

IDENTIFYING ADVERSE DRUG INTERACTIONS: A UNIFIED APPROACH

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## ABSTRACT

THIS PAPER DESCRIBES A MICROPROCESSOR-BASED IMPLEMENTATION OF A SYSTEM WHICH CAN IDENTIFY POTENTIALLY ADVERSE DRUG INTERACTIONS, FOR USE BY A PHYSICIAN PRIOR TO PRESCRIBING DRUGS. THE SYSTEM IS INTENDED FOR USE IN SMALL-TO-MEDIUM SIZED MEDICAL PRACTICES AND GROUPS, AND ALSO PERFORMS DETAILED PATIENT MEDICAL RECORD KEEPING, APPOINTMENT SCHEDULING, CUSTOMER AND THIRD-PARTY BILLING, AND ACCOUNTING. THE SYSTEM IS SPECIFICALLY DESIGNED TO BE OPERATED BY PERSONNEL WITH NO COMPUTER EXPERTISE.

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## THE PROBLEM

- 0 THE PROBLEM OF ADVERSE REACTIONS DUE TO COMBINATIONS OF DRUGS IS MOUNTING, AND IS RECEIVING INCREASING ATTENTION. EACH YEAR, ADVERSE DRUG REACTIONS CAUSE THOUSANDS OF ILLNESSES, AND EVEN DEATHS, AND EXTENDED HOSPITAL STAYS ESTIMATED TO COST MORE THAN \$4.5 BILLION.

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## AN APPROACH

- 0 ONE WAY TO SOLVE THIS PROBLEM IS BY EMPLOYING A COMPUTER SYSTEM WHICH CAN IDENTIFY POTENTIALLY ADVERSE DRUG INTERACTIONS PRIOR TO PRESCRIBING DRUGS.
- 0 COMPUTERS ALREADY HAVE A PLACE IN MANY PHYSICIAN'S PRACTICES:
  - WIDELY EMPLOYED TO HELP WITH BILLING AND ACCOUNTING; OTHER USES, SUCH AS PATIENT RECORD-KEEPING AND APPOINTMENT SCHEDULING, ARE GAINING IN POPULARITY.
- 0 A UNIFIED APPROACH TO AUTOMATION IN THE PHYSICIAN'S OFFICE IS ONE WHICH PROVIDES ALL OF THESE FEATURES IN ONE COHERENT, COHESIVE PACKAGE.

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### THE REALIZATION

- O THIS PAPER DESCRIBES MEDSAFETM, A MICROPROCESSOR-BASED IMPLEMENTATION OF SUCH A UNIFIED APPROACH.
  - DRUG INTERACTION ANALYSIS IS COMBINED WITH AN RAPID-ACCESS, VISIT-BY-VISIT PATIENT MEDICAL RECORD-KEEPING SYSTEM.
  - CAN AUTOMATICALLY PRODUCE A LIST OF CURRENTLY-ACTIVE PRESCRIPTIONS FROM THE PRESCRIPTION RECORDS IN THE PATIENT'S VISIT-BY-VISIT MEDICAL RECORD.
  - DRUG INTERACTION ANALYSIS SPANS MORE THAN 30,000 DRUGS, AND CAN EMPLOY THE COMPUTER-GENERATED LIST OF ACTIVE PRESCRIPTIONS.
  - VISIT-BY-VISIT PATIENT MEDICAL RECORDS ALSO CONTAIN CODED ENTRIES FOR PROCEDURES, WHICH DRIVE THE BILLING FUNCTION.
- O CURRENTLY UNDERGOING FINAL SITE-TESTING.

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### CONSIDERATIONS

- 0 A UNIFIED MEDICAL OFFICE SYSTEM MUST HAVE CERTAIN ATTRIBUTES BEYOND THE CAPABILITY TO PERFORM ALL OF THE FUNCTIONS PREVIOUSLY SPECIFIED. FOR EXAMPLE:
  - MUST BE OPERABLE BY PERSONNEL WHO DO NOT HAVE A COMPUTER-OPERATOR BACKGROUND.
  - MUST HAVE A FEASIBLE GROWTH PATH, WHICH WILL ALLOW FOR VIABLE INCREASES IN BOTH SYSTEM CAPACITIES (NUMBER OF USERS, AMOUNT OF MASS STORAGE, ETC.) AND IN SYSTEM FUNCTIONALITY (E.G., NEW FUNCTIONS).
- 0 THESE ATTRIBUTES EVOLVE INTO SPECIFIC HARDWARE AND SOFTWARE REQUIREMENTS, EACH OF WHICH IS ASSOCIATED WITH SPECIFIC TECHNICAL CHALLENGES. THE REMAINDER OF THIS PAPER DISCUSSES SOME OF THE PROMINENT SYSTEM REQUIREMENTS, AND DESCRIBES THEIR IMPLEMENTATION IN MEDSAFF.

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### INTEGRATED FUNCTIONALITY

- O CERTAIN DATA WITHIN THE SYSTEM IS NEEDED BY MORE THAN ONE OF THE MAJOR FUNCTIONS. FOR EXAMPLE:
  - ADDRESSES, INFORMATION ABOUT LEGAL GUARDIANSHIP, AND LISTS OF SPECIFIC MEDICAL PROCEDURES PERFORMED DURING ANY ONE VISIT ARE REQUIRED FOR BOTH PATIENT MEDICAL RECORDS AND ACCOUNTING/BILLING PURPOSES.
  - LISTS OF CURRENTLY-ACTIVE PRESCRIPTIONS ARE REQUIRED FOR PATIENT MEDICAL RECORDS, AND ARE ALSO REQUIRED TO SUPPORT THE IDENTIFICATION OF POTENTIALLY ADVERSE DRUG INTERACTIONS.
- O IT IS DESIRABLE THAT THESE DATA ARE ENTERED ONLY ONCE, AND THAT THE RELEVANT INFORMATION IS THEN AUTOMATICALLY SHARED.
  - FEWER DATA INCONSISTENCIES, FEWER OPERATOR ERRORS, AND LESS DATA ENTRY WORK.
- O UNDERSCORES LIABILITY OF CONSTRUCTING SUCH A SYSTEM BY OBTAINING AND INTEGRATING SEVERAL EXISTING SOFTWARE PACKAGES; SUCH PACKAGES WOULD NOT BE ABLE TO SHARE AND PROPERLY CONTROL DATA IN THIS FASHION.

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## CONSISTENT USER INTERFACE

- 0 CONSISTENCY IS THE KEY INGREDIENT OF THOSE COMPUTER-TO-HUMAN INTERFACES WHICH ARE WELL-ACCEPTED BY USERS, ARE EASY TO LEARN, AND ARE EASY TO USE. THERE ARE TWO ASPECTS OF IMPLEMENTING THIS: THE COMPUTER-TO-HUMAN INTERFACE AND THE HUMAN-TO-COMPUTER INTERFACE.
- 0 MAJOR ELEMENT OF THE MEDSAFE COMPUTER-TO-HUMAN INTERFACE IS THE DISPLAY SCREEN.
  - USES VIDEO ATTRIBUTES TO CREATE A FILL-IN-THE-BLANK LOOK.
  - DEDICATED SCREEN AREAS, CONSISTENT USE

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Active Patient: Smith, Rupert 3306 La Cienega Boulevard, Los Angeles, California 90008

PATIENT BIOGRAPHY

Smith, Rupert CHART # 2715  
HOME: 3306 La Cienega Boulevard, Los Angeles, California 90304  
PHONE: (213) 649-5525  
WORK NAME: Tom's Toy Store PHONE: (213) 393-1393  
ADDR: 213 14th Street, Santa Monica, California 92361  
BIRTHDATE: 02/19/54 SOCIAL SECURITY: 272-72-7272  
DOCTOR: GDV PATIENT TYPE: I PRIMARY DOCTOR: GDV REFERRING DOCTOR: KNA

SPOUSE: Smith, Betty CHART# 2716  
HOME: 3306 La Cienega Boulevard, Los Angeles, California 90304  
PHONE: (213)649-55525  
WORK NAME: none PHONE: n/a  
ADDR: n/a

EMERGENCY CONTACTS

NAME	HOME PHONE	WORK PHONE	RELATION
Smith, Beverly	(714) 828-1913	none	mother
Jones, Gerald G.	(213) 474-1234	(213) 393-1393	friend
Williams, Nanda	(213) 333-6363	(213) 555-1212	lawyer

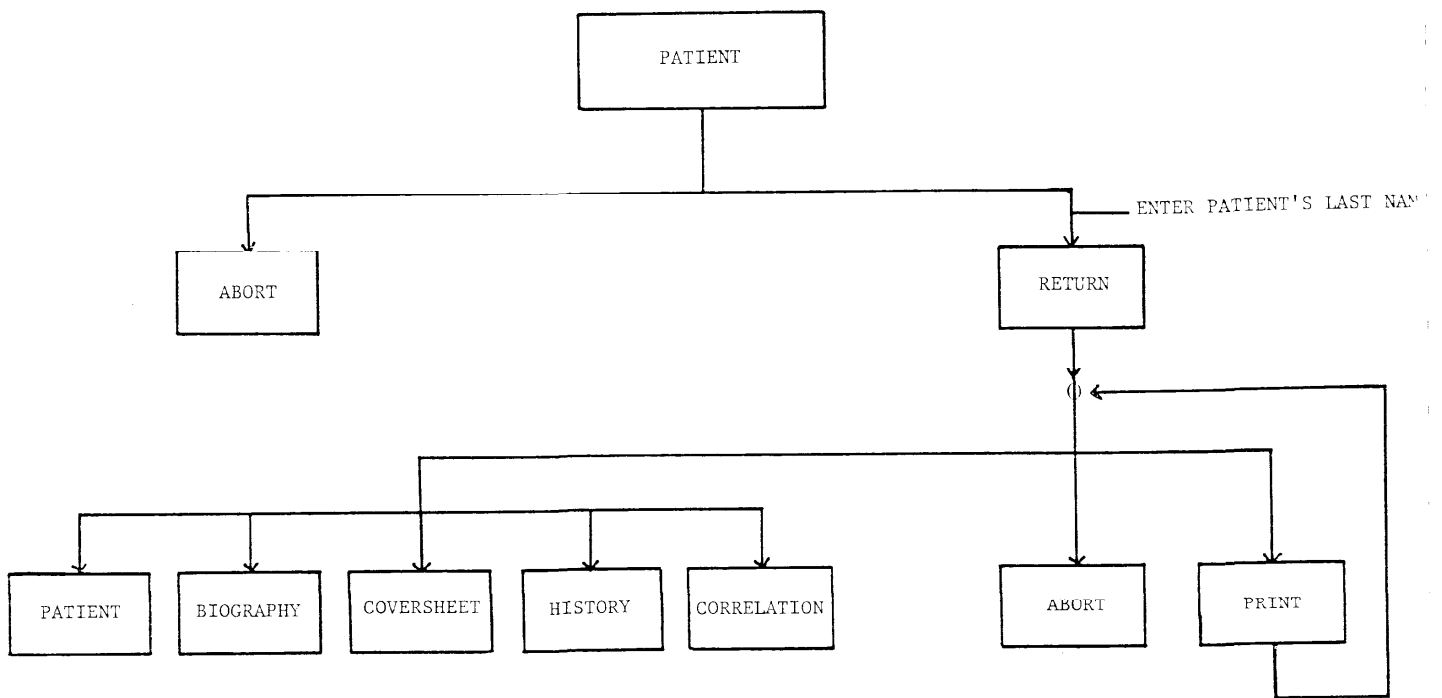
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### HUMAN-TO-COMPUTER INTERFACE

- 0 THE OPERATIONAL SEQUENCES, WHICH FORM THE HUMAN-TO-COMPUTER INTERFACE, IS ALSO IMPLEMENTED WITH AN EYE TO CONSISTENCY. RELATED OR SIMILAR OPERATIONS ARE ALWAYS PERFORMED THROUGH THE USE OF SIMILAR OPERATIONAL SEQUENCES.
- 0 THE USER INTERACTIONS ARE IMPLEMENTED THROUGH THE USE OF SPECIAL-PURPOSE KEYS. THERE ARE SIXTEEN OF THESE 'FUNCTION KEYS' IN A ROW ALONG THE TOP EDGE OF THE KEYBOARD, JUST BELOW THE DISPLAY SCREEN. THE KEYBOARD INCLUDES A TYPE-AHEAD FEATURE.

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EXAMPLE OPERATIONAL SEQUENCES



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EXAMPLE DISPLAY SCREEN SEQUENCE

Enter lastname of patient: Smith  
 No active patient

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Position cursor at desired patient & depress desired function key  
 No active patient

NEW PATIENT  
 Smith, Adam, C. 3305 Pacifica Lane, Beverly Hills, CA  
 Smith, Barbara 411 S. Sperry Road, S.W. Santa Monica, CA  
 Smith, Beverly 14321 San Pasqual Avenue, San Marino, CA  
 Smith, Marilyn 16598 11th Street, Los Angeles, CA

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Active Patient: Smith, Beverly 14327 San Pasqual Avenue, San Marino, CA

Height: 53" Weight: 123 Sex: F DOB: 02/19/61

CURRENT PRESCRIPTIONS:

DRUG CODE	DRUG NAME	STRENGTH	DOSE	TIMES	TOTAL	EXPIRES
000002 0806 02	darvon compound 65	65 ml	2 TAB	4/day	50 TAB	05/01/82

ALLERGIES AND CHRONIC CONDITIONS:  
 CODE # NAME  
 802 Penicillin

DIAGNOSES:  
 Code Name Date

PROCEDURES:  
 Code Title Date

COMMENTS:

1/EDIT

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### SUMMARY OF USER INTERFACE

- 0 THE USER INTERFACE IS A KEY ELEMENT OF A SYSTEM WHICH IS INTENDED TO BE USED BY PERSONNEL WITH NO COMPUTER OPERATOR BACKGROUND.
- 0 IN MEDSAFE, A USER INTERFACE HAS BEEN IMPLEMENTED WHICH IS QUITE EASY TO LEARN AND TO OPERATE, EVEN FOR THOSE INDIVIDUALS WITH NO UNDERSTANDING OF COMPUTERS, AND NO EXPERIENCE AS A COMPUTER OPERATOR.
- 0 CONSTRUCTING SUCH A SYSTEM OUT OF EXISTING SOFTWARE PACKAGES (EVEN IF SUCH PACKAGES EXISTED FOR ALL OF MEDSAFE'S FUNCTIONS) WOULD RESULT IN A LESS SATISFACTORY IMPLEMENTATION, AS THE USER INTERFACE AND 'CONCEPT-OF-OPERATION' WOULD BE DIFFERENT FOR EACH PACKAGE.

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## STORAGE AND BACKUP

- O MUST PROVIDE STORAGE SUFFICIENT FOR THOUSANDS OF PATIENTS, A RELIABLE, SIMPLE, AND RAPID METHOD FOR CREATING BACK-UP COPIES OF DATA, AND BE ABLE TO EXPAND TO ACCOMMODATE FUTURE NEEDS.
- O ON-LINE STORAGE CAPACITY OF OVER 25,000,000 CHARACTERS.
- O CAN BACK-UP OR RESTORE THIS ENTIRE DATA SET USING A CARTRIDGE TAPE IN UNDER TEN MINUTES.
- O PATIENT MEDICAL AND ACCOUNTING DATA IS BACKED-UP ONTO ONE TAPE CARTRIDGE; THE SOFTWARE, DRUG DATA BASE, AND DRUG INTERACTION RECORDS ARE BACKED-UP ONTO ANOTHER. THIS ALLOWS THE USER TO FREQUENTLY BACK-UP HIS PATIENT DATA WITHOUT HAVING TO ALWAYS TAKE THE ADDITIONAL TIME TO BACK-UP THE RELATIVELY STATIC PORTIONS OF THE SYSTEM.
- O THE STORAGE SUB-SYSTEM CAN BE READILY EXPANDED BY THE ADDITION OF MORE DISC DRIVES. CURRENTLY, THE MAXIMUM NUMBER OF DRIVES WHICH CAN BE SUPPORTED IS FOUR. IN ADDITION, PLUG-COMPATIBLE DRIVES WHICH HAVE STORAGE CAPACITIES LARGER THAN 35 MEGABYTES ARE BECOMING AVAILABLE.

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### PERFORMANCE RATES

- 0 DESPITE HAVING OVER 30,000 DRUGS IN ITS DATA BASE, IT IS NECESSARY THAT RESPONSE TIMES BE SHORT AND CONSISTENT.
- 0 MEDSAFE REQUIRES A MAXIMUM OF FIVE TO TEN SECONDS TO PERFORM A COMPLETE DRUG INTERACTION ANALYSIS ON A SET OF SEVERAL DRUGS.
- 0 MEDSAFE CAN CALL-UP AND DISPLAY ANY PORTION OF ANY PATIENT'S MEDICAL OR ACCOUNTING RECORD IN 1 TO 3 SECONDS.

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### REMOTE ACCESS

- 0 IN ORDER TO SERVICE THE NEEDS OF THE PHYSICIAN 'ON-CALL', IT IS DESIRABLE FOR SUCH A SYSTEM TO PROVIDE AN ECONOMICAL WAY FOR THE PHYSICIAN TO GET ACCESS TO THE DATA IN HIS SYSTEM FROM REMOTE LOCATIONS, SUCH AS THE PHYSICIAN'S HOME, OR FROM THE EMERGENCY ROOM AT A LOCAL HOSPITAL.
- 0 MEDSAFE PROVIDES REMOTE ACCESS TO ALL OF ITS SERVICES, TO REMOTE SITES OF THE USER'S OWN CHOOSING. THIS IS ACCOMPLISHED BY MEANS OF A REMOTE TERMINAL (A DUPLICATE OF THE TERMINAL UNIT IN THE OFFICE) WHICH GIVES THE USER 24-HOUR ACCESS TO THE MEDSAFE SYSTEM. THE SYSTEM INCLUDES THE NECESSARY 1200-BAUD MODEMS AND ALL CABLING.

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### HARD COPY

- 0 THE SYSTEM MUST BE CAPABLE OF PRODUCING PERMANENT COPIES OF PATIENT RECORDS, DRUG INTERACTION ANALYSES, AND SO FORTH, AS WELL AS PRINTING BILLS AND ACCOUNTING RECORDS. MEDSAFE PROVIDES A SPOOLED PRINTER FUNCTION, SO THAT THESE ACTIVITIES CAN TAKE PLACE WITHOUT PREVENTING THE SYSTEM FROM CONTINUING WITH OTHER OPERATIONS WHILE PRINTING IS TAKING PLACE. THE WIDELY-USED CENTRONICS-TYPE PARALLEL INTERFACE IS IMPLEMENTED, ALLOWING A WIDE VARIETY OF PRINTERS TO BE EMPLOYED. A BI-DIRECTIONAL DOT-MATRIX PRINTER CAPABLE OF PRINTING OVER 100 CHARACTERS PER SECOND IS SUPPLIED WITH THE SYSTEM.

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### UPDATES TO THE DRUG AND INTERACTION DATA BASES

- O NEW DRUGS ARE CONTINUALLY BEING INTRODUCED, AND NEW INTERACTIONS ARE CONTINUALLY BEING DISCOVERED. THEREFORE, IT IS VITAL THAT THE DRUG AND INTERACTION DATA BASE BE PERIODICALLY UPDATED. AN UNMAINTAINED DATA BASE WOULD QUICKLY BECOME OBSOLETE.
- O THE DATA BASE EMPLOYED IN MEDSAFE WAS DEVELOPED (IN ASSOCIATION WITH THE DIVISION OF ADVERSE EFFECTS OF THE FDA) BY MEDICARE-GLASER CORPORATION OF ST. LOUIS, A MAJOR PHARMACY FIRM, WHICH ITSELF USES THE DATA BASE IN ITS OWN COMPUTERIZED PHARMACY SYSTEM. THE DATA BASE CURRENTLY CONTAINS OVER 30,000 DRUGS AND THEIR INTERACTION PATTERNS. A TEAM OF PHYSICIANS AND PHARMACOLOGISTS REGULARLY REVIEW THE CLINICAL LITERATURE IN ORDER TO IDENTIFY NEW INTERACTIONS WHICH SHOULD BE INCLUDED INTO THE DATA BASE.
- O COPIES OF STANDARD REFERENCE WORKS (THE EVALUATION OF DRUG INTERACTIONS, AND ITS SUPPLEMENT) ARE PROVIDED WITH EACH SYSTEM. A FOLDER WHICH DESCRIBES INTERACTIONS TOO NEW FOR INCLUSION INTO THE EDI AND ITS SUPPLEMENT IS ALSO PROVIDED. MEDSAFE GIVES A REFERENCE (TO THE PAGE) FOR EVERY ANALYSIS RESULT. THE DATA BASE AND THE REFERENCE DOCUMENTS ARE UPDATED QUARTERLY BY COMPUJET. FIGURE 4 SHOWS AN EXAMPLE INTERACTION ANALYSIS RESULT.

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Interaction analysis completed

Active Patient: Smith, Rupert 3306 La Cienega Boulevard, Los Angeles, California

CORRELATION DRUG LIST

0000054438 ARTANE SEQUELS  
0000710531 DILANTIN WITH PHENOBARBITAL  
0000743773 DICUMAROL  
0000220129 DICYCLOMINE HYDROCHLORIDE  
0000021408 PENICILLIN C POTASSIUM

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INTERACTION ANALYSIS RESULTS  
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0000710531 DILANTIN WITH PHENOBARBITAL  
0000743773 DICUMAROL  
SOURCE E PAGE 291 SIGNIFICANCE: EXPECTED TO OCCUR - POTENTIALLY SERIOUS

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0000710531 DILANTIN WITH PHENOBARBITAL  
0000743773 DICUMAROL  
SOURCE E PAGE 193 SIGNIFICANCE: EXPECTED TO OCCUR - POTENTIALLY SERIOUS

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0000710531 DILANTIN WITH PHENOBARBITAL  
SOURCE E PAGE 205 SIGNIFICANCE: OCCURS 20-30% OF THE TIME

1/resume

## SECURITY

- O THE SYSTEM MUST BE SECURE, CAPABLE OF PREVENTING UNAUTHORIZED USE.
- O MEDSAFE HAS A BUILT-IN SECURITY SYSTEM:
  - MULTI-LEVEL PASSWORDS LIMIT DISPLAY OR CHANGE OF THE DRUG INTERACTION DATA BASE AND PATIENT MEDICAL RECORDS TO AUTHORIZED USERS.
  - UP TO SIXTEEN SEPARATE PROTECTION CLASSES (E.G., READ MEDICAL RECORDS, CHANGE MEDICAL RECORDS, READ ACCOUNTING RECORDS, CHANGE ACCOUNTING RECORDS, ENABLE REMOTE PROCESSING, GRANT REMOTE ACCESS, VIEW THE CURRENT PASSWORDS, ETC.)
  - CAN SET PASSWORDS TO CONTROL EACH CLASS, OR ANY COMBINATION OF CLASSES.

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### MULTI-USER

- 0 LARGER GROUP PRACTICES, CLINICS, AND OTHER SIZEABLE ORGANIZATIONS MAY REQUIRE MORE THAN ONE OPERATOR STATION.
- 0 MEDSAFE CAN ALSO BE CONFIGURED AS A MULTI-STATION SYSTEM, WITH UP TO SIX TERMINALS UNITS BEING SUPPORTED BY A SINGLE STORAGE UNIT, WITH NO CHANGE IN PERFORMANCE AS COMPARED TO THE SINGLE-STATION CONFIGURATION. THIS CONFIGURATION CAN ALSO SUPPORT MULTIPLE PRINTERS (WHICH CAN BE OF VARYING TYPES) AND MULTIPLE REMOTE TERMINALS.
- 0 THIS IS ACCOMPLISHED BY PROVIDING THE ABILITY FOR THE STORAGE UNIT TO SHARE DATA AMONG THE TERMINAL UNITS. EACH TERMINAL UNIT PROVIDES ITS OWN HIGH-SPEED MEMORY AND PERFORMS ALL OF ITS OWN COMPUTATIONS; ONLY THE DATA STORAGE AND ACCESS RESOURCES ARE SHARED. BECAUSE THE ACCESS TIMES AND INPUT/OUTPUT BANDWIDTH OF THE MEDSAFE STORAGE UNIT ARE MANY TIMES HIGHER THAN IS REQUIRED BY ANY ONE TERMINAL UNIT, EACH TERMINAL IN A MULTI-STATION CONFIGURATION CAN OPERATE AT A PERFORMANCE RATE COMPARABLE TO THE SINGLE-USER SYSTEM.
- 0 THE MULTI-STATION VERSION OF MEDSAFE IS INTENDED TO SUPPORT LARGER GROUP PRACTICES, NON-PHARMACY HOSPITAL APPLICATIONS, AND LARGE PUBLIC AND PRIVATE MEDICAL CLINICS. THE STATIONS COULD EACH BE SEPARATED FROM THE STORAGE UNIT BY UP TO ONE KILOMETER.

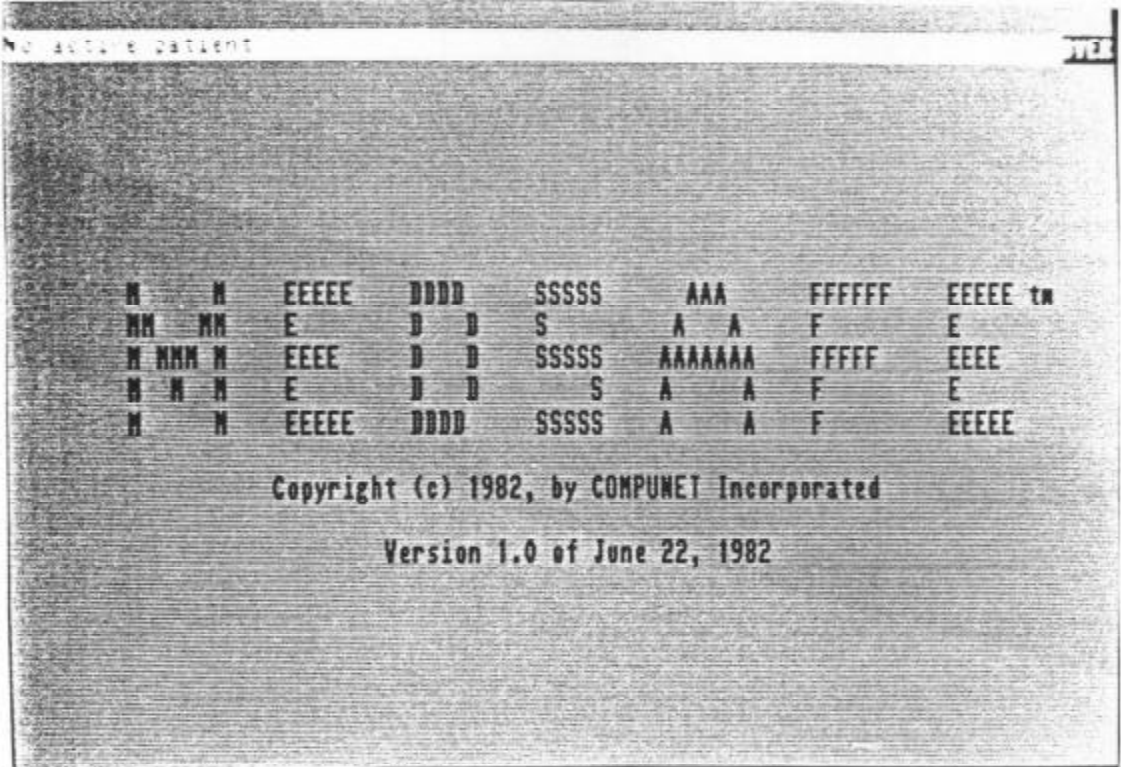
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### SUMMARY

A SYSTEM HAS BEEN DESCRIBED WHICH PROVIDES A SINGLE, POWERFUL TOOL FOR DIRECTING THE LATEST TECHNIQUES OF AUTOMATION AT THE GOAL OF IMPROVING PATIENT CARE, BY PROVIDING A UNIQUE COMBINATION OF SERVICES IN ONE UNIFIED, COHESIVE PACKAGE. PARTICULARLY IMPORTANT IS THE SYSTEM'S CAPABILITY TO RAPIDLY AND RELIABLY IDENTIFY POTENTIALLY ADVERSE DRUG INTERACTIONS. THE AVAILABILITY OF SUCH A TOOL WILL ALLOW PHYSICIANS TO CONFIDENTLY EXPAND THE REPERTOIRE OF DRUGS WHICH THEY PRESCRIBE. MICROPROCESSOR TECHNOLOGY BRINGS THIS FUNCTION FOR THE FIRST TIME INTO A PRICE RANGE ACCESSIBLE TO INDIVIDUAL PRACTICES.

BY A NOVEL AND INNOVATIVE APPLICATION OF MICROPROCESSOR HARDWARE TECHNOLOGY AND SOFTWARE DEVELOPMENT METHODOLOGY, A SYSTEM HAS BEEN DEVELOPED WHICH BREAKS NEW GROUND FOR MEDICAL MICROCOMPUTER SYSTEMS IN MANY KEY AREAS, SUCH AS STORAGE CAPACITY, THE LOGISTICS OF DATA BACK-UP, EASE-OF-LEARNING AND EASE-OF-USE, REMOTE ACCESS, AND COMPREHENSIBILITY OF THE DISPLAYS.

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