

THE MDC MEDICATION DOSAGE COMPUTER

*PROGRAMMING & USER
INSTRUCTION
MANUAL*

©1990 BCMC
BETTER CONTROL MEDICAL COMPUTERS INC.
TORONTO, CANADA

THE MEDICATION DOSAGE COMPUTER

Introduction

The BCMC Medication Dosage Computer represents a totally new concept in the control of diabetes. This personalized micro-computer incorporates the contributions of many world renowned diabetologists. Together with their knowledge and experience as well as your input, the MDC is now able to assist you in achieving better control of your diabetes. Its technical characteristics are documented. The results of clinical trials have been published. See References, Scientific Publications, Abstracts, and Book Chapters on pages 39-41.

The Medication Dosage Computer (MDC) can be used by any person who has IDDM or NIDDM. It may be programmed to recommend short- and intermediate-acting oral hypoglycemic agents and/or short- and intermediate-acting Insulins.

The MDC accepts data on body weight and will evaluate and declare to the User whether the weight is stable, is going up, or is going down.

The computer may be used simply as a data recording device. It will then accept information about body weight and glucose levels (either in blood or in urine). In this case the MDC will not recommend any medication.

CONTENTS

Introduction.....	1
The Computer.....	3
Algorithms for Insulin Dosage Adjustment.....	4
Glucose Concentrations Above Target.....	5
Glucose Concentrations Below Target.....	5
Pre-Meal Supplements.....	6
Safety Features.....	6
Configuring the MDC.....	8
Targeting for Blood or Urine Glucose.....	9
Selecting Normal or Tight Control.....	10
Accommodating Small Insulin Doses.....	12
Measuring Glucose in Urine or Blood.....	12
Meal Timing.....	14
Hypoglycemia.....	15
Hyperglycemia.....	16
Illness.....	16
Using the Exercise Option (EX).....	17
Using the Carbohydrate Option (CHO).....	18
The Mean: A Measure of Diabetes Control.....	19
Using the Mean to Evaluate the Diet.....	20
Programming Instructions.....	21
User Information Sheet.....	22
Step by step Programming.....	24
To Examine/Change Programming.....	30
User Instructions.....	31
Printing-Out MDC Data.....	34
Warnings.....	36
Maintenance and Service.....	36
Care of Your MDC.....	36
Battery Replacement.....	37
Nonexistent.....	38
References.....	39
Additional Scientific Reports.....	40
Abstracts.....	40
Book chapters.....	41
Sample Patient Data Print Out.....	42
Interpreting the Print-Out.....	43
User Keyboard Diagram.....	44
Alphabet Keyboard for Programming.....	45

The Computer

The MDC is a handheld computer which has been programmed to help achieve a pre-determined target glucose level. It does this by making medication dosage adjustments based on blood and/or urine glucose levels which the MDC stores in its memory.

The MDC is a single function computer capable of receiving, storing and processing User-measured data in regards to glucose concentrations, dietary carbohydrate and physical exercise. It is firmware programmed with sophisticated algorithms for dosage adjustments based on the chosen method of glucose measurement, as well as other important initial parameters concerning the User. Subsequently, at each entry, the MDC refers to the data in its memory and, if indicated, calculates changes in the current dosages of medication in order to achieve or maintain a target glucose level in blood or urine. The dosage computing algorithms in general follow certain assumptions and published guidelines¹⁻⁴ as outlined below.

To ensure long-term safety, the MDC is 'non-aggressive' in its operations. Dosage

adjustment is gradual rather than immediate, minimising risk of hypoglycemia while still achieving improved glycemic control over the long term.

Algorithms for Insulin Dosage Adjustment

In general the algorithms for dosage adjustment assume:

1. That the User follows a consistent lifestyle, is free of intercurrent acute illness and keeps a constant level of activity, although unpredictable exercise can be compensated with food intake whereas predictable exercise can be entered into the MDC.
2. That a basic food plan is consistently followed according to recommended nutritional guidelines.
3. That the medications are used in a multiple component regimen, so that one component coincides with each period of the day and each meal. Accordingly, changes in medication are then made when User measured glucose concentrations are above or below the targets. If insulin is used, supplements may also be added or subtracted, as detailed below.

Glucose Concentrations Above Target

1. If the fasting pre-breakfast blood/urine glucose concentration is greater than the reference target for two or more days, the evening intermediate-acting medication is increased.
2. If blood glucose/urine glucose before dinner in the evening is greater than the reference target for two or more days, the morning intermediate-acting medication is increased, if the User is on a two injection regimen.
3. If the User is on a three or more injection or medication regimen and the pre-dinner glucose level is above target two or more days, then the lunch-time medication will be increased appropriately.
4. If the pre-lunch at midday or pre-snack at bedtime blood glucose/urine glucose is above the reference target for two or more days, then the short-acting medication at breakfast or the short-acting medication at dinner is increased.

Glucose Concentrations Below Target

1. If the blood glucose/urine glucose is below target at any of the measurement times as above, the appropriate medication dose is reduced.

2. If there is a hypoglycemic reaction, the key labelled RXN must be pressed at the next meal entry and the appropriately responsible medication dose is then cut by 10%.

Pre-Meal Supplements

If a User has been prescribed insulin rather than tablets, the following applies:

1. If the blood glucose on arising or before evening dinner is greater than the target, then extra regular insulin is given according to a scale which adds 1 extra unit for each 100mg/dl (in X1 mode) above target, but only at that time.
2. If the blood glucose at breakfast or dinner is below target, then the regular insulin is reduced according to the same scale.
3. The MDC programmed to accept urine glucose concentrations does not usually recommend supplements of Regular insulin at pre-meal injections.

Safety Features

The following are the more significant safety features included in the design of the MDC.

1. Initial insulin requirements or oral-hypoglycemic agent requirements are

programmed into the MDC for each User individually, as are other parameters of the User's regimen.

2. Limits can be set on the maximum allowable single medication dose the MDC can recommend.
3. Maximum changes are limited to small increments of 3 units of insulin and 0.2 tablets or less regardless of the specific mode (X1 or X2) of operation programmed.
4. Up to 90 days of entries by the User and all corresponding dosages recommended are stored in random access memory and can be printed to review consistency and compliance.
5. The program is in a protected, masked, silicon, read-only-memory (ROM) module so that the User can never change any of the parameters or change the algorithms. The binary program in the ROM is non-volatile, and is one of the safest digital storage mediums made.
6. Reference glucose targets are programmed into the MDC but cannot be set to values so low that the risk of hypoglycemia is unduly increased.
7. Appropriate medication dosage adjustments are made immediately when a special "RXN" key is utilized to advise the MDC of hypoglycemia or an insulin reaction.

8. Access to the programming parameters requires a numeric code known only to the programmer.
9. If the MDC has been programmed for tight control (X2 Mode), it will automatically reduce the tightness of control to normal (X1 Mode) as soon as the User experiences three or more episodes of hypoglycemia within a 14 day period.
10. Extra carbohydrate entry by the insulin injecting diabetic is limited to $\pm 75g$.
11. Exercise entry by either the insulin taking diabetic or the non-insulin taking diabetic is limited to 5 levels.
12. The MDC monitors the dosages and tells the User when any single dose reaches the MAXIMUM programmed. When this occurs, it so advises the User and then suggests to contact his doctor.

Configuring the MDC

The MDC is configured in simple interactive steps prior to first use. This is done through the programming mode. To do this, the programmer responds to the prompts and sequentially enters the types of insulins or oral hypoglycemic agents, User's name, the starting or current doses of short and intermediate-acting insulins and/or tablets, the desired pre-meal capillary blood glucose or

urine glucose targets. The User also specifies other important safety parameters such as the maximum medication doses and whether a 2, 3, or 4 dosing regimen is to be followed.

Targeting for Blood or Urine Glucose

When the MDC is to be used with capillary blood glucose measurements, the reference blood glucose (RG) may be targeted from 100 mg/dl to 200 mg/dl. The User's lifestyle and compliance will determine the proper blood glucose target. Most start the treatment process with a target of 140 to 160 mg/dl. Target blood glucose levels less than 100 mg/dl are automatically reset to this value as a safety feature to avoid hypoglycemia.

When the MDC is to be used with urine glucose measurements, the reference urine glucose (RG) may be targeted between 0.1 and 5 g/dl. Although desirable, it is not necessary to establish the renal threshold. However, all urine measurements must be first-voided specimens and the urine glucose target can never be set at 0 g/dl. Again, as a safety feature, the MDC will automatically reset a target glucose of zero to 0.1 g/dl. It should be noted that if the User has diabetic or

unrelated renal disease, this should be considered when programming the User's target levels for urine glucose losses. Users whose urine glucose levels are between 4 and 5 g/dl should initially be targeted to 1.5 g/dl and assessed a month later when the target, if achieved, can be lowered.

The possibility of precipitating retinopathy⁵⁻⁶ by too rapid glycemic normalization should be considered when setting and/or lowering target glucose levels.

Once programmed the MDC receives and processes subsequent information entered by the User on glucose concentrations ascertained before each of the four meals, (breakfast, lunch, dinner, evening snack), on each day of the week. After storing sufficient readings to establish initial glucose concentration trends, the MDC calculates appropriate changes in the short and intermediate-acting dosages to achieve and then maintain the targeted glucose values and to counteract any upward or downward trend.

Selecting Normal or Tight Control

There may be occasions in a person's life when tight glycemic control is essential. Many doctors believe this is necessary before and

during pregnancy. Two modes are possible when using the MDC for dosage adjustment.

The Normal Control (or X1 MODE), allows the programmer to choose a non-aggressive approach to glucose control for the User. In this mode the MDC recommends one extra unit of insulin when the blood glucose is 100 mg/dl above target before meals.

The second (X2 MODE) is for Tight Control. It allows the programmer to choose tighter control for the User. As a consequence, the insulin dosages are adjusted more aggressively to keep abreast of changing glucose levels every day. This is effectively accomplished by doubling(X2) the dosing changes derived in accordance with the algorithms described earlier in this manual. The result is a more aggressive approach to medication dosage adjustments.

As a safety feature, the Tight Control (X2 Mode) may automatically be changed to the Normal Control (X1 Mode). This happens only if a person's lifestyle or sensitivity to medication result in three or more episodes of hypoglycemia within a two week period. This change is not reported to the User but is declared during the programming of the MDC and shown on the print-out.

Should the programmer decide that episodes of hypoglycemia are nonetheless justified for tight control, the MDC must be re-set for the Tight Control Mode (X2).

Accomodating for Very Small Insulin Doses

Sometimes very small doses of insulin must be prescribed, because the User is an infant or a child, or is otherwise very sensitive to insulin.

To facilitate this difficult situation, the MDC recognizes small doses whose sum is less than a total of 10 units and then displays the recommended dose(s) to the nearest tenth of a Unit, ie, one decimal place.

Measuring Glucose in Urine or Blood

The MDC can be programmed to accept blood glucose measurements⁷ or urine glucose measurements⁸. All urine measurements used by the MDC to adjust medication are based on first-voided specimens.

Specimens voided after a given meal and just before the next meal are collectively an

indication of urinary glucose spillage over the entire preceding period of time and reflect the relative insulinization of the User. The MDC algorithms are specifically designed to make dosage changes from this perspective. Second-void samples are of no value since they are eventually always zero.

To achieve maximum benefit from this measurement modality all inter-prandial voidings must be measured and entered into the computer. For example, if a User must void after breakfast at about ten o'clock, he/she should measure this and enter this number. The User must make sure to measure again before lunch to completely empty the bladder and enter this value as well into the computer again. The MDC will average these two numbers before it uses these data for medication dosage adjustments.

Urine glucose measurements should only be made using reagent strips based on the glucose oxidase/peroxidase system which quantifies the concentration of glucose in the urine according to a visual colour scale ranging from 0 (negative) to 5 g/dl. Decimal fractions i.e. 2.50 are accepted. All other methods are insufficiently accurate⁸ and affected by intercurrent antibiotic as well as vitamin therapy⁹.

Blood glucose measurements should be made in accordance with the specific strip manufacturer's instructions, just 4 times each day: before breakfast, lunch, dinner and evening snack. Any visually estimated or meter assisted method can be used but the User's methodology should be reviewed⁷ and the accuracy should be verified by laboratory assay of simultaneously drawn whole blood.

The MDC requires a maximum of 4 glucose (blood or urine) measurements each day if four doses are to be adjusted. If only intermediate acting medication is used, then two measurements each day suffice. Measuring less often has no adverse effect but does slow down the process of optimal dosage adjustment.

Meal Timing

The User should consider how much time to allow between the acts of medicating and eating¹⁰⁻¹¹. Sometimes it is advantageous to allow the short-acting component of insulin or oral-hypoglycemic agent to begin acting for 15-30 minutes before a meal. The MDC can be programmed to declare a waiting period in minutes, which serves to remind the User how long to wait between medicating and eating.

Hypoglycemia

A User should use the key labelled RXN or HPO when an episode of hypoglycemia was experienced. If the User is unsure about the symptoms, a capillary blood glucose measurement should be performed to verify the symptoms. At the next meal entry, the special key labelled RXN must be pressed instead of entering a blood or urine glucose value. The appropriate medication dose will be reduced immediately, although the change may only be apparent the following day.

However, the User must be cautious only to use the RXN or HPO key if the reaction was caused by too much medication and not because of failure to eat the usual amount or because strenuous exercise occurred without compensating with extra food.

At the beginning of an intensified medication regimen, most doctors suggest the User should set the alarm around 3:00 a.m. and make sure that hypoglycemia is not occurring, especially if the MDC is used in X2 Mode or with targets of 100-110 mg/dl. If hypoglycemia is detected, then the RXN key should be

pressed at breakfast time instead of entering the pre-breakfast urine glucose or pre-breakfast blood glucose value.

Hyperglycemia

If blood glucose values are over 400mg/dl (22 mmol/l) or 240 mg/dl (13 mmol/l) with ketones in the urine, a doctor should be notified promptly.

Illness

The MDC should not be used during hospitalization or postoperatively unless specifically advised to do so by the attending physician.

If a User is experiencing an infection or intercurrent illness that destabilizes the blood/urine glucose control, it is best to call the doctor immediately and follow his advice until the condition stabilizes. Only then should use of the MDC resume.

Using the Exercise Option (EX)

An Exercise Option¹² can be invoked by Users who wish to adjust their insulin or medication in keeping with their exercise program. The following example illustrates the use of the Exercise Option.

Suppose a vigorous game of tennis is planned in the afternoon by a User who is on a two injection regimen, taking regular- and intermediate-acting insulins at breakfast and at dinner. This person would press the key labelled EX while the dose is displayed at breakfast time. The MDC will then ask what level of exercise is planned.

There are five exercise levels: 1 is light, 2 is moderate, 3 is medium, 4 is strenuous, and 5 is very, very strenuous exercise. The User must learn from experience the levels suitable for each activity. Fractional levels (i.e. 2.5 or 3.5) of exercise are acceptable.

The MDC will ask if the Exercise is Soon or Late: Soon means in the morning and Late means in the afternoon. The game of tennis after lunch should be entered as being Late. A person may also wish to exercise at a certain level in the morning and at another level in the afternoon. The appropriate insulin doses will be altered to accomodate both times of exercise by keying in first Soon and then Late

when the dose is displayed. This must be done sequentially.

If the User is on a three injection regimen, the afternoon exercise would be entered at lunch time and the exercise timing would be Soon since it is soon after the lunch meal.

As a safety feature, the User cannot enter a higher exercise level than 5 . If a higher level is attempted, the MDC will display : MAX 5 and redisplay the current insulin dose(s) without calculating any reduction due to exercise.

Using the Carbohydrate Option (CHO)

A User may activate the carbohydrate (CHO) option either at breakfast, lunch, dinner or bed-time snack to enter more or less carbohydrate intake. To do this, the User must press CHO while the dose or sign-off is displayed, and then enter the amount of extra or reduced carbohydrate, which is estimated in grams. One carbohydrate or bread exchange is about 15g. When planning less CHO, a User must first enter the number of grams and then press the Minus key.

Again, as a safety feature, one cannot enter more than ± 75 g of extra CHO. If more than

75g of CHO are entered, the display will indicate MAX 75 and redisplay the current dose without any reduction due to extra carbohydrate.

For a person with Non-Insulin Dependent Diabetes who is taking oral-hypoglycemic agents the Extra Carbohydrate Option is not suitable. Usually this type of diabetes is associated with obesity and extra medication will aggravate this condition and may bring about undesired weight gain.

The Mean: A Measure of Diabetes Control

The MDC permits the User to compute and display the mean of glucose readings entered at each meal over the preceding seven days. When the MDC displays DAY=?, the mean function can be activated by pressing the key labelled RXN. It is an important feature whereby the User can monitor improvements achieved in on-going glucose control.

When a User measures urine glucose the mean function is especially important in evaluating diabetes control. Suppose the programmer has targeted the User to spill 1 g/dl of glucose in the urine at breakfast. The User should check the mean function once a

week. If all pre-breakfast glucose values have reached a mean of 1 g/dl or are close to it, then this is the time to do a blood glucose profile with measurements before and after meals. If fasting blood glucose measurements are close to normal then the target of 1 g/dl is the right one for this individual. If the fasting blood glucose measurements are below or above normal, then the urine glucose target(s) should be correspondingly raised or lowered.

Frequent hypoglycemia indicates that too low a reference target of blood or urine glucose has been set in light of the User's lifestyle, compliance with diet, meal timing, activity and/or emotions, and the target should be raised.

Using the Mean to Evaluate the Diet

Sometimes a User's diet is inconsistent with good control. The mean function can be used to evaluate the User's diet at a glance. For example, if the four mean pre-meal glucose levels (in urine or blood) have reached the target previously set then a review of the diet is probably not necessary. However, if one of the pre-meal values is unusually elevated, say for example the pre-dinner value, then a review of

the diet is indicated. It will probably show that the User is taking a late afternoon snack which is too rich in carbohydrate and cannot be accommodated by the waning action of the morning intermediate-acting medication. Deletion of the snack, reduction of the carbohydrate component or substitution with fibre, i.e. vegetables should be considered. Alternatively, switching to the 3 or 4 injection mode may be suggested.

Notably, substitution of carbohydrate with protein and fat are not indicated because protein can stimulate glucagon release and induce hyperglycemia even if there is no carbohydrate in the snack.

Programming Instructions

It is important to collect pertinent User information before attempting to program the MDC. A sample User information sheet is included overleaf.

The programming steps follow a logical sequence. Simply answer the prompted questions by pressing the appropriate numeral which will also be displayed and follow by pressing the key labelled YES. The MDC asks you to verify each entry. This is done by pushing the YES key alone.

USER INFORMATION SHEET

NAME:

LANGUAGE:

MEDICATION (Rx)

Short-Acting OHAs:

Glipizide (GLP) _____

Metformin (MET) _____

Tolbutamide (TLB) _____

Maximum Daily Short-Acting OHA

Dose _____

Intermediate-Acting OHAs:

Acetohexamide (ACE) _____

Glibenclamide (GLB) _____

Gliclazide (GLC) _____

Gliquidone (GLQ) _____

Tolazamide (TLZ) _____

Maximum Daily Intermediate-Acting OHA

dose: _____

Species of Insulin: _____

Initial Doses (Units)	REG	NPH/LEN
Breakfast	_____	_____
Lunch	_____	_____
Dinner	_____	_____
Snack	_____	_____

Intermediate-Acting Insulin: NPH ____ LEN ____

Maximum Intermediate-Acting

Insulin: _____ U

No Medication: NIL _____

Waiting Period for Rx:

At Breakfast WAIT B _____ MIN

At Lunch WAIT L _____ MIN

At Dinner WAIT D _____ MIN

At Snack WAIT S _____ MIN

Reference Glucose (RG): *always in G/DL*

	Blood	Urine
Breakfast	_____	_____
Lunch	_____	_____
Dinner	_____	_____
Snack	_____	_____

Weight Reference (WT REF):

Current Weight: _____ in lbs or kg,
depending on scale used at home.

Measurement Unit:

grams per decilitre _____,

millimoles per litre _____

Dose Mode: _____ X/DAY

Tightness Control (Adjustment Rate):

Normal X1 _____, Tight X2 _____

STEP BY STEP PROGRAMMING INSTRUCTIONS

To begin custom programming:

1. Press ON and immediately press YES.
Ignore the random number displayed.
Note: After pressing ON, press YES at the first tone sound. Do not wait until the MDC prompts DAY =? If you have, wait until the MDC shuts itself off (this takes about 8 seconds) and begin again.
2. Press 1 2 3
Display shows: 1 2 3_
3. Press RXN
Display shows: CLEAR DATA 1
Note: If you wish to clear all the data from memory press 1 followed by YES. If you wish to retain the data and only change some of the parameters then press the YES key only.
4. Display shows: English 1
Note: To choose that displayed language, press 1 followed by pressing the YES key. To choose an alternate language, repeatedly press the YES key until the desired language is displayed, then press 1 followed by YES.
5. Display shows: 0 RX 1
Note: To enter de novo or to change the medication previously selected, press 1 and go to step 6. To keep previously selected medications, press 0 followed by YES and go ahead to step 13.
6. Display shows: 1
Press the YES key.

7. Display shows: GLIPIZIDE 1
Choose this medication by pressing 1 followed by pressing the YES key and go to step 8. Otherwise, to continue to alternate medication, just press the YES key without pressing the numeral 1. If you wish none of the short-acting medications, press the key 1 when the display shows: NIL 1 , followed by the YES key. Go to step 10.
8. Display shows: MAXIMUM MG X
If you chose a short-acting medication, the display will show the maximum allowed dose and frequency per day. You may reduce the maximum by keying in other numerals, or you may accept the recommended maximum by simply pressing YES.
9. The display will now show you the most common tablet size. Key in the appropriate numerals for the tablet size the User is taking followed by YES. Verify carefully and press YES or revise the entry and press YES.
10. Display shows: ACETHEXIMID. 1
To choose this intermediate-acting medication, press the key 1 followed by the YES key and go to step 11. To choose an alternate medication just press the YES key until the desired medication is displayed. To choose no intermediate-acting medication, press the YES key until the display shows: NIL 1. Press 1 followed by YES. Once the appropriate medication has been chosen, the display will indicate the maximum possible allowed dose

and frequency per day. To lower this dose, key in the desired dose by entering the numerals followed by the YES key to continue.

Verify carefully and press YES or revise the entry and press YES.

11. The display will now show you the most common tablet size. Key in the appropriate numerals for the actual tablet size the User is taking followed by YES.

Verify carefully and press YES or revise the entry and press YES.

12. Display shows: 2, 3, 4 X/DAY

Choose either 2, 3 or 4 to indicate how often the medication is to be taken per day.

Press YES to continue

13. Display shows: NAME = ???

Now key in the name of the User. To enter the name refer to the alphabetic keyboard on page 45. Do not exceed 12 alphabetic characters.

Note: If a mistake was made, delete each character by pressing the back-space key labelled <--

Press YES to continue.

14. Display shows: [OHA specified] B = 0.0

TAB if a specified OHA was chosen or REG B = 0.0 U if insulin was chosen. [OHA] stands for GLP, MET, etc.

Key in the numerals for the short-acting component of the initial dose at breakfast.

Display shows medication for breakfast. Verify carefully and press YES or revise the entry and press YES.

15. Continue this sequence until all initial medication doses have been entered for each meal.
16. Display shows: WAIT B = 15 ?
The MDC will tell the User to wait 15 minutes between taking the medication and eating his meal. If you wish to change this period of time you can key in the desired waiting period in minutes to a minimum of 1 minute.
The MDC will display the changed waiting period.
Verify carefully, revise if necessary.
Press YES to continue.
17. Continue this sequence until all waiting periods have been entered for each meal.
18. Display shows: RG B = 1.0 G/DL
To choose a different reference glucose (RG) at breakfast use a number between 100 and 200 for blood glucose or a number between .1 and 5 for urine glucose. You may choose a different glucose reference for each meal. For instance a User may be asked to measure blood glucose at breakfast and urine glucose at other meal times.
Verify carefully, revise if necessary.
Press YES to continue.

All reference glucoses must be entered in gram units, whether the User measures in grams or millimoles.

19. Continue this sequence until all reference (RG) targets have been entered for each meal.
20. Display shows: WT REF = 0 ?
Enter the current body weight of the User. Only numerals are accepted. The units kilogram and pounds are not used. The person can measure in either unit. If body weight measurement is not required, simply press the YES key and continue or enter the numeral 0 and press YES.
Verify carefully, revise if necessary.
Press YES to continue.
21. Display shows: G 0 / MMOL 1
Choose 0 if the User measures in grams.
Choose 1 if the User measures in millimoles.
Note: If the User measures both blood glucose and urine glucose, make sure the unit of measurement is the same for blood and urine. Do not mix grams and mmoles.
22. Display shows: X1 X2
Choose the adjustment rate appropriate for your User. Please remember the X2 control mode is for pregnancy only.
Press the appropriate numeral 1 or 2 and continue by pressing YES.

23. Display shows: Mode: 2 / DAY, X1 or
 Mode: 2 / DAY, X2 or
 Mode: 3 / DAY, X1 or
 Mode: 3 / DAY, X2 etc
 Press YES to continue.
24. Display shows: ...in MMOL / L or
 ...in G / DL
 Press YES to continue.
25. Display briefly shows:
 MEAL: MEAN +-SD N and then
 B:
 if there are no User data stored in
 memory or
 B: 146 +- 38 7
 if for example seven days of User data
 were entered at Breakfast and the mean
 (average) of these data was 146 with a
 standard deviation (SD) of 38.
26. Press YES to continue to Lunch means.
27. Press YES to continue to Dinner means.
28. Press YES to continue to Snack means.
29. Press YES and the computer will shut itself
 off.
30. At any step you can terminate the
 programming sequence by pressing the
 ON key. You do not need to step all the
 way through.
31. If at any time you have made a mistake,
 you must start at the beginning by
 keying in the access numerals 123,
 pushing the key labelled RXN to start the
 programming sequence over again.

TO EXAMINE/CHANGE PROGRAMMING

1. Press ON and immediately follow with YES.
2. Press 1 2 3 and push the key labelled RXN.
3. If you do not wish to CLEAR DATA then just push YES to continue.
4. Display shows: 0 RX 1
If you do not wish to change medications, press 0 followed by YES. If you wish to change medications, press 1 followed by YES to continue.
5. The medication will now be displayed if you have elected to change the medication. Step through the medications and change any parameter by pressing the appropriate numerals. Verify carefully and press YES to continue.
6. If you elected to change the medications the display shows:
2, 3, 4 X/ DAY
Choose the correct numeral 2, 3 or 4 for the number of times the medications are to be taken.
7. Press YES to continue.
8. Display shows: Name = User
Change by using the alphabet keys and/or press YES to continue.
9. Now the display will show each medication dosage currently being recommended at each meal. If you wish to change the one displayed, press the appropriate

numerals and follow with YES. If you do not wish to change any medication then just press YES to continue.

10. Continue through all the other doses and programming parameters by pressing YES. If you wish to change a displayed parameter, press the appropriate keys and then press YES to continue. Verify the change and press YES again to continue.
11. Termination of the programming sequence can then be done at any time by pressing ON.

USER INSTRUCTIONS

Assume for this example that it is friday (FRI) before breakfast (B) and that you measure urine glucose (UG). Follow these steps:

1. Measure your urine glucose concentration.
2. Measure your body weight if so decided.
3. Press ON. Wait for DAY = ?
4. Press FRI key. Wait for MEAL = ?
5. Press B (Breakfast).
Wait for FRI WT = ? (if you decided to measure your weight every day).
6. Press the numerals to correspond to your weight today.
7. Verify your weight and continue by pressing YES.
Wait for FRI UG B = ?

8. Key in your UG (urine glucose reading) and press YES.
9. Verify data entered. If correct press YES. If not, press NO, and start over again.
10. If display shows: ? MISSED UG ↑
you have not entered your UG at the previous meal. You can check for yourself by looking at the tiny numerals in the display. The numerals 1234 stand for each meal entry. Breakfast is 1, Lunch is 2, Dinner is 3, and Snack is 4. If a small zero is in the display it means medications are taken more than 2 times a day.

Press NO if you want to start again and enter the missed data.

Press YES if you missed the previous measurement and wish to continue.

11. Your Medication will be displayed.
12. If you missed seeing the medication dosage displayed, you may recall it by pressing ON, wait for DAY = ? and then press the key INS or (MED).
13. If you take insulin as your medication and wish to enter more or less carbohydrates, press the CHO key while the current meal dosage or sign-off is displayed and answer the questions. You may also recall the last dose by starting over at step 12 then pressing CHO.
14. If you are taking insulin or oral hypoglycemic agents you may alter your medication with exercise. To do so,

press the key EX while the dosage is displayed. Answer questions as they are prompted. You may also recall the last dose by starting over at step 12 and then pressing EX. Fractional exercise levels, eg 2.5, are permitted.

15. At any time you may review the means achieved over the last 7 days. To do this press ON, wait for DAY=? and then press the key labelled RXN. The MDC will calculate your mean blood/urine glucose concentrations before meals.

Display will show: MEAL: mean +-SD N

For example:

B: 156 +-48 5

Breakfast: Mean +- Standard Deviation Number of Entries

Press YES to continue to the Lunch Means.

Press YES to continue to the Dinner Means.

Press YES to continue to the Snack Means.

Press YES and the MDC will shut itself off.

16. HYPOGLYCEMIA: If a reaction was experienced anytime before the current meal, you must press RXN at this meal entry when the MDC asks for the blood/urine glucose value. You do not need a glucose reading.
17. Multi-voidings: When using urine as a glucose measurement, it is best if you can pass urine only before each meal. If however this is not possible you should measure at each void and enter each into the MDC.

If, for example, you pass urine at 10 o'clock in the morning, you should measure this and enter it into the MDC in the following way:

- Press ON. Wait for DAY = ?
- Press FRI key.
 Wait for FRI Meal = ?
- Press NO. Wait for FRI UGX = ?
- Key in numerals for UG value.
- Follow with YES.
- Verify display.
- If Correct press YES.
- MDC will store the data.
- MDC will sign itself off.

You can enter multiple voiding in this manner up to a limit of 5 times between meals.

Be sure to always empty your bladder before each meal. Measure and enter this value as well.

18. Always follow the recommendations of the MDC in regard to waiting and medication dosages. If you disagree with either of them, promptly call your doctor to discuss the reasons why.

Printing-Out MDC Data

A printer may be attached to the MDC to print out a User's data. It will print out current doses, means for each meal over the last 28 days as well as all meal blood/urine glucose

entries for the last 90 days together with all medications recommended on each of the previous 90 days.

The most convenient printer to use with the MDC is a small Hewlett Packard Infrared Printer Model Number HP 82240A (HP 8824A). An Infrared Module (HP82242 A) must also be purchased to link the MDC to the printer.

To attach the printer, follow these steps.

1. Make sure both the MDC and the printer are turned off.
2. Remove the port cap that is in #4.
Remember not to unplug port #1 since this contains the MDC ROM CHIP.
3. Insert the Infrared Module (HP82242 A) into the open port. Make sure it is not upside down.
4. Turn the Printer ON.
5. Turn the MDC ON.
6. The Printer will now print all the data stored in the MDC which will shut itself off when finished.
7. Be sure both units are off before unplugging the printer module from the MDC.

Warnings

Do not unplug any of your devices when they are ON. To do so may damage the MDC. Do not unplug the MDC ROM chip when trying to print out data.

Do not try to use the MDC as an ordinary calculator because your glucose and other data may be erased.

Do not attempt to recharge the batteries. Do not store batteries near a source of high heat or dispose of them in fire. Doing so may cause them to leak or explode.

Maintenance and Service

Care of Your MDC

Your MDC requires virtually no attention to ensure proper operation. All you need to do is:

1. Replace the batteries when the BAT symbol appears in the display - see section on battery replacement.
2. Do not insert any objects into the ports at the back of your MDC. To do so could erase your data or otherwise damage the computer.

3. Do not remove the MDC microchip from its port since this may erase your accumulated data.

Battery Replacement

Because your MDC uses so little power, the batteries will provide many months of operation, usually 1-2 years. Use only the following alkaline batteries in your MDC.

Eveready E90, Mallory MN9100, UCAR E90 National AM5(s), Panasonic AM5(s), VARTA 7245, Duracell MN 9100, Energizer E90 NEDA 910A

The MDC takes 4 SIZE N (1.5 Volt) batteries

These batteries, like those originally supplied with your MDC, are not rechargeable.

You must turn the calculator off before removing the batteries in order to preserve Continuous Memory. This gives you ample time to replace the batteries with new ones. Leaving batteries out of the calculator for extended periods will result in loss of the information in the MDC. If this occurs, the MDC will have to be reprogrammed .

To replace the batteries, follow these steps:

1. Make sure the MDC is off.

2. Turn the MDC over and press upwards on the ridge on the battery holder. This releases the battery holder and you may remove it from the calculator.
3. Remove the old batteries from the battery holder.
4. Check the polarity marks (+ and -) on the end of the battery holder and insert the new batteries properly.
5. Replace the battery holder into the MDC. Then snap the lower edge of the holder back into place.
6. Turn the MDC ON
Wait for the display to show DAY = ?
Press INS.
The IDC should display the last dosages recommended and turn itself off.
If any of the batteries are inserted incorrectly, the MDC may not turn on. If this happens remove the battery holder and check the orientation of each of the batteries.

NONEXISTENT

Occasionally your MDC will display the word NONEXISTENT. This will mean your data was erased. The circumstances under which this happens vary :

- Perhaps your computer received an electrostatic shock.

- Perhaps some keys were pushed accidentally and erased RAM Memory (your data).

- Perhaps one of the batteries failed. If so check the freshness of all four batteries. They should be replaced if they read less than 1.2 Volts.

REMEMBER: When NONEXISTENT is displayed only your data was lost out and not the algorithms in the ROM Microchip.

REFERENCES

1. *A. Schiffrin and M.M. Belmonte:* Comparison between continuous subcutaneous insulin infusion and multiple injections of insulin. A one-year prospective study. *Diabetes* 31:255-64, 1982.
2. *J.S. Skyler, D.L. Skyler, D.E. Seigler, et al:* Algorithms for adjustment of insulin dosage by patients who monitor blood glucose. *Diabetes Care* 4:311-18, 1981.
3. *J.S. Skyler, et al:* Instructing patients in making alterations in insulin dosage. *Diabetes Care* 2:39-45, 1979.
4. *A.M. Albisser:* Intelligent instrumentation in diabetic management. *CRC Critical Reviews in Biomedical Engineering*, 17:1-24, 1989.
5. *R.L. Blandford, A.L. Edwards, P.R. Chaudhuri and J.R. Hearnshaw:* Rapidly developing retinopathy following improvements in diabetic control with conventional therapy. *Practical Diabetes* 1:31-34, 1984
6. *N.W. Rodger (ed):* Proceedings of a conference on insulin pump therapy in diabetes: multicenter study of effect on microvascular disease. *Diabetes* 34:(Suppl. 3), 1-89, 1985.
7. *A. Schiffrin, A. Desrosiers, and M.M. Belmonte:* Evaluation of two methods of self blood glucose monitoring by trained insulin-dependent diabetic adolescents outside the hospital. *Diabetes Care* 6:166-69, 1983.
8. *R.C. Galagan, T.R. Strack, B.S. Leibel, and A.M. Albisser:* Urine glucose measurements: reappraisal of their clinical limitations and value. *Diab. Nutr. Metab.* 1:89-98, 1988.
9. *L.N.W. Daae and A. Juell:* A new and more ascorbic acid-resistant dipstick test for the detection of glucosuria has been introduced. *Scand. J. Clin. Lab. Invest.* 45:289, 1985.
10. *M.R. Witt, N. White and J.V. Santiago:* Roles of site and timing of the morning insulin injection in Type 1 diabetes. *J. Pediatr.* 103:528-33, 1983
11. *G.D. Dimitriadis and J.D. Gerich:* Importance of timing of preprandial subcutaneous insulin administration in the management of diabetes mellitus. *Diabetes Care* 6:374-77, 1983.
12. *A. Schiffrin, A.M. Albisser:* Evaluating a computer algorithm for exercise in Type 1 diabetics. *Diab. Nutr. Metab.* 1:29-35, 1988.

ADDITIONAL SCIENTIFIC REPORTS

1. *A. Schiffrin, M Mihic, B.S. Leibel, A.M. Albisser*: Computer assisted insulin dosage adjustment. *Diabetes Care* 8:545-552, 1985.
2. *A.M. Albisser, A. Schiffrin, M. Schulz, J. Tiran, B.S. Leibel*: Insulin dosage adjustment using manual methods and computer algorithms: a comparative study. *Med. Biol. Eng. & Comput.* 24:577-584, 1986.
3. *S. Sozzi, T. Strack, M. Schulz, A.M. Albisser*: Compliance in microcomputer assisted conventional therapy: results of a computer simulation study. *Am. J. Physiol.* 254:E237-E242, 1988.
4. *A.M. Albisser*: The development of an intelligent system for the diabetic. *Biomed. Meas. Infor. Contr.* 2:3-9, 1987-88.
5. *M. Mihic, J. Pyper and A.M. Albisser*: Conventional insulin therapy in private practice: a one year controlled prospective study. *Diab. Nutr. Metab.* 1:125-131, 1988.
6. *I. Hermanyi and G. Tamas Jr.*: Management of diabetics with the use of a microprocessor: comparison of insulin treatments based on blood and urine glucose levels. *Acta Diabetol. Latina* 25:33-40, 1988.
7. *S. Sozzi, G. De Giorgio, G.P. Reboldi, P. Brunetti and M. Massi Benedetti*: Application of computerized programmes for optimization of insulin therapy based on glycosuria in diabetic children. Proceedings of the IFACWorkshop on Decision Support for Patient Management: Measurement, Modelling and Control. Institute of Measurement and Control, London, pp. 320-329, 1989.
8. *A.M. Albisser*: Six generations of the insulin dosage computer: a new clinical device for diabetes self-management through specialized centres. *Horm. Metab. Res.* in press, 1989.

ABSTRACTS

1. *A. Schiffrin, A.M. Albisser, and M. Mihic*: Optimizing conventional insulin therapy using an insulin dosage computer. *Diabetes* 33 (Suppl. 1): 29A, 1984.
2. *A.M. Albisser, A. Schiffrin, M. Mihic, B.S. Leibel and M. Schulz*: The insulin dosage computer: A new approach to optimizing conventional insulin therapy. *Diabetologia* 27:250A-251A, 1984.
3. *J. Tiran, A. Schiffrin, and A.M. Albisser*: Optimization of insulin therapy in Type I diabetics using the insulin dosage computer. Presented at the 6th International Beilinson Symposium on Future Trends in Juvenile Diabetes, Herzliya-on-Sea, Israel, October 21-28, 1984.
4. *A.M. Albisser, K. Perlman, and M. Schulz*: Titrating the insulin dose by computer: the effects of measurement error in capillary blood glucose estimation. *Diab. Res. and Clin. Prac.* (Suppl. 1): S9, 1985.
5. *A.M. Albisser, M. Mihic, M. Sperlich, and J. Pyper*: Conventional insulin therapy with a computer: a one-year clinical prospective study. Proceedings of the Fourth Milano International Meeting on Diabetes, Milan, Italy, March 12-14, 1987.
6. *W.D. Loughheed, A. M. Albisser*: The use of hand-held computers in controlling patient therapy. (Metabolism, Chaos and the Design of Expert Medical Systems). Presented at Bio '87: Sensing and Control, London (U.K.), October 1987.
7. *A.M. Albisser and M. Mihic*: Microprocessors in diabetes management: a one year controlled prospective study. Presented at the 7th Workshop of the AIDSPIT-Study Group (EASD), Igls, Austria, February 2, 1988.
8. *E. Lieberman, S. Weitzman, A.M. Albisser and J.E. Bearman*: Insulin dosage computer vs conventional intensive care: a randomized, controlled clinical trial. Presented at the 7th Workshop of the AIDSPIT Study Group (EASD), Igls, Austria, January 31 - February 2, 1988.

9. *S. Sakkal and A.M. Albisser*: Strict safe blood sugar control in a brittle diabetic with pocket insulin dosage computer (IDC). *Diabetes* 37 (Suppl. 1):1988.
10. *S. Halimi, H. Leblanc, A. Murat, M. Pinget, M. Massi-Benedetti and A. Pernet*. Testing the insulin dosage computer (IDC): a multi-center European study. *Diabetologia* 31:499A, 1988.
11. *A.M. Albisser and M. Mihic*: Advances in insulin therapy: the role of the microprocessor. Presented at the 13th IDF Congress, Sydney, Australia, November 1988.

BOOK CHAPTERS

1. *A.M. Albisser and B.S. Leibel*: Diabetes technology: from the pump to the microprocessor. In: *Pathogenesis and Treatment of Diabetes Mellitus*. J.K. Radder, H.H.P.J. Lemkes, and H.M.J. Krans, eds. Martinus Nijhoff Publishers, Dordrecht (Netherlands), pp. 142-151, 1986.
2. *A.M. Albisser*: Insulin therapy: Closing the loop with a microprocessor. In: *Methods in Diabetes Research, Vol II: Clinical Methods*, W.L. Clarke, J. Larner and S.L. Pohl, eds; John Wiley & Sons, Inc., New York, pp. 330-345, 1986.
3. *A.M. Albisser, M. Mihic, and B.S. Leibel*: Intelligent instrumentation for the diabetic: the role of the microprocessor in optimizing insulin therapy. Proceedings of the 3rd Imeko Conference: Measurement in Clinical Medicine. Institute of Measurement and Control, London, 1986, pp. 25-28.
4. *A.M. Albisser, and M. Mihic*: How to judge insulin dosage in Type I diabetics. In: *Recent Trends in Management of Diabetes Mellitus (Proceedings of the Second International Symposium on Treatment of Diabetes Mellitus, Nagoya, Japan, 13-15 November 1985)*. N. Sakamoto, K.G.M.M. Alberti and N. Hotta, eds. Intl. Congress Series 726, Elsevier Science Publishers B.V., Amsterdam, 1987, pp. 144-149.
5. *A.M. Albisser*: Insulin therapy: closing the loop with a microprocessor. In: *Advanced Models for the Therapy of Insulin-Dependent Diabetes*. P. Brunetti and W.K. Waldhausl, eds. Serono Symposia, Vol. 37, Raven Press, New York, 1987, pp. 165-170.
6. *A.M. Albisser*: Mechanical Systems for Diabetes Control. In: *Diabetes Mellitus: Theory and Practice, Fourth Edition*, H. Rifkin and D. Porte, Jr., eds. Elsevier Science Publishing Company, Inc., New York, in press, 1989.
7. *A.M. Albisser*: Artificial pancreas and related devices. In: *Textbook of Diabetes*, J.C. Pickup and G. Williams, eds. Blackwell Scientific Publications, London, in press, 1989.
8. *A.M. Albisser*: New treatment approaches for insulin dependent diabetes mellitus: the contribution of technology from pumps to dedicated computer expert systems. In: *International Textbook of Diabetes Mellitus*, K.G.M.M. Alberti, R.A. DeFronzo, H. Keen, P. Zimmet, eds., John Wiley Publishers, London, in press, 1989.

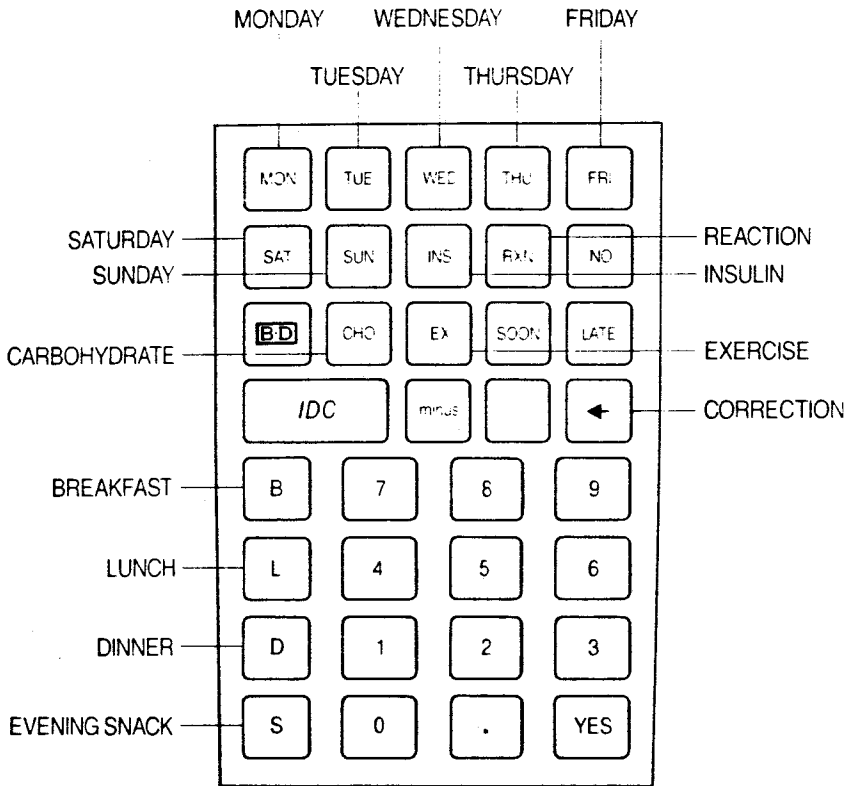
Sample Patient Data Print Out

NAME=DEBRA	NAME=DEBRA1
REG B= 7.6 U	REG B= 7.6 U2
REG B= 12 U	REG B= 12 U3
REG D= 5.2 U	REG D= 5.2 U4
NPH S= 17 U	NPH S= 17 U5
INS = 42 U/DAY	INS = 42 U/DAY6
REG MAX = 15 U	REG MAX = 15 U7
NPH MAX = 30 U	NPH MAX = 30 U8
MIN	MIN	
WAIT B = 15	WAIT B = 159
WAIT L = 15	WAIT L = 1510
WAIT D = 30	WAIT D = 3011
WAIT S = 5	WAIT S = 512
RG B = 120 MG/DL	RG B = 120 MG/DL13
RG L = 130 MG/DL	RG L = 130 MG/DL14
RG D = 100 MG/DL	RG D = 100 MG/DL15
RG S = 140 MG/DL	RG S = 140 MG/DL16
WT REF = 85	WT REF = 8517
MODE:4/DAY ,X2	MODE:4/DAY ,X218
...IN MMOL/L	...IN G/DL19
MEAL:MEAN+- SD N	MEAL:MEAN+- SD N20
B: 12 +- 5.8 18	B: 218+-105 1821
L: 9.4+- 3.9 17	L: 170+- 69 1722
D: 9.0+- 4.2 18	D: 161+- 76 1823
S: 12+- 3.8 16	S: 218+- 68 1624
WT: 80+- 1.5 18	WT:86+- 1.5 1825
DATA IN MMOL/L	DATA IN MG/DL26
DAY B L D S	DAY B L D S27
BG BG BG BG	BG BG BG BG28
WED 16 11 6.7 17	WED 280 200 120 30029
THU 16 14 5.6 16	THU 280 250 100 28030
FRI 17 8.3 4.4 14	FRI 300 150 80 25031
SAT 17 11 5.6 14	SAT 300 200 100 25032
SUN 16 14 5.6 14	SUN 280 250 100 25033
MON 17 11 6.7 10	MON 300 200 120 18034
TUE 8.3 8.3 6.7 14	TUE 150 150 120 25035
WED 9.4 7.8 5.6 11	WED 170 140 100 20036
THU 8.3 7.8 17 17	THU 150 140 300 30037
FRI 7.2 7.8 14 14	FRI 130 140 250 25038
SAT 28 2.8 11 11	SAT 500 50 200 20039
SUN 6.7 6.7 11 10	SUN 120 120 200 18040
MON 11 5.6 11 5.6	MON 200 100 200 10041
TUE 15 5.6 11 11	TUE 270 100 200 20042
WED 5.6 17 13 2.8	WED 100 300 240 5043
THU 6.7 6.7 17 13	THU 120 120 300 24044
FRI 11 6.7	FRI 200 12045
SUN RXN	SUN RXN46
MON 4.4 16 2.8	MON 80 280 5047
Σ MISSED f=6 IN 19 DAYS	Σ MISSED f=6 IN 19 DAYS48
Σ # RXNS =1 IN 19 DAYS	Σ # RXNS =1 IN 19 DAYS49

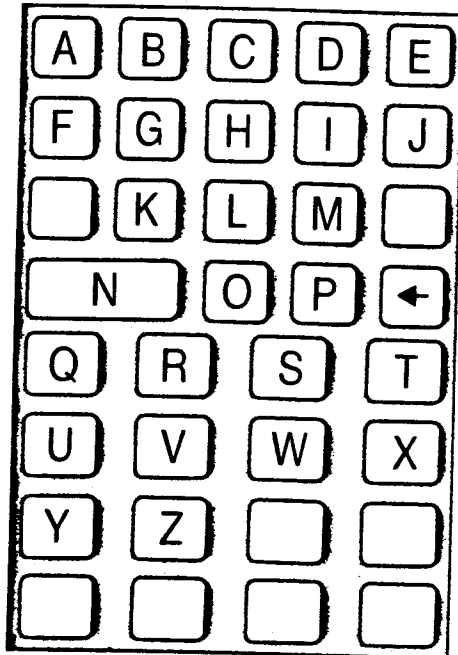
Interpreting the Print-Out

- Line 1: Name of the User
- Line 2-5: Current internal insulin dosages at breakfast (B), lunch (L), dinner (D), and snack (S). The internal dosages are displayed to 0 or 1 decimal place.
- Line 6: The total insulin dose for the day.
- Line 7-8: The maximum doses.
- Line 9-12: The WAIT periods recommended at each meal
- Line 13-16: The pre-meal reference glucose (targets) in mg/dl or g/dl.
- Line 17: The reference weight
- Line 18: The number of injections per day and the sensitivity. X2 is mainly for pregnancy.
- Line 19: Shows whether the Units to be used to measure BG or UG ...in mmol/l or ...in_g/dl.
- Line 20: Headings for the next four rows
- Lines 21-25: Shows the average achieved for each meal, the standard deviation or variation, and the number of meal or weight entries over the last 28 days.
- Lines 26-28: Headings for the data listing of daily entries by the User. Shows the type of measurement chosen for each meal.
- Lines 29-47: Data listing grouped by weeks for easy reading. Data array is arranged by day of the week and by meal. Print-out will show up to 90 days of BG or UG data and in similar format the corresponding dosages taken each day (medications not shown).
- Line 48: Indicates number of missed data entries over total days used.
- Line 49: Indicates number of hypo-glycemic events entered by the User as RXNs or HPOs over total days used.

User Keyboard Diagram



Alphabet Keyboard for Programming



©1990 BCMC Better Control Medical
Computers Inc.
52 Wendover Rd. Toronto, Ontario,
Canada.

BCMC Better Control Medical
Computers Inc. International,
Lewiston, New York.