ANGELINI

MAKY 21.1

Training
Program

The purpose of the following training program is to outline the features to be covered during an In-service of the MAKY 21.1. After the training program the user has been instructed in the proper use of the MAKY 21.1. Mentions to the Operator's Manual may be given as reference for further details on specific functions.

This program also outlines the training agenda that should be followed during the Inservice.

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DOCUMENT: Angelini Pharma, MAKY Training Program
Revision: 4
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1. INSTALLATION

The MAKY has the following connections on its back panel:

1. WATER:

    This connection represents the INPUT WATER for the MAKY. Its quality has to meet AAMI standards for reuse. Recommended *dynamic pressure* is 35 psi. It should not exceed 50 psi. In cases of *new* installations AlcavisHDC recommends the use of a filter to prevent tubing debris from getting into the MAKY.

2. WASTE:

    This connection represents the DRAIN. It has to be placed bellow the level of the MAKY and should be able to handle a maximum of 3 liters per minute flow.

3. CLEANER:

    This connection represents the input of the chemical agent to be used in the DIALYZER CLEANING. The MAKY has been cleared by the FDA to use Bleach and Peracetic Acid for Dialyzer Cleaning. Both chemicals will be diluted by the MAKY. Contact AlcavisHDC before changing chemicals. Refer to the Operator's Manual for further details.

4. DISINFECTION:

    This connection represents the input of the chemical agent to be used in the DIALYZER and MACHINE DISINFECTION. The MAKY has been cleared by the FDA to use Peracetic Acid and Formaldehyde for Dialyzer Disinfection. Both chemicals will be diluted by the MAKY. Refer to the Operator's Manual for further details.
    Every 200 reprocessing cycles the MAKY will inform that a Formula 409 or Bleach Procedure is needed. This procedure is intended to remove build-up of material and is not intended for disinfection of the system. Refer to the Operator's Manual for further details.

All chemicals connected to this port will be diluted by the MAKY 21.1 in the configured dilution. Contact AlcavisHDC before changing chemicals.

5. GLUTARALDEHYDE / WATER:

This connection represents the input of GLUTARALDEHYDE intended to be used in DIALYZER DISINFECTION. The MAKY WILL NOT dilute Glutaraldehyde. Instructions to use Glutaraldehyde require pre-dilution. It will also serve as a RO water connection when different chemicals are used for cleaning and disinfection. Refer to the Operator's Manual for further details.

6. PRINTER:

This connection is intended to be used with a parallel port printer to print the reports that the MAKY offers. Refer to the Operator's Manual for further details.

7. BAR CODE PRINTER:

This connection is intended to be used with a Label printer that meets the specifications pointed out in the Operator's Manual. This printer will print Labels that will be used with the dialyzers reprocessed in the MAKY. It will also print labels for Volume Check, System Disinfection and Culture Procedures.

8. BAR CODE SCANNER:

This connection is intended to be used with a bar code scanner that meets the specifications pointed out in the Operator's Manual. This bar code scanner is intended to scan the ID Labels that the MAKY prints to ease the operation.

9. NETWORK:

This connection is intended to interconnect different MAKYs.

10. PC:

This connection is intended to connect a PC to the MAKY. It also serves as a port to download information from one MAKY to another.

11. TRAFFIC:

This connection is intended to connect an external module that will mimic the 3 lights on the control panel.

2. GENERAL CONCEPTS

The MAKY is an aggressive reprocessing system. It uses dynamic procedures to clean the dialyzers. The agitation used will be noted during the HPAP process. HPAP stands for Hydro-Pneumatic Agitation Process. When the cleaning phase finishes the MAKY will Test the dialyzer. The Volume Test uses Hydrostatic Pressure, thus no load cell is needed. If the test fails the MAKY will repeat it one more time automatically. If it still fails, it will give the option to Preclean, Reprocess the Dialyzer again, Repeat the Test or Discard the Dialyzer. When the Volume Test is passed, the Pressure Test (MIT- Membrane Integrity Test) will be performed. If it fails it will be repeated one more time automatically. If it still fails, it will give the option to repeat the test or to discard the Dialyzer. Once both tests are passed the MAKY will disinfect the Dialyzer and print a Label informing the outcome of the Reprocessing Cycle.

3. DIFFERENCES

- ♣ Everything is connected to the MAKY, no ancillary PC is needed
- ♣ More Operating Programs
- ♣ More Aggressive cleaning
- ♣ Automatic repetition of the Volume and Pressure Test
- ♣ Self Calibration during Volume Check
- ♣ Self explanatory 409 procedure
- ♣ Etc…

4. MENU CHOICES

a. PURGE

Rinse of internal paths if the MAKY was turned off during active dwelling of Long Term Disinfection or Formula 409/Bleach Procedures.

b. PREPROCESS

PREPROCESS DIALYZER

This option will determine the original (first) TCV. This value will be used as the 100% value for future comparison. Dialyzer preprocessing also serves to wash out any manufacturing residue in the dialyzer, the presence of which may contribute to "first use syndrome" which ranges from reactions to discomfort. The preprocessed dialyzer may be linked to a specific patient during this same procedure. The preprocess option is only available when the database is being used. When the database is not used, selecting this option will have no effect.

ASSIGN DIALYZER TO PATIENT

This function is intended to assign a Patient Number to a specific Dialyzer. The Dialyzer may be in the Preprocess List or a new Dialyzer.

REPROCESS without USE

The purpose of this menu selection is to refill the dialyzer with the appropriate disinfectant if the dialyzer has not been used during the maximum allowable shelf time, or if the dialyzer failed the potency test. The reuse number will not change, but the TCVT result and date will be updated. This function is not available if the database is not being used.

c. PRECLEAN
   ♣ HARD TO CLEAN DIALYZERS
   ♣ LABEL WITH DATE & TIME
   ♣ AGGRESSIVE PRECLEAN ACTION

This function is intended to stop the MAKY 21.1 after the cleaning phase. In hard to clean dialyzers this option will fill them with the cleaning solution and allow them to rest until a complete reprocessing cycle is performed. The MAKY 21.1 will print a PRECLEAN Information Label containing the dialyzer number, the patient's name and the date and time when the PRECLEAN program finished.

d. SYSTEM DISINFECTION
The system must be disinfected once a day minimum. It may be disinfected in either of two ways: Standard or Long-Term. The chemical agent that will be used is the one connected to the disinfectant port (Refer to Figure 4-3, Page 4-11-Operator's Manual). Both options require that the MAKY 21.1 is configured according to Figure 5-11, System Disinfection Configuration. These options may be entered by pressing the MENU key while in the Presentation screen, or by pressing the #5 / #6 keys at the end of the reprocessing cycle.

Before and after either a Long Term or a Standard Disinfection procedure, the external surfaces of the MAKY 21.1 must be cleaned. Use a soft cotton cloth soaked in non-expired 1% Peracetic Acid solution.

STANDARD DISINFECTION
   ♣ After a "Dirty" Dialyzer
Standard disinfection consists of pre-rinsing, disinfectant loading, recirculation, final rinse and emptying of the circuit with air . Standard disinfection may be used:
   a.   Between treatments, or
   b.   As mandated by the responsible physician for safety reasons.

LONG TERM DISINFECTION
   ♣ Overnight Procedure
Long-term disinfection consists of pre-rinsing, disinfectant loading, short recirculation, active dwelling, final rinse and emptying of the circuit with air. Long-term disinfection is used as an overnight procedure or if the machine will not be used for more than 24 hours

WATER LOOP

♣ Overnight Procedure with loop at water-waste

Same as Long Term but with recirculation through the water line and waste ports. This is useful in places were heated disinfection is used.

FORMULA 409 / BLEACH PROCEDURE

♣ After 200 cycles or as mandated by the center's policies.

The INSTITUTIONAL FORMULA 409 / Bleach procedure consists of pre-rinsing, Institutional Formula 409 / Bleach loading, short recirculation and active dwelling. The INSTITUTIONAL FORMULA 409 / Bleach procedure is used as an overnight procedure to allow the chemical to remove possible build-up of material in the internal fluid paths. AlcavisHDC recommends performing an Institutional Formula 409 procedure every two weeks. The MAKY 21.1 has an internal counter that counts the number of dialyzers that have been reprocessed.

e. VOLUME CHECK

♣ Daily Operation

The volume should be within a 3ml range of the rated value of the Cell. If so, the MAKY 21.1 will print a label showing the obtained volume and the date. If not, the MAKY 21.1 will **automatically** repeat the VOLUME CHECK. If after this retest, the volume is within a 3ml range of the rated value, the previously mentioned label will be printed. If not, the MAKY 21.1 will **automatically self calibrate** the System Volume.

DO NOT TURN THE MAKY OFF WITH * PM * MESSAGE DURING VOLUME CHECK

f. DISCARD DIALYZER

♣ Discard Dialyzers for any other reasons that Volume or Pressure.

g. ERASE PATIENT

♣ Erase Patient's history from the database.
♣ WILL NOT ERASE THE NAME

h. LABEL

♣ REPRINT OLD LABELS
- ID (BAR CODE)
- INFORMATION (LAST/PREVIOUS)

i. CALIBRATION

♣ If Volume Check Fails. Refer to Section 9 of Operator's Manual.
♣ Culture Procedure. Calibration / Diag / Cul

j. ERRORS

TROUBLESHOOTING GUIDE

A **"*"** symbol at the end of an error code indicates that the MAKY 21.1 may try to overcome the error situation by pressing YES.

The message "PM required" will appear every three months (or value preprogrammed). By pressing YES the message will be skipped until the next reprocessing cycle. By pressing YES, the message may be skipped any number of times. The message will appear until the PM (Preventive Maintenance) function (refer to page 9-8) is performed. AlcavisHDC strongly recommends to perform a PM with 3 days after this message appears.

The message "409-Bleach Recommended" will appear every 200 (or value pre-programmed) reprocessing cycles. By pressing YES, the MAKY 21.1 will perform 25 reuses more until the message appears again. The previous operation may be repeated until the 409 – Bleach procedure is performed.

The message "PM required" will also appear if a Volume Check was interrupted during self-calibration. Refer to Section 9 for details on System Volume calibration.

Pressing RESET after every error code will reset the system. If a dialyzer is tried to be reprocessed the MAKY 21. will prompt the operator to configure the MAKY in Sanitizing Mode and to Press YES. Refer to Figure 5-11, Page 5-21 for connection details.

k. NAMES
♣ Use to Create NEW NAMES
♣ PATIENT/BRAND/CAUSE/UNIT NAMES
♣ EXTERNAL PC KEYBOARD

5. OPERATING PROCEDURES

a. HOW TO CREATE A PATIENT

♣ SELECT THE LIST OF ACTIVE PATIENTS
REPORTS
TOTALS & LIST
PATIENTS
\Find a Patient Number NOT IN USE

♣ GIVE A NAME
MENU
NAME
PATIENT
\Enter the NOT USED Patient Nr.
\Type LAST NAME, FIRST NAME (up to #20 digits)
\Type Patient ID (up to #9 digits) (optional)

b. HOW TO PREPARE A SPARE DIALYZER

♣ PREPROCESS and DO NOT ASSIGN TO PATIENT

MENU
PREPROCESS
PREPROCESS PROCEDURE
DO NOT ASSIGN PATIENT
\ Select a Program
\ Select a Brand
\ PRINT ID-LABEL

When CAN IT BE ASSIGNED?
AFTER DIALYSIS
- Connect the Dialyzer
- Scan PREPROCESSING LABEL as a normal Reprocessing Cycle
- The MAKY will ask for the Patient
- Select it from the displayed List.
- The MAKY will ask for the PROGRAM.
- Select the right program for that dialyzer type.
BEFORE DIALYSIS
MENU
PREPROCESS
ASSIGN PATIENT TO DIALYZER
\ Select from PREPROCESS LIST (PRESS YES)
\ Select the dialyzer number from the LIST
No Need to Connect the Dialyzer.

c. HOW TO PREPROCESS A PATIENT'S DIALYZER

♣ PREPROCESS and ASSIGN TO PATIENT

MENU
PREPROCESS
PREPROCESS PROCEDURE
ASSIGN PATIENT
\ Select Patient
\ Select a Program
\ Select a Brand
\ PRINT ID-LABEL

d. HOW TO REPROCESS A DIALYZER

♣ Press ANY NUMERIC KEY from 1 to 9.

♣ Either SCAN the ID-LABEL or MANUALLY ENTER the information prompt by the MAKY 21.1

♣ Confirm the PATIENT's NAME by either pressing YES or the EXTENDED VERSION of the corresponding PROGRAM.

♣ The MAKY will reprocess the DIALYZER.

♣ IF NO ERRORS APPEAR DURING THE VOLUME TEST or THE PRESSURE TEST; THE MAKY WILL PRINT AN INFORMATION LABEL.

♣ IF THE VOLUME TEST FAILS; THE MAKY WILL REPEAT THE TEST ONE MORE TIME AUTOMATICALLY. IF THE FAILURE PERSISTS, THE MAKY WILL GIVE THE OPTION TO PRECLEAN, TO REPROCESS THE DIALYZER AGAIN, TO REPEAT THE TEST OR TO DISCARD.

♣ IF THE PRESSURE TEST FAILS; THE MAKY WILL REPEAT THE TEST ONE MORE TIME AUTOMATICALLY. IF THE FAILURE PERSISTS, THE MAKY WILL GIVE THE OPTION TO REPEAT THE TEST OR TO DISCARD THE DIALYZER.

e. HOW TO REPROCESS WITHOUT USE
MENU
PREPROCESS
REPROCESS without USE
\ Proceed as normal reprocessing

f. HOW TO REPROCESS A HARD-TO-CLEAN DIALYZER
Option 1:
PRECLEAN + REPROCESS

Option 2:
USE EXTENDED PROGRAMS BY PRESSING HE+/HF+/STD+ WHEN THE PATIENT'S NAME IS DISPLAYED. If the dialyzer always needs extended program, consider the possibility of changing the program on the label.

g. WHAT'S A DRY PACK
♣ REPROCESS A DIALYZER ALREADY USED with a PATIENT BUT NOT PREPROCESSED in THE MAKY

from LOGO Screen press any Number > 0
enter the FREE DIALYZER NUMBER
select the patient from List
enter Program
enter Brand

♣ The MAKY WILL REPROCESS THE DIALYZER and when the VOLUME TEST is COMPLETED the MAKY will ask to PRESS YES
♣ The MAKY will ask to ENTER the EXPECTED PREPROCESS VALUE. Enter a value higher or equal to the displayed value. The entered value should not exceed in 15ml the displayed one
♣ PRINT the ID LABEL
♣ Proceed as normal reprocessing cycle.

h. HOW TO ENTER A DIALYZER'S DATA FROM ANOTHER REUSE MACHINE

a. Find a new dialyzer number:
b. From LOGO, Press any number > 0
c. Take note of the FREE DIALYZER NUMBER displayed.
d. PRESS RESET to go back to the LOGO
e. Create OLD DATA:

    f.   PRESS REPORTS
    g. Go to NO NET
    h. Enter the FREE DIALYZER NUMBER
    i.   Select the PATIENT
    j.   ENTER PROGRAM
    k. ENTER BRAND
    l.   ENTER REUSE #00
    m. ENTER VOLUME
    n. ENTER MONTH (MTH)
    o. ENTER DAY

The above steps constitute the creation of dialyzer preprocess value and its assignment to a patient.

    p. Go to NO NET
    q. Enter the same dialyzer Number
    r.   Select Reuses #1 to last one available
    s.   Enter corresponding volume and dates.

The above steps constitute the creation of dialyzer values for reuses following preprocess.

    t.   PRINT ID-LABEL:
        -   from LOGO go to MENU
        -   LABEL
        -   ID
        -   Enter dialyzer number
        -   Confirm Name
        -   Press DOWN for REGULAR PROGRAM / UP for EXTENDED

6. REPORTS

Refer to Operator's Manual Section 7 for further details.

a. INTRODUCTION

By pressing the REPORT key on the control panel while in the Presentation screen, the operator will enter the REPORT Menu. Selecting the REPORT option in the MAIN MENU screen will also enter this function.

Note: The information shown is for DEMONSTRATION purposes ONLY. It DOES NOT represent actual data.
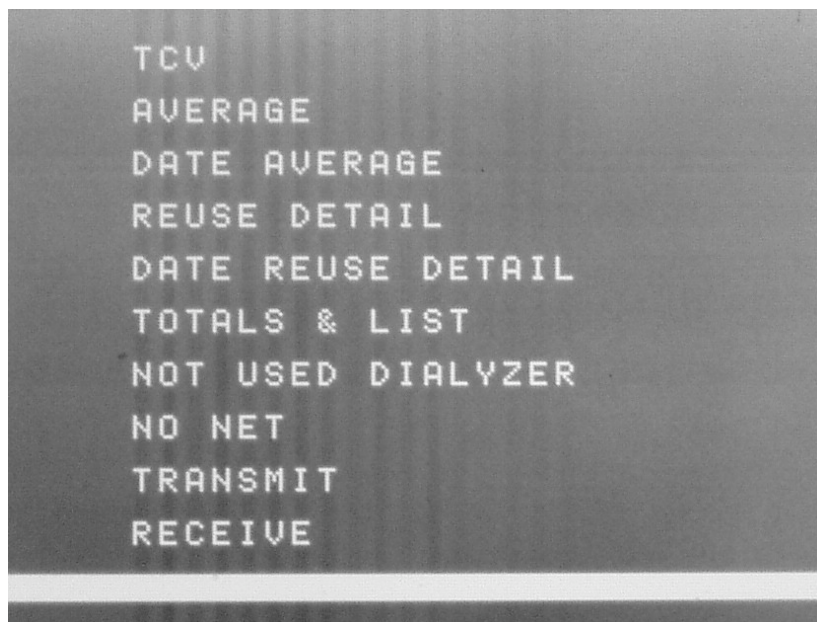

Figure 7-1 Report Menu Screen

DOCUMENT: Angelini Pharma, MAKY Training Program
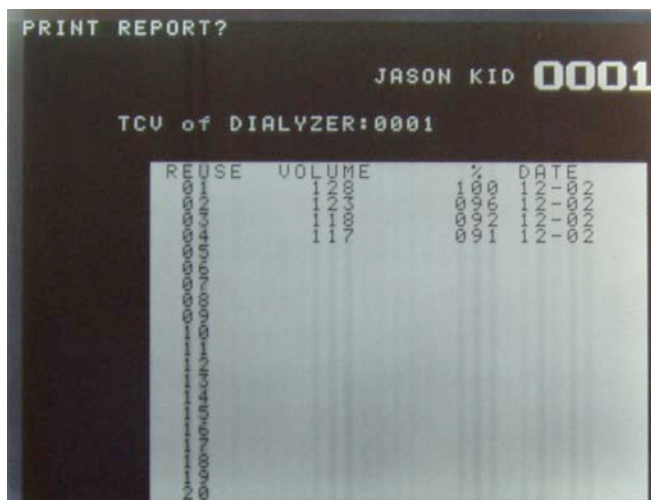Revision: 4
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b. TCV

Figure 7-2 TCV Values Report Screen

The MAKY 21.1 will show the original TCV, the last 19 results, its respective relative percentages of the dialyzer, and the reuse date.

c. AVERAGE

Figure 7-3 Average Report Screen
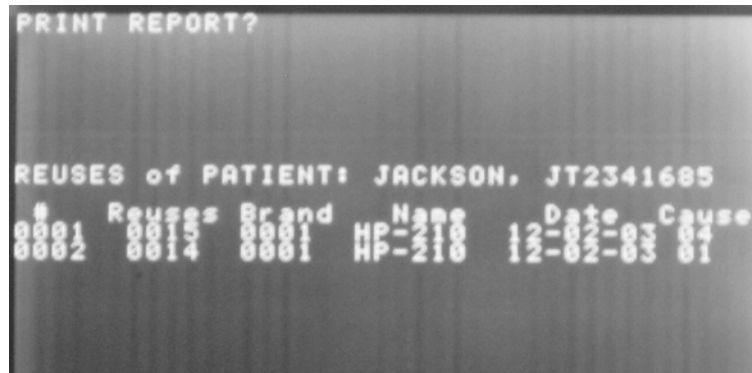
The AVERAGE Report shows:

Patient Number / Number of dialyzer involved in that average / Average / Patient Name / Patient ID

It can display the complete Database, a Range of Patients or a specific patient.

d. DATE AVERAGE

The MAKY 21.1 will prompt the operator to enter the INITIAL and FINAL months and years of the period to be analyzed. The format is exactly the same as the one noted on c.

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e. REUSE DETAIL

Figure 7-4 Reuse Detail Report Screen

The REUSE DETAIL report shows:

Number of dialyzer/ Reuses achieved/ Brand Number/ Brand Name/ Discard Date /Discard Cause

Note: The MAKY 21.1 stores the information of up to 50 dialyzers per patient. On the 51st discard, the first dialyzer will be deleted. The option of printing / viewing the report will be given before the database is reset.

f. DATE REUSE DETAIL

The MAKY 21.1 will prompt the operator to enter the INITIAL and FINAL months and years of the period to be analyzed. The format is exactly the same as the one noted on e.

g. TOTALS & LIST

The following sub-menu will be displayed:

TYPE
BRAND
CAUSE
MONTH
TOTAL
RESET TOTAL
LINK
PREPROCESS
PATIENTS
BRAND LIST
CAUSE LIST

TYPE
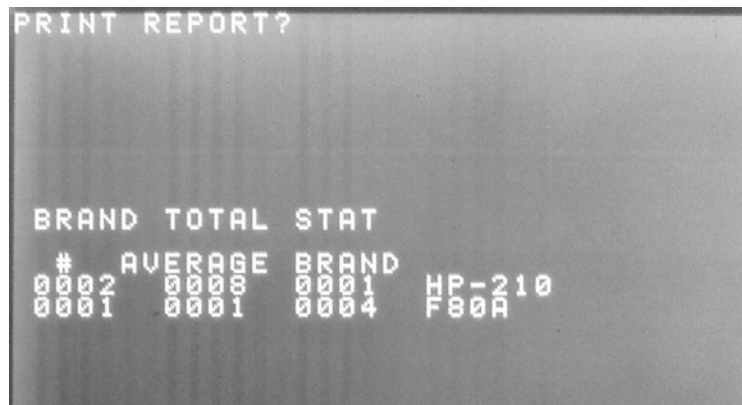
Figure 7-5 Type Statistics Report Screen

The TYPE Report shows:

Number of dialyzers used of each type / Average / Type (STD/HE/HF)

BRAND

Figure 7-6 Brand Statistics Report Screen

The BRAND Report shows:

Number of dialyzer of each brand / Average / Brand Number / Brand Name

The MAKY 21.1 stores data that includes the TOTAL average and can be split into each of the last 12 months.

Using the UP or Down Keys the operator will be able to see the TOTAL and each month statistic.

CAUSE

Figure 7-7 Cause Statistics Report Screen

The CAUSE Report shows:

Number of dialyzers failing for each cause / Average / Cause Number and Name

MONTH

Figure 7-8 Month Statistics Report Screen

The MONTH Report shows:

Number of dialyzers for each month / Average / Month-Year   of the last 12 months

TOTAL
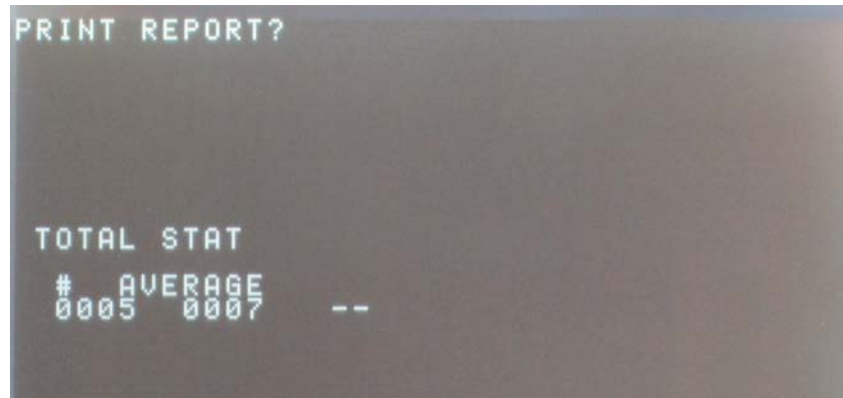
Figure 7-9 Total Statistics Report Screen

The TOTAL Report shows:

Number of dialyzers/ Average

RESET

The GENERAL statistics reports may be reset from time to time by selecting this option.

h. LINK
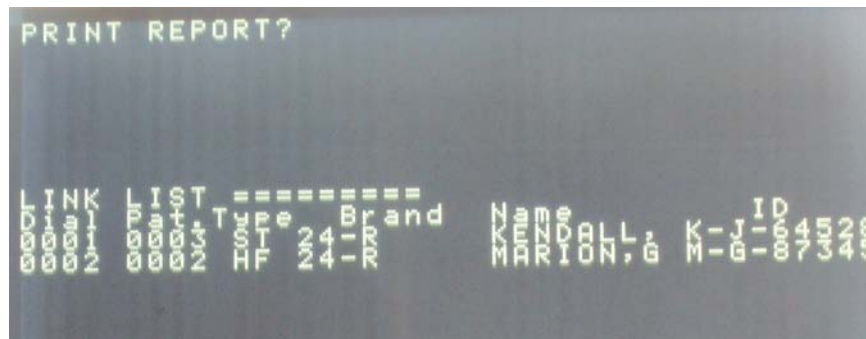
Figure 7-10 Link List Report Screen

The Link List Report shows the Patient that each dialyzer has been assigned to:

Dialyzer Nr. / Patient Nr. / Type / Brand Nr. / Patient's Name / Patient's ID

i. PREPROCESS

Figure 7-11 Preprocess List Report Screen

The Preprocess List Report shows the dialyzers that have been preprocessed but remain un-assigned:

Dialyzer Nr. / Date / Volume / Brand Nr. / Type

j. PATIENTS

Figure 7-12 Patient List Report Screen

The Patient List Report shows the active patients in the system:

Patient's Name / Patient's Nr. / Patient's ID

k. BRAND LIST

Figure 7-13 Brand List Report Screen

The Brand List Report shows the brands in the system:

Brand Nr / Brand Name

l. CAUSE LIST

Figure 7-14 Cause List Report Screen

The Cause List Report shows the different Discard Causes in the system:

Cause Nr / Cause Name

m. NOT USED DIALYZER

The MAKY 21.1 will display all dialyzers that have not been reprocessed within the number of days entered. The NO USE Report shows:

Dialyzer Number / Last Reuse Date

n. NO NET

This option is intended to load previous information of dialyzers that were not used with the MAKY 21.1 or to load the data that couldn't be stored when working ONLINE because of a loss of communication.

o. TRANSFER

This option is intended to transmit the memory of the MAKY 21.1 to another MAKY 21.1 or to the ECNET

p. RECEIVE

This option is intended to receive the memory of the MAKY 21.1 from another MAKY 21.1 or from the ECNET.

1. Connect both MAKY 21.1 using the corresponding cable to the PC port.
2. Select the Transmit option on the MAKY 21.1 that will receive the data.
3. Select the Receive option on the MAKY 21.1 that will transmit the data.
   The Report Screen will be displayed when the transfer is finished. It usually takes around 10 minutes.

7. TRAINING QUESTIONNAIRE

Use the following questions to evaluate the personnel being inserviced.

MAKY 21.1 DIALYZER REPROCESSING SYSTEM
INSERVICE QUESTIONAIRE

NAME:

DIALYSIS UNIT:

RESULTS:

DATE:

COMMENTS:

Circle the right answer/s.

1. The **Purge function** in the Main Menu is consists of:
    A) Rinse + Chemical Cycle + Rinse + Empty Circuit using Air;
    B) Rinse + Empty Circuit;
    C) Empty Circuit;
    D) Rinse + Chemical Cycle + Rinse.

2. The Purge function is **primarily** intended to be used:
    E) After a Standard Disinfection;
    F) Before each reprocessing cycle;
    G) After each reprocessing cycle;
    H) After a Long Term Disinfection if the MAKY 21.1 was turned off during dwelling.

3. **One of the purposes** of the **Preprocess Dialyzer** function is:
    A) Enter the manufacturer's priming volume to the system;
    B) Enter old data of the patient's dialyzer into the system;
    C) Calculate the actual priming volume;
    D) Enter the 80% value for that dialyzer.

4. The **Reprocess without Use** function is intended to:
    A) Enter reprocess information of dialyzers that have not been used;
    B) Reprocess dialyzers and do not increase reuse numbers;
    C) Modify the reuse number of a dialyzer;
    D) Reprocess a dialyzer that has not been used in the MAKY.

5. The **Standard Disinfection** is indicated:
    A) As an oversight procedure;
    B) In between shifts;
    C) After every reprocessing cycle;
    D) Before the daily operations starts.

6. The **Long Term Disinfection** consists of:
    E) Rinse + Chemical Cycle + Rinse + Empty Circuit using Air;
    F) Rinse + Empty Circuit;
    G) Empty Circuit;
    H) Rinse + Chemical Cycle + Active Dwelling + Rinse+ Empty Circuit using Air.

7. The **Long Term Disinfection** is indicated:
    I)   As an overnight procedure;
    J)   In between shifts;
    K)   After every reprocessing cycle;
    L)   Before the daily operations starts.

8. The **Volume Check** will fail **ALWAYS** fail if:
    A)   The obtained volume is 75ml;
    B)   The obtained volume is 66ml;
    C)   The obtained volume is 4ml higher or lower than the entered value;
    D)   The obtained volume is 70ml;

9. The **Volume check ALWAYS** has to be done using:
    E)   A High Flux dialyzer;
    F)   A 70ml Volume Cell;
    G)   Any Volume Cell;
    H)   The machine in Sanitizing Configuration.

10. If the **Volume Check fails** to read a Volume with an acceptable range:
    I)   The MAKY always has to be recalibrated;
    J)   The MAKY will self calibrate automatically;
    K)   An error will be indicated;
    L)   The user should run a calibration procedure.

11. The **Discard Dialyzer primary** function is intended to:
    A)   Discard dialyzers that failed during the reprocessing cycle;
    B)   Delete dialyzers that have expire their shelf time;
    C)   Discard dialyzers for other reasons that Volume or Pressure;
    D)   Reprocess dialyzers that were not passing the Volume Tests in other machines.

12. The **Labels** menu is intended to:
    A)   Generate labels for a new dialyzer;
    B)   Re-print old labels;
    C)   Generate Preclean labels;
    D)   Print labels of future dialyzers.

13. Before the **reprocessing** cycle starts, the MAKY:
    A)   Checks that the tubing is not connected in sanitizing mode;
    B)   Asks the user to check the dialyzers connections;
    C)   Asks the user to validate the patients name;
    D)   Asks the user to enter the minimum volume.

14. If the **volume fails**, the MAKY will:
    E)   automatically discard the dialyzer;
    F)   ask the user to press YES before discarding the dialyzer;
    G)   give the option to Discard, Preclean, Repeat the test or Reprocess again the dialyzer;
    H)   keep on trying until the volume testis passed.

15. If the **MIT (Pressure Test) fails**, the MAKY will:
    I)   retry the test two more times automatically;
    J)   retry the test one more time automatically;
    K)   give an error signal immediately;
    L)   discard the dialyzer automatically.

8. DAILY LOG BOOK SHEET

Use the Log Book Sheet for daily logging purposes on the operation of the MAKY 21.1.