold is available for multiple sample testing. This offers an even more convenient method to draw reagents through the Filtravette.)

ASSAY PRINCIPLES

The *PROFILE-1* process quantitates Adenosine Triphosphate (ATP), an energy rich molecule found within all living cells. Somatic Cell Releasing Agent (SRA) is used to lyse (rupture) all non-bacterial cells allowing removal of their ATP content in the first stage of the quantitative process. The Bacterial Cell Releasing Agent (BRA) lyses bacteria cells retained on the surface of the filter and releases ATP. LL is then added to the BRA solution and a burst of energy is released in the form of Relative Light Units (RLUs).

The amount of bacterial ATP present in the Filtravette is proportional to the number of bacteria cells that were contained in the original sample. Once the Filtravette is introduced into the

microluminometer, a high sensitivity light detector is exposed to the light emission from the solution. As the light emission increases, so does the signal strength which is an indication of the amount of bacteria present in the original sample.

FEATURES AND FUNCTIONS

Figure 1 identifies important features of the Model 3560 Microluminometer. Each feature is listed below with a function description.

a. READOUT DISPLAY / DISPLAY INDICATORS

The readout display provides the reading, in relative light units (RLU) for the sample being tested. A higher reading indicates a higher level of bacterial present in the sample. Closure of the Drawer Slide initiates a 2-two second (zero reading) delay followed by a 10-second integration period.
When the unit is first powered by either the AC adapter or the 9V battery, the message "**NHD-Model 3560**" will be displayed for 2-seconds and will be followed by a countdown from "**Wait 10 seconds**" to "**Wait one second,**" after which a "**Ready**" signal will appear. Opening and closing the Drawer Slide will display dual series of bars progressively decreasing in number until the result "**RLU ___**" is displayed.

b. SAMPLE DRAWER

The Sample Drawer carries the Filtravette into the Microluminometer, placing it close to the light detector. Closing the Drawer Slide correctly positions the Filtravette and prevents ambient light from entering the Luminometer.

c. POWER JACK

The power jack is the AC power source interface for the Microluminometer. Use only the AC adapter provided with the unit. Plug adapter into the wall outlet and into the Power Jack of the Model 3560. Sample Drawer should remain closed during this procedure.

d. OFF/ON SWITCH (green/black circles):

Switch is located on the back of the unit. Toggle switch on the GREEN Circle indicates that the unit can run on battery (however, if plugged into AC, AC will be utilized). Toggle switch on the BLACK circle shuts off the battery and when plugged into AC, the unit is activated. **CAUTION: Be sure to turn toggle switch to BLACK (battery off) position when not in use to preserve the 9V battery.**

NOTE: *DO NOT OPEN* the Sample Drawer during this process. If this is done inadvertently, an "**Error**" message will be displayed followed three seconds later by a "**Ready**" signal for repeat testing.

e. BATTERY COMPARTMENT:

The internal, changeable 9V battery is located on the bottom side of the Readout Display. To change battery, have ON/OFF switch in OFF (black) position. Pull back slide cover and remove old battery. Snap new 9 volt battery (Alkaline, Nickel-Cadmium [8.4v, externally rechargeable] or Nickel-Metal Hydride [externally rechargeable]) into position. Tuck the lead wires to prevent rattling and replace slide cover.

f. BATTERY DEPLETION:

A "**Low Battery**" message will appear on the display when the battery runs less than 7 volts. All further operation is aborted until the battery is replaced or the AC adapter is used.

NHD's PROFILE SYSTEM
Microluminometer, Model 3560

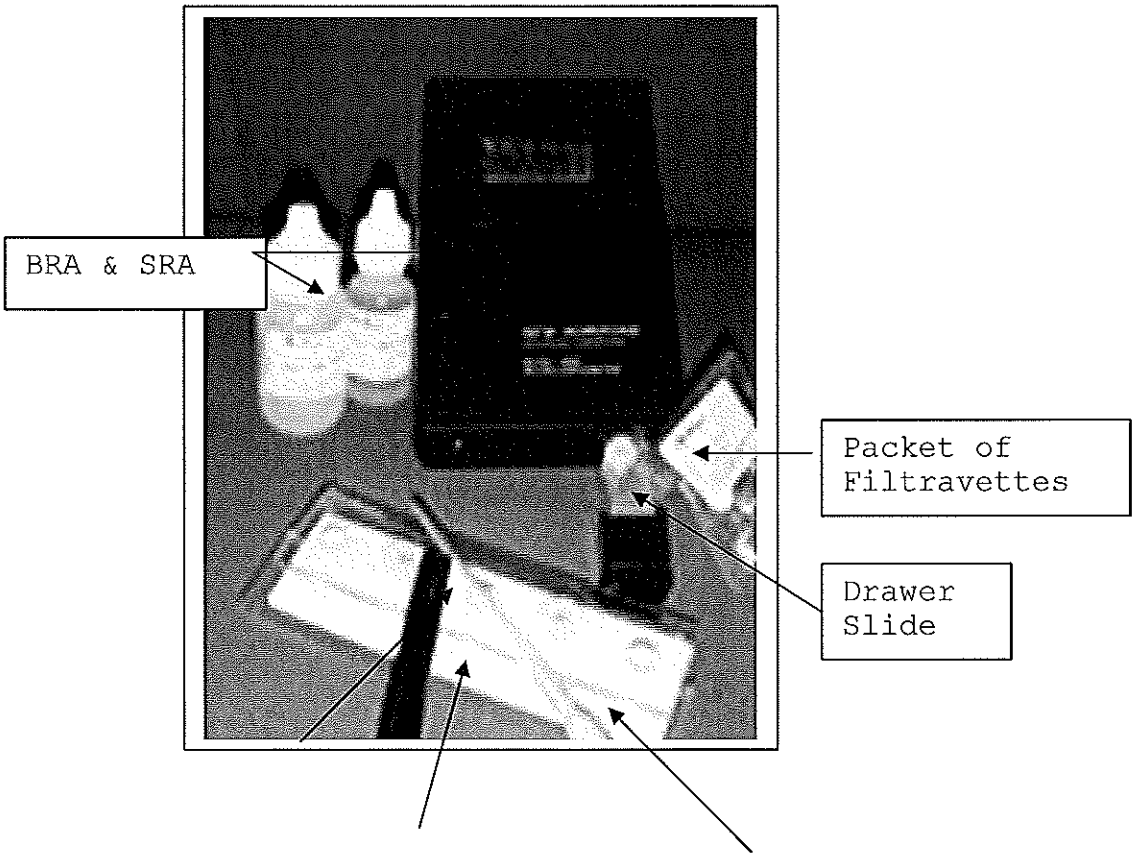
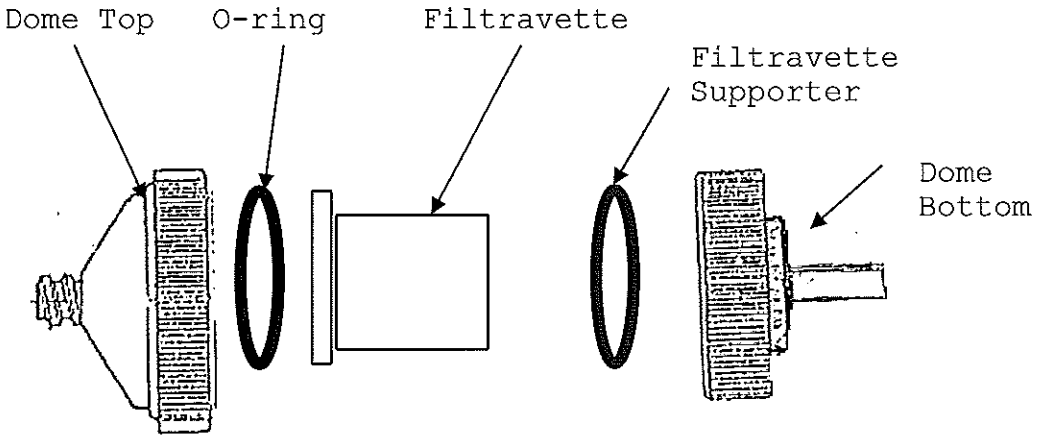


FIG. 5: Cell Concentrator

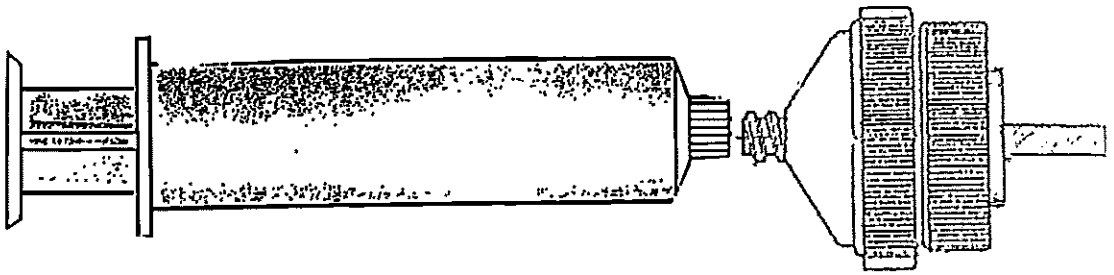
The Cell Concentrator is actually a device for holding the Filtravette™ so that large volumes of the sample may be filtered. This allows for increased sensitivity due to the concentration of cells onto the Filtravette membrane. Studies performed at the University of Michigan have shown this method can detect <300 bacteria.



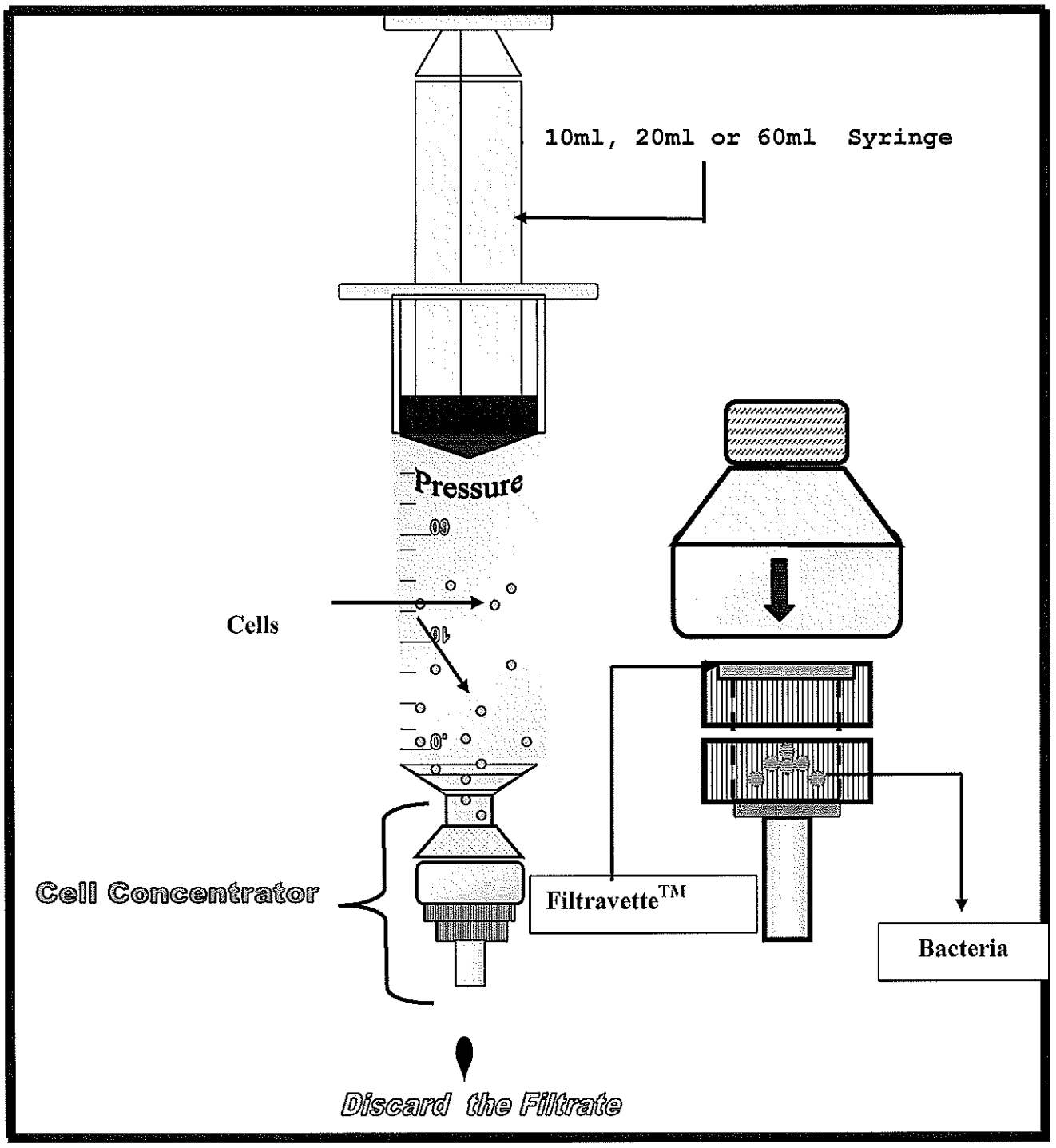
The dome top has a luer-lok to which a syringe can be affixed and the contents of the syringe filtered through the Filtravette. The black 0-ring must be in place or it will leak. It's advisable to use a syringe protective tip on the Dome Bottom tip of the Cell Concentrator when not in use.

The bottom of the device should have the 9mm polypropylene support disc at the bottom. The Filtravette is placed on that, and the top and bottom are screwed together

Once the desired sample volume is passed through the Filtravette, remove the Filtravette and process as usual. The Cell Concentrator and its 0-ring and supporter should be washed in alcohol and then rinsed in water before each use. . New Cell Concentrators are packaged with residual alcohol for shipment



Push the Sample Through the Cell Concentrator by Applying Moderate Pressure to the Syringe Plunger, Concentrating the Cells on the Filtravette™ Membrane



REAGENT PREPARATION AND HANDLING

The reagents supplied with the *PROFILE-1* system are formulated specifically for use with this system. ***No substitutes are acceptable.*** Careful storage and handling of all reagents is extremely important. ***Only sterile pipette tips should ever enter a reagent bottle*** since contamination of a reagent may lead to artificially high or low bacterial readings during subsequent analyses.

The LL reagent requires reconstitution before use and particular care in handling. ***LL must be kept refrigerated until it is ready to be used.*** Preparation of the LL consists of removing the black cap from the amber L/L bottle while leaving the gray rubber stopper in place, open a single reconstitution fluid, remove the gray rubber stopper from the bottle of L/L and transfer the reconstitution fluid into the bottle of L/L to reconstitute. Allowing the solution to sit for 15 minutes prior to initial use. After this time has elapsed the LL is ready to use, but ***only sterile pipette tips may be used to withdraw the reagent.*** The ***reconstituted LL has a limited life of 5 days and should not be left unrefrigerated for more than 6 hours.*** This time includes the period during which the LL is in use. If useful life of the reconstituted LL has expired, discard and prepare a new solution. Additional LL/reconstitution buffer sets are sold as a separate package.

PRELIMINARY PREPARATION

The Model 3560 Microluminometer is extremely sensitive to the presence of bacteria. Therefore, for accurate sample readings to be obtained, it is imperative that outside sources of contamination be eliminated. Good work techniques, a disinfected work area and gloves (optional) are necessary to help insure a clean reading. When Filtravettes are removed from their storage bags, gloves and/or forceps should be used. It is preferable to prepare the work area before beginning the procedure by placing as many Filtravettes and blotter papers required for a complete session on a decontaminated surface within easy reach of the user. These items can then be retrieved as needed without risking contamination of the remaining stock of supplies.

When using the pipetter, ***install pipette tips immediately before the pipetter is to be used.*** Then eject and dispose of used pipette tips properly. This will prevent contamination of clean tips and work surfaces. When using the pipetter, ***exercise care when drawing samples from deep containers so that neither the pipetter unit nor the container become contaminated.*** Similarly, ***do not immerse the pipette tip more than 2 cm (3/4 inch) below the top surface of the liquids being drawn.*** Finally, be careful when setting the pipetter down so that the tip end of the unit does not contact any potentially contaminated surfaces.

Lastly, a disinfectant wipe down or rinse of several *PROFILE-1* kit components should occur following each use of the device. See "CLEANING OF *PROFILE-1* COMPONENTS" for more information.

Water and BASIC PROCEDURE FOR PROFILE, MODEL 3560

This Model may be operated with the internal 9 v battery (or plug the AC Adapter into an appropriate AC power source and insert the power plug into Microluminometer Power Jack. (*Use no other power source with this instrument*).

MATERIALS NEEDED:

PROFILE luminometer	LL (Luciferin-Luciferase)
BRA(Bacteria Releasing Agent)	Filtravettes
SRA(Somatic cell Releasing Agent)	Pipettor / Pipette Tips
Positive Pressures Device	Filtravette Holder with Blotter Paper

- **Samples should be obtained in accordance with a defined procedure.**
  - If working from a swab, you would need to add to a standard test tube ~ 0.5 mL of SRA. Wet the swab with the SRA, sample site, and return swab to SRA tube. Agitate swab in tube to free sample from swab. Remove swab and discard, retaining as much fluid as possible in the test tube. Pipette 50 µl of sample into Filtravette and begin at Step 7.
  - If working with a liquid, collection of consistent samples is left to the responsibility of the user.

1. **Place blotter paper into Filtravette holder (Figure 3).** *Use only as many blotter paper sections as needed for the number of tests planned. Do not reuse blotter papers. Paper towels or any other blotter paper may be used.*

2. **Place Filtravette(s) (Figure 2)in the Filtravette holder (Figure 3).** *Use 1 Filtravette for each test planned.*

3a. Pipette 50 µl test sample into each Filtravette. *Use a clean pipette tip for each Filtravette/sample.*

***3b. For Drinking Water: utilizing the Cell Concentrator (Page 10) push 10 or > cc water through Filtravette in Concentrator. Remove Filtravette from Concentrator and place in Filtravette Holder. Using Positive Pressure Device, push liquid from Filtravette.**

4. **Place four (4) drops of SRA in each Filtravette.**

5. **Force fluid through Filtravettes using air pressure from the Positive Pressure Device (Figure 4).** ***O****ver pressurization can damage the Filtravette leading to erroneous readings. Use slow steady pressure to prevent this from happening. Hold Positive Pressure Device in place*

until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.

6. **Repeat Step 4: Place four (4) drops of SRA in each Filtravette.**

7. **Repeat step 5: Force fluid through Filtravettes using Positive Pressure Device.** *As in Step 5, hold positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.*

8. **For each assay, remove the appropriate Filtravette from the Filtravette holder and place it into the well of the luminometer Sample Drawer Slide (Figure 1-b).**

9. **Place two (2) drops of BRA into the Filtravette.**

10. **Pipette 50 µl of LL** (u*se a sterile pipette tip for each Filtravette/sample)* **into the Filtravette and mix the solution 2 - 3 times by withdrawing and expressing the liquid 2 - 3 times with the pipetter. Immediately place Filtravette into Drawer Slide of Luminometer and close sample drawer to begin 10 second integration period.** *Do not open Sample Slide Drawer before the RLU reading is displayed and recorded.*

11. **Record results for this sample. Continue at Step 8 if other samples remain to be processed.**

❖ *NOTE: If Total ATP is desired, eliminate Steps 4 through 8. These SRA Wash Steps remove inhibitors (that could cause false negatives) and non-microbial cells (that could cause false positives).*

SAMPLE ANALYSIS INSTRUCTIONS
FOR EQUIPMENT AND WORK SURFACES

ADDITIONAL MATERIALS NEEDED:

Sterile Dacron Swab	50 µl Pipettor
Test Tube with 0.5 ml PBS	Pipette tips

This Model may be operated with the internal 9 v battery or plug the AC Adapter into an appropriate AC power source and insert the power plug into the Microluminometer Power Jack. ***Use no other power source with this instrument.***

1. **Measure a 100 cm^2 area to the sample, using a template or other method.**

2. **If testing on a dry surface, moisten a sterile Dacron swab by placing the tip into 0.5 mL of PBS. Squeeze out excess solution by pressing the swab against the wall of the test tube holding the PBS. Proceed to Step 4.**

3. **If the surface you are testing is wet, use only an unmoistened sterile Dacron swab.**

4. **Wipe the sample area by moving the swab 10 times up and down, and 10 times left to right. Place the swab into the tube containing the 0.5 mL PBS and mix the solution thoroughly. Withdraw the swab, pressing the side of the tube to wring out as much sample as possible. Dispose of swab.**
   It is recommended that you rotate the swab while sampling. This will ensure the entire swab meets with the sampling area.

5. **Pipette 50 µl test sample into each Filtravette.** *Use a clean pipette tip for each Filtravette/sample.*

6. **Place blotter paper into Filtravette holder (Figure 3).** *Use only as many blotter paper sections as needed for the number of tests planned. Do not reuse blotter papers. Paper towels or any other blotter paper may be used.*

7. **Place Filtravette (Figure 2) in the Filtravette holder (Figure 3).** *Use 1 Filtravette for each test planned.*

8. **Place four (4) drops of SRA in each Filtravette.**

9. **Force fluid through Filtravettes using air pressure from the Positive Pressure Device (Figure 4).** ***O****ver pressurization can damage the Filtravette leading to erroneous readings. Use slow steady pressure to prevent this from happening. Hold Positive Pressure Device in place*

until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.

10. **Repeat Step 8: Place four (4) drops of SRA in each Filtravette.**

11. **Repeat step 9 Force fluid through Filtravettes using Positive Pressure Device.** *As in Step 5, hold positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.*

12. **For each assay, remove the appropriate Filtravette from the Filtravette holder and place it into the well of the luminometer drawer slide (Figure 1-b).**

13. **Place two (2) drops of BRA into the Filtravette.**

14. **Pipette 50 µl of LL** (use *a sterile pipette tip for each Filtravette/sample)* **into the Filtravette and mix the solution 2 - 3 times by withdrawing and expressing the liquid 2 - 3 times with the pipetter. Immediately place Filtravette into Drawer Slide of Luminometer and close sample drawer to begin 10 second integration period.** *Do not open Sample Slide Drawer before the RLU reading is displayed and recorded..*

15. **Record results for this sample. Continue at Step 5 if other samples remain to be processed.**

❖ *NOTE: If Total ATP is desired, eliminate Steps 6 -11. These SRA Wash Steps remove inhibitors (that could cause false negatives) and non-microbial cells (that could cause false positives).*

SAMPLE ANALYSIS: SPORE

The LL reagent requires reconstitution before use. ***LL must be kept refrigerated until it is ready to be used.*** Allow the solution to sit for 15 minutes prior to initial use (with cap and stopper off). ******Only sterile pipette tips may be used to withdraw the reagent***.***

ADDITIONAL MATERIALS to PROFILE Reagent Kit NEEDED:

TSB (tripticase soy broth) Syringe, luer-lok (10 cc) Cell Concentrator

For Measurement of Bacterial Spores, the following protocol is recommended. Spores are deficient of high ATP levels and are virtually undetectable by the standard luminescence technique. Therefore one needs to transition the low ATP producing spore to a vegetative state so that the cellular process necessary for ATP production is initiated. It is best if the sample is evaluated within one hour of collection, or steps should be taken to maintain bacteriostasis within the sample.

I. Divide sample into equal parts A and B. Run sample A for baseline of bacterial contamination. Run sample B after incubation to determine presence of spores. Initial each Step of the procedure.

A. **BASELINE: Results 1._____ 2._____ 3._____**

____ 1. Place Filtravette in the Filtravette holder (with blotter papers in place) and add 50µl of liquid sample. Discard pipette tip.

____ 2. Add four (4) drops SRA wash to sample in Filtravette and express liquid by use of the Positive Pressure Device.

_____ 3. Repeat Step 2 wash by again adding four (4) drops SRA and expressing liquid. (This process removes nonbacterial sources of ATP and interfering substances.)

_____ 4. Remove Filtravette and place in Drawer Slide of Microluminometer.

_____ 5. Add two (2) drops BRA to sample in Filtravette to lyse bacterial cells.

_____ 6. Immediately after adding the BRA, using a clean pipette tip, add 50µl L/L reagent (Luciferin-Luciferase), and mix by pipetting up and down 3-4 times.

_____ 7. Quickly close Drawer Slide.

_____ 8. Record RLU results from Readout Display in spaces at **A. BASELINE**. (Duplicate runs are suggested, and space is allocated for a total of three (3) times.)

B. **SPORES: Results 1._____ 2._____ 3._____**

_____ 1. Add 0.5mL Sample into NHD's 0.5mL TSB vial (equivolume TSB & Sample).

_____ 2. Incubate at ~ 37°C for ~15 minutes.

_____ 3. Remove entire sample with appropriate sized syringe or transfer pipette.

_____ 4. Attach Cell Concentrator (with new Filtravette inside) to syringe and filter Sample B through Filtravette. Collect filtrate into vial used for TSB and hold until assay is completed, then properly discard.

_____ 5. Remove Filtravette from Cell Concentrator and process Sample B according to the A BASELINE protocol above. Place check (√) next to initials in Steps A1-A8 to indicate completion. Record RLU for Spore sample under B: Spores. Look for delta increase between sample A & B (difference between reading A and B). (Duplicate runs are suggested, and space is allocated for a total of three (3) times.)

DETECTION LIMIT: Nominal detection limit is 1000 spores/mL of ATP (10^5 CFU/mL). Detection limit can easily be improved by either increasing the L/L concentration or increasing the sample volume.

SAMPLE ANALYSIS INSTRUCTIONS FOR BEEF, PORK, AND LAMB

This Model may be operated with the internal 9 v battery or plug the AC Adapter into an appropriate AC power source and insert the power plug into the Microluminometer Power Jack. **Frozen or refrigerated samples may need recovery time if organisms are stressed.**
(*Use no other power source with this instrument*).

ADDITIONAL MATERIALS NEEDED:

Template (or ruler and edible ink)
25 ml Stomacher Solution
Stomacher Bag w/ATP-free sponge
Filtered Stomacher Bag

1. **Select the area you wish to test, this will determine the sample size needed. Hot spots, for beef and pork, include the mid-line, rump, hock, brisket and anal areas. It is recommended to use a 500 cm^2 testing area for the brisket area in beef and a 100 cm^2 area for the anal area of pork.** *A stainless steel template of 100, 150 or 500 cm^2 could be used in sampling or the sample area could be measured out using a ruler and edible ink.*

2. **Add 25 ml of the stomacher solution to the stomacher bag containing the ATP free sponge.** *Stomacher solution can be purchased separately or prepared in house by mixing .085% Sodium Chloride, .05% Tween 20 and purified water. Adjust the pH to 7.8 and filter through a .22 filter or autoclave for sterility.*

3. **While wearing gloves, gently squeeze the sponge to remove excess moisture.**

4. **Using the ATP free sponge, swipe the carcass using a standard swabbing area of 100, 150 or 500 cm^2. Swipe 10 times across and then turn over the sponge and swipe 10 times up and down to insure that all of the area has been in contact with the sponge.** *Templates for the swabbing area are available at additional cost.*

5. **Place the sponge into the stomacher bag and stomach (or hand mix) the sample for two (2) minutes.** *This can be done using a stomacher blender or by using manual pressure.*

6. **Transfer all contents of the stomacher bag to a filtered stomacher bag by pouring all contents in the larger opening.**

7. **Place blotter paper into Filtravette holder (Figure 3).** *Use only as many blotter paper sections as needed for the number of tests planned. Do not reuse blotter papers.*

8. **Place Filtravette(s) in the Filtravette holder (Figure 3).** *Use 1 Filtravette for each test planned.*

9. **Pipette 50 µl of test sample, from the smaller opening of the filtered stomacher bag, into each Filtravette.** Use a clean pipette tip for each Filtravette/sample.

10. **Place four (4) drops of SRA in each Filtravette.**

11. **Force fluid through Filtravettes using air pressure from the Positive Pressure Device (Figure 4).** *Over pressurization can damage the Filtravette leading to erroneous readings. Use slow steady pressure to prevent this from happening. Hold Positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.*

12. **Repeat Step 10. Place four (4) drops of SRA in each Filtravette.**

13. **Repeat Step 11. Force fluid through Filtravettes using Positive Pressure Device (Figure 4).**
As in step "11", hold positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.

14. **For each assay, remove the appropriate Filtravette from the Filtravette holder and place it into the well of the luminometer drawer slide (See Figure 1-b).**

15. **Place two (2) drops of BRA into the Filtravette.**

16. **Pipette 50 µl of LL into each Filtravette and mix the solution 2 - 3 times by withdrawing and expressing the liquid 2 - 3 times with the pipettor.**
Use a sterile pipette tip for each Filtravette/sample.

17. **Close sample drawer immediately to begin 10 second integration period and obtain sample reading.** *Do not open Sample Slide Drawer before the RLU reading is displayed and recorded. Dispose of Filtravette after each test.*

SAMPLE ANALYSIS INSTRUCTIONS FOR POULTRY

ADDITIONAL MATERIALS NEEDED:

ATP Free Sponge
25 ml Buffered Peptone Water
(0.05% Tween 20 and 0.05% glucose)
Filtered Stomacher Bag
Powder Free Gloves

This Model may be operated with the internal 9 v or plug the AC Adapter into an appropriate AC power source and insert the power plug into the Microluminometer Power Jack. **Frozen or refrigerated samples may need recovery time if organisms are stressed.**
Use no other power source with this instrument.

1. **Select the bird for testing.**

2. **Add 25 ml of the buffered peptone water to the stomacher bag containing the ATP free sponge.**
   Buffered peptone water can be purchased separately or prepared in house by mixing 0.05% Tween 20, .05% glucose and purified water.

3. **While wearing gloves, gently squeeze the sponge to remove excess moisture.**

4. **Using the ATP free sponge, wipe down the entire surface of the bird, turning the sponge at least two times to ensure that the whole sponge has been in contact with the surface of the bird.**

5. **Place the sponge into the stomacher bag and stomach (or hand mix) the sample for two (2) minutes.** *This can be done using a stomacher blender or by using manual pressure.*

6. **Transfer all contents of the stomacher bag to a filtered stomacher bag by pouring all contents in the larger opening.**

7. **Place blotter paper into Filtravette holder (Figure 3).** *Use only as many blotter paper sections as needed for the number of tests planned. Do not reuse blotter papers.*

8. **Place Filtravette(s) in the Filtravette holder (Figure 3).** *Use 1 Filtravette for each test planned.*

9. **Pipette 50 µl of test sample, from the smaller opening of the filtered stomacher bag, into each Filtravette.** Use a clean pipette tip for each Filtravette/sample.

10. **Place four (4) drops of SRA in each Filtravette.**

11. **Force fluid through Filtravettes using air pressure from the Positive Pressure Device (Figure 4).** *Over pressurization can damage the Filtravette leading to erroneous readings. Use slow steady pressure to prevent this from happening. Hold Positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.*

12. **Repeat Step 10. Place four (4) drops of SRA in each Filtravette.**

13. **Repeat Step 11. Force fluid through Filtravettes using Positive Pressure Device (Figure 4).**
As in step "11", hold positive Pressure Device in place until Filtravette is evacuated of fluid and significant progression of fluid on blotter paper has stopped.

14. **For each assay, remove the appropriate Filtravette from the Filtravette holder and place it into the well of the luminometer drawer slide (See Figure 1-b).**

15. **Place two (2) drops of BRA into the Filtravette.**

16. **Pipette 50 µl of LL into each Filtravette and mix the solution 2 - 3 times by withdrawing and expressing the liquid 2 - 3 times with the pipettor.**
Use a sterile pipette tip for each Filtravette/sample.

17. **Close sample drawer immediately to begin 10 second integration period and obtain sample reading.** *Do not open Sample Drawer Slide before the RLU readomg os dos[;aued amd recorded. Dispose of Filtravette after each test.*

CLEANING OF *PROFILE-1* COMPONENTS

Appropriate cleaning of *PROFILE-1* kit components should occur following each use of the device. This will help to prevent cross contamination of future samples. It will also help to keep the carrying case clean.

MODEL 3560 MICROLUMINOMETER

Frequently wipe the drawer slide using cloth (Kimwipe) moistened slightly with isopropyl alcohol. Care must be taken to assure that no liquid enters the device. Wipe the external surface as needed with moistened cloth.

INSTRUCTIONS FOR BATTERY OPERATION OF THE LUMINOMETER

This Model Microluminometer is supplied with a regulated 15 VDC adapter and a changeable 9-V battery. Use of any other adapter with the Luminometer or rechargeable Battery Pack may cause permanent damage and will VOID the warranty.

1) **LINE OPERATION**

Plug the adapter cord into the wall outlet and insert the adapter plug into the jack at the rear of the Luminometer.

2) **BATTERY OPERATION**

Remove the adapter cord. Move the slide switch at the rear of the instrument to the Green Circle position. ***IMPORTANT!** To preserve the charge of the battery, move the switch to the Black Circle position at which numbers DO NOT appear on the display immediately after finishing the run.

3) **LOW BATTERY INDICATOR**

A "LOW BATTERY" message will appear on the display when the battery is < 7v. All further operation is aborted until the battery is replaced or the AC adapter is used.

TROUBLESHOOTING

The list in Table 1 offers probable cause and solutions for some unexpected microluminometer readings. Should you require additional help, you may contact us by phone at (800) 888-5015 (USA only) or (410) 992-9357 or fax us at (410) 992-0328.

TABLE 1

CONDITION	CAUSE - SOLUTION
High background reading from activated unit with closed Drawer Slide. No Filtravette™ or sample present.	1. Contaminated sample drawer - clean and disinfect drawer with alcohol. 2. Light sensing unit faulty - return unit for service. 3. High humidity has affected device - place in dry environment for 24 hours before resuming use.
No reading when sample drawer is closed.	1. Unit in Battery Mode: Switch to AC and/or replace 9-Volt Battery (if indicated on display) 2. Poor AC Adapter connections - check and correct 3. No power - verify that the Power Outlet is providing power. 4. Incomplete closure of Drawer Slide.
Output readings significantly lower than expected.	1. Dirt in Drawer Slide - clean sample drawer. 2. High humidity - place in dry environment for 24 hours before resuming use. 3. Light sensing unit or high voltage power faulty - return unit for service. 4. Stressed (frozen or refrigerated) organisms have significantly less ATP until fully revived to growth phase.

SUPPLIES AND ACCESSORIES

CATALOG NO.	DESCRIPTION
89-117012	Profile-1 System and Carrying Case Includes: 1 Model 3560 or 3560 10X Microluminometer 1 50µ Pipetter 1 Filtravette Tray 1 Positive Pressure Device 1 9-volt Battery 1 Power Cord Adaptor
89-117015 or X	Profile-1 Reagent Kit, 100 Det. Includes: 100 Filtravettes 10 Luciferin-luciferase (L/L) 10 L/L Reconstitution Buffers 1 Bacterial Cell Releasing Agent 1 Somatic Cell Releasing Agent 1 Blotter Paper (20 Pack)

Profile™-1 / Disposables and Accessories

CATALOG NO.	DESCRIPTION
89-117060	Model 3560 Microluminometer (ONLY)
89-117061	Model 3560 10X Microluminometer (ONLY)
89-117021	Filtravettes (1 Bag of 10)
89-117043	Yeast Filtravettes (10 per bag)
89-117005	Luciferin-luciferase: 10 vials of 10 determinations each also includes 10 packets of L/L Reconstitution Buffer
89-117003	BRA: Bacterial Cell Releasing Agent (100 Det.)
87-117013	SRA: Somatic Cell Releasing Agent (100 Det.)
89-117013	Blotter Paper (20 Sheets, 100 Det.)
87-117010	Positive Pressure Device
89-117024	Cell Concentrator
87-117033	ATP Control, 1 vial (10 det.)
87-117042	TSB(enrichment broth for spores) ea
89-117014	Stomacher Solution, 25mL
89-117025	Model 4560 Microluminometer (ONLY)
89-117016	Model 4560 Reagents (100 det)

USER SUPPORT

NHD is committed to customer satisfaction. It is our hope that this manual has been clear and complete in describing both function and use of the *PROFILE-1* system. Should, however, you require additional information, please contact us on our customer support line at (800) 888-5015 (USA only) or (410) 992-9357; email is NHDiag@aol.com.

WARRANTY

New Horizons Diagnostics Corporation warrants the Model 3560 Microluminometer and power supply against defects in materials and workmanship for a period of 1 year from date of purchase. This warranty does not cover misuse or abuse of instrument as may or may not be evidenced by physical damage to instrument components. No other warranties or guarantees either written or implied are in effect. Neither New Horizons Diagnostics Corporation, nor their subsidiaries, successors or joint operations are responsible for occurrences resulting from or following the use, misuse or procedures related to the use of this device.

INSTRUMENT REPAIR AND SERVICE

RGA# _____ **Authorized by:** _____

MODEL NO._____ **SERIAL NO.**_____

If it should become necessary to return your microluminometer for service, please contact NHD and obtain an RGA# and shipping instructions. Then copy this page, fill it out, and send it with your instrument. **Send instrument only … no case, cords, battery, or accessories.**

NAME/TITLE:_____

COMPANY/ORGANIZATION: _____

ADDRESS: _____

City:_____ State:_____ Zip:_____

Country (if other than USA): _____

TELEPHONE NO.(____)_____-_____ FAX NO.(____)_____-_____

DESCRIPTION OF PROBLEM: _____

_____

_____

_____

SHIP TO: NEW HORIZONS DIAGNOSTICS
Attn: Instrument Repair
9110 Red Branch Road
Columbia, MD 21045 USA
(800) 888-5015 Fax (410) 992-0328 email: NHDiag@aol.com