PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : **B42D 15/02**

A1

(11) International Publication Number: **WO 88/ 02700**

(43) International Publication Date: 21 April 1988 (21.04.88)

(21) International Application Number: PCT/GB87/00702

(22) International Filing Date: 5 October 1987 (05.10.87)

(31) Priority Application Numbers: 8624013
8628345

(32) Priority Dates: 7 October 1986 (07.10.86)
27 November 1986 (27.11.86)

(33) Priority Country: GB

(71) Applicant *(for all designated States except US):* MAINFRAME DATA LIMITED [GB/FR]; 46, rue Saint-Didier, F-75116 Paris (FR).

(72) Inventor; and
(75) Inventor/Applicant *(for US only) :* NASSIM, Labib, Alfred [GB/FR]; 46, rue Saint-Didier, F-75116 Paris (FR).

(74) Agent: MARCH, Gary, Clifford; Kings Patent Agency Limited, 146a Queen Victoria Street, London EC4V 5AT (GB).

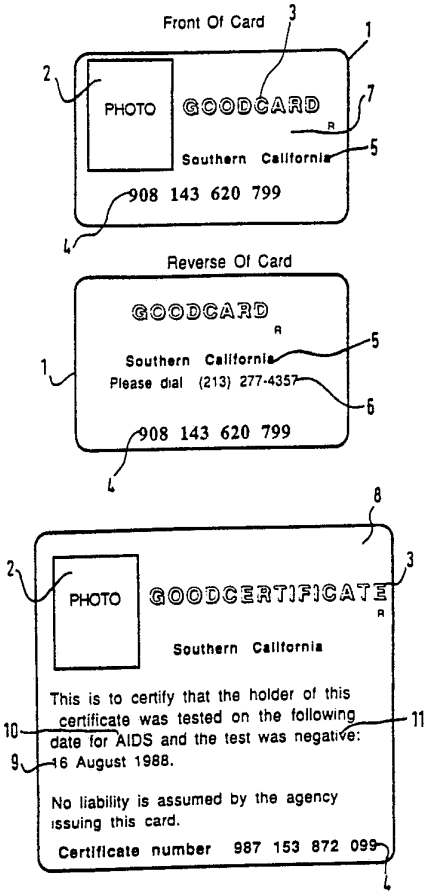
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent), SU, US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: APPARATUS AND METHOD FOR CONTROLLING TRANSMISSION OF DEFECTS

(57) Abstract

Apparatus useful in preventing or reducing risks of transmitting an infectious disease, primarily AIDS, or genetic disorder, comprises identification means such as a personal card bearing identity particulars of a first participant and security feature(s) and a storage medium such as certificate or database, bearing legible or retrievable test result data concerning the particular defect. A second participant consults the result before permitting intimate contact or accepting a donation of blood, body tissue or similar material.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**FR**	France	**ML**	Mali
AU	Australia	**GA**	Gabon	**MR**	Mauritania
BB	Barbados	**GB**	United Kingdom	**MW**	Malawi
BE	Belgium	**HU**	Hungary	**NL**	Netherlands
BG	Bulgaria	**IT**	Italy	**NO**	Norway
BJ	Benin	**JP**	Japan	**RO**	Romania
BR	Brazil	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SN**	Senegal
CH	Switzerland	**LI**	Liechtenstein	**SU**	Soviet Union
CM	Cameroon	**LK**	Sri Lanka	**TD**	Chad
DE	Germany, Federal Republic of	**LU**	Luxembourg	**TG**	Togo
DK	Denmark	**MC**	Monaco	**US**	United States of America
FI	Finland	**MG**	Madagascar		

TITLE

Apparatus and method for controlling Transmission of Defects

This invention is concerned with apparatus and methods for preventing or reducing the risks of transmission of defects from one participant to another, e.g. from one human being to another human being or to an organisation. More particularly it is concerned with such apparatus and methods for i.e. preventing, or substantially reducing the risk of transmission of a communicable disease or disorder. By communicable disease or disorder we include, for example infectious ailments be they viral, bacterial or the like and genetically transmissible disorders.

The invention may find application amongst humans who are contemplating intimate contact or contemplating donation of body fluids or material for reception or use by a second participant. The invention may also be useful to persons or organisations responsible for such donations as blood banks, hospitals, transfusion centres, medical teams and the like. The invention could even be

useful in the field of animal husbandry as a means of controlling undesirable disease or disorder under human supervised breeding conditions.

Use of the invention may be a systematic control method to help stop the spread of communicable disease or disorder in which medical treatment is not required. As will become apparent, the invention has a principal application in stemming further spread of sexually communicable diseases amongst humans, notably Acquired Immune Deficiency Syndrome (AIDS) for which there is currently no cure and to a lesser extent, the venereal diseases such as syphilis, gonorrhoea or herpes. The invention may also find application in preventing, or substantially reducing the risks of transmission of a genetic disorder from one generation to another e.g. to an offspring of a participant. In this field of hereditary defects the invention may be useful in controlling such communicable defects as, for example, mongolism, cystic fibrosis, haemophilia, diabetes and sickle cell anaemia.

The following terms and expressions are used throughout the description and claims to include the following:

"First Participant": - an individual contemplating intimate contact with or donation to a second

participant; or a first animal for breeding or donation purposes.

"Defect": - communicable disease or disorder being infectious or genetic which may adversely affect the health or function of an individual or animal. The term is used to include any sexually communicable disease amongst living beings, especially AIDS.

"Second Participant":- an individual contemplating intimate contact with a user, a second animal for breeding or donation-receiving purposes or an individual, group, team, organisation and the like which receives or monitors donated body fluid or material, or contemplates such receipt.

As examples of body fluid or material that may be donated we include human or animal blood that can be used either immediately or subsequently for transfusion, for conversion into blood products such as separation into blood plasma, or concentration and separation in factor VIII, and e.g. bone marrow for immediate or subsequent transplantation. We also include organs for transplantation, for example, one kidney from an individual (first participant) to a related individual (second participant) when both such individuals are live or posthumous donation of vital organs such as kidneys, heart, lungs in

the event of an untimely death of first participant. Individuals wishing to donate any such organs may carry a donor card expressing a wish or preference for a donation or, alternatively, the decision to donate may be made by representatives of the donor, for example, the parents (as second participants in a monitoring function) of an individual recently killed. Before a medical team may wish to use any donated organs they may require up-to-date information in respect of potentially damaging defects such as contamination by the AIDS virus or subject to haemophilia genetic disorder and the like.

As a suitable body fluid which may be donated by individuals or animals we also include semen which may be stored in a sperm bank and used for artificial insemination. It may be advantageous for the recipient (second participant) of such semen to have up to date information in respect of any required defect by having access to a test result in respect of that defect for such donated material.

The invention is useful in preventing transmission of disease or disorder from a potential carrier, which may be anyone or any animal within a given population, to

a potential recipient of that disease or disorder. The invention may therefore be useful to people concerned with animal husbandry but principally to individuals as first and second participants contemplating intimate contact where there exists a risk of acquiring an infectious disease. As will become apparent this can be provided by independent test result for assessment by a second participant.

In many countries there is a considerable anxiety over the spread of the communicable disease known as AIDS. Three possible methods of controlling the spread include find a cure, find a vaccine or separate the AIDS infected carriers from intimate or other risky contact with the rest of the population. The first two solutions are currently considered to be unobtainable in the immediate future. The separation proposal has been the only practicable step at the present time.

The importance of controlling further spread of AIDS into the non-AIDS infected population is becoming more and more important in the United Kingdom and is already a problem in countries such as the United States where a large proportion of the homosexual community are AIDS infected.

The majority of organised attempts to isolate carriers of the AIDS human immunodeficiency virus HIV

from contact with the remaining population have been directed at isolating the sick from the healthy, i.e. those infected from those who are not. The AIDS virus has a long incubation period and for this reason any control measures are likely to affect the sensitive issue of personal liberty. The present invention is based on a surprisingly different approach to the problem in that it is concerned with isolating the healthy from the sick rather than the converse. Any attempts by individuals to isolate themselves from potential or actual carriers of AIDS have been haphazard. It has been observed that individuals at risk of contacting AIDS have limited the number of intimate contacts made with others.

Use of the present invention permits a still further and significant reduction of risks and therefore may save lives and reduce anxiety and stress amongst individuals who use the apparatus and/or method according to the invention.

According to a primary aspect of this invention there is provided apparatus useful in a method of controlling transmission of a communicable disease or disorder comprising an identification means bearing identity information relating to a first participant and one or more security features, and a storage

medium carrying legible or retrievable information concerning a test result performed upon or in connection with the first participant, the test result relating to a communicable disease or disorder.

According to a second aspect of this invention there is provided a method of controlling transmission of a defect from a first to second comprising:

(a) supplying the first participant with identification means,

(b) performing a test for presence or absence of the defect upon or in relation to the first participant,

(c1) producing in legible or retrievable form a test result on a storage medium identifying the first participant or (c2) storing the test result in a database followed by (c3) retrieval of that result,

(d) informing the second participant of the test result,

(e) establishing an accept or reject decision by or on behalf of the second participant, and

(f) permitting contact between first and second participant or donation from first to second participant if step (e) results in a decision

to accept.

Optionally the first participant may repeat that test or have a different test for another communicable disease or disorder performed at any stage after (a). Furthermore, the first participant may decide to terminate the sequence before step (d) if the particular test is unfavourable, e.g. after a diagnosis of AIDS antibody positive.

In the apparatus and step (c1) of the method the result may be stored legibly on an independently issued certificate and this proof of result may be presented to or sent to the individual (first participant) immediately upon completion of the test. The individual will then be at liberty to disclose this to any second participant of his choosing. Alternatively, the test result may be stored on or in electronic, optical or magnetic storage medium such as a database and subsequently retrieved by the second participant with express or implicit permission from the first participant. This may be achieved by the second participant interrogating the appropriate storage medium to retrieve the result and possibly have a permanent record of it by certificate, print out or the like. This may be done in the presence of the first participant or by furnishing consent to a data centre operator who stores a plurality of test

results on a specific database. A second participant may be given a secret access code from the first participant to retrieve the test result from the storage medium (e.g. database) without the intermediary of an operator.

Such interrogation of a database may produce a result by audio and/or visual means such as, for example, a printed record being obtained at the request of the recipient.

It may be convenient for the identification means to comprise a personal identity card similar to plastic credit cards in common use. The identity information may include a photograph, a name, a legible code and/or a secret code. Examples of security features include predetermined patterns and/or holograms. The storage medium may simply comprise paper such as a certificate bearing a legible test result giving date, type and result of test, plus information identifying the first participant. Alternatively the storage medium may be electronic, optical or magnetic, in which case the test result would be retrievable and then could be made permanently legible if desired.

In one embodiment the identification means is a personal card bearing a magnetic strip having the test

result stored on it. The result can be retrieved subsequently.

One convenient test for a first participant is carried out on a blood sample, e.g. the test for AIDS antibodies. The present apparatus and method is especially useful in controlling the further spread of sexually transmissible disease or disorder.

The present apparatus can be used in conjunction with means for retrieving a non-legible test result carried on the storage medium. For example an electronic decoder and display unit optionally with printing means.

In order that the invention may be illustrated and readily carried into effect, embodiments thereof will now be described by way of example only with reference to the accompanying drawings, in which:

Figure 1 shows a front and reverse sides of identification means,

Figure 2 shows a storage medium carrying legible test result, and

Figures 3 and 4 show flow charts of methods that may be carried out using the apparatus features.

Referring to the drawings and particularly Figures 1 and 2, this embodiment relates to proposed intimate

contact between a first participant and a second individual participant. It may equally apply with some modifications where intimate contact is proposed between animals, under human-supervised breeding conditions or for establishing the suitability of donated body fluid or material for subsequent transfusion or other use. All participants may subscribe to a defect screening system in which a data centre, controlled by an operator, stores test results on a database and permits retrieval of results under authorised terms.

The first participant is provided with a card similar to a credit card 1. The card has a legible code 4, a secret code 7 (invisible), a photograph 2 of the holder, and a hologram (not shown). It should be noted that the name and signature of the user are unnecessary. The card also has a logo 3, an address 5 and telephone number 6 of a data centre which stores the test results.

The first participant has his blood tested at least once, preferably periodically, at a suitable location e.g. one approved by the above noted screening system operator. The data centre would verify the authenticity of the card and note the legible code. The result of the test, the type of test, the date of the test and the code on the card would be sent to the operator if it is to be stored on a database for subsequent retrieval.

This information could even be applied to a magnetic, electronic or optical recording strip on one side of the card (not shown).

Instead of storage the test result can be compiled as a certificate, see Figure 2, which shows a tangible certificate 8 having optional logo 3, photograph 2 of first participant, security feature 4, date of test 9, type of test 10 and result of test 11. This certificate can be retained by the first participant.

At any time that the first participant may wish to establish absence of defect to a second participant he may interrogate this database in the presence of that second participant or otherwise expressly consent to interrogation in his absence. The secret code may be used to give right of access to this database. An alternative way of presenting this data after retrieval would be for a data centre operator to produce, on demand, a certificate explaining the test results of the first participant. At any time desired the first participant may show this certificate of independent test to a second participant to establish absence of defect. At that time a more informed decision to permit intimate contact or accept donation can be made thus helping control of the particular disease of disorder tested.

It should be the responsibility of the second

participant to interpret test results to determine whether intimate contact or receipt/use of donation can be permitted.

Plastic cards are only one of many possible identification means to establish a link between first participant, the test result, the second participant and the storage means, e.g. database.

Operators may wish to communicate anonymous data across regions and countries in order to improve the method and freedom of first participants.

Many feasible ways exist for presenting test result data in such a way as to enhance the ease of use while preventing fraud. For example, by telephone, by videotex, by certificate and the like.

Participants using the apparatus and method may therefore make substantial contributions to controlling the spread of communicable disease or disorder and consequently enhancing the health and well being of the human or animal population.

For a general application of the method which illustrates the use of the apparatus the reader is referred to Figure 3 whilst for a more specific example, based on the Figures 1 and 2 apparatus the reader is referred to Figure 4. The flowcharts themselves are self-explanatory with an index given relating to each

particular step in the method as defined above.

The invention can be seen to involve testing of living beings or live organs or useful body fluid/material for certain physical parameters and a secure system of passing information to individuals or groups etc. at the choice of the first participant.

Testing for presence or absence of defects is meant to include all means and methods for performing such tests, for example by testing samples of blood, urine, skin, flesh, organs, semen, breath, hair or nails. In some cases certain tests may not require removal of a sample but these may be performed in situ.

An important application of the present invention is in the screening of blood donations by blood banks acting as second participants. Present arrangements for screening are not altogether satisfactory and in certain countries blood is donated for financial reward. In such a situation the donors (first participants) can be infected by a communicable disease such as AIDS or hepatitis virus but the blood bank unknowingly accepts their donation and payment is made. It is only after payment that such blood is tested and sometimes destroyed because of the presence of a potentially harmful defect.

By using the present apparatus or method these unnecessary expenses and risks may be circumvented,

particularly if the test results are securely stored on a database and access thereto is carefully controlled.

The data centre, if used, may pair or twin participants by e.g. supplying both participants' identity card numbers to the operator. When such links are present in the data centre all such participants may be notified who could have become infected by e.g. AIDS virus through contact with other participants. When the participant interrogates their own data, they may receive a warning to have medical attention and/or exercise caution in future intimate contacts or donations.

CLAIMS

1. Apparatus useful in a method of controlling transmission of a communicable disease or disorder comprising an identification means bearing identity information relating to a first participant and one or more security features, and a storage medium carrying legible or retrievable information concerning a test result performed upon or in connection with the first participant, the test result relating to a communicable disease or disorder.

2. Apparatus as claimed in Claim 1 in which the identification means comprises a personal card.

3. Apparatus as claimed in Claim 1 or 2 in which the identity information comprises one or more of the following: a photograph of the first participant, a legible code, a name or signature.

4. Apparatus as claimed in any preceding claim in which the security feature comprises a predetermined pattern, a hologram and/or a magnetically or optically readable access code.

5. Apparatus as claimed in any preceding claim in which the storage medium bears a legible test result, optionally in the form of a certificate.

6. Apparatus as claimed in any one of Claims 1 to 4, in which the storage medium is magnetic or optical or electronic and carries a retrievable test result, such as a database or data centre.

7. Apparatus as claimed in Claim 6 comprising a personal card bearing a magnetic strip which carries a retrievable test result and/or a non-legible access code as a security feature.

8. Apparatus as claimed in any preceding claim in which the test result relates to a test performed on a first participant's blood.

9. Apparatus as claimed in any preceding claim in which the test result relates to a sexually communicable disease or disorder.

10. Apparatus as claimed in Claim 9 in which the test result relates to presence or absence of Human immunodeficiency virus HIV.

11. Apparatus as claimed in any preceding claim in combination with retrieval means for retrieving a stored test result carried on the storage medium.

12. Apparatus as claimed in Claim 11 in which the retrieval apparatus can display and/or print the test result.

13. Apparatus useful in a method of controlling transmission of a communicable disease or disorder substantially as herein described.

14. Apparatus as claimed in Claim 13 as illustrated in Figure 1 or 2 of the accompanying drawings.

15. A method of controlling transmission of a communicable disease or disorder from a first participant to a second participant comprising:

(a) supplying the first participant with identification means,

(b) performing a test for presence or absence of the defect upon or in relation to the first participant,

(c1) producing in legible or retrievable form a test result identifying the first participant, optionally

(c2) storing the test result in a storage means, then

(c3) retrieving the result for presentation,

(d) informing the second participant of the test result,

(e) establishing an accept or reject decision by or on behalf of the second participant, and

(f) permitting contact or donation between first and second participants if step (e) results in a decision to accept.

16. A method as claimed in Claim 15 substantially as herein described.

17. A method as claimed in Claim 15 substantially as illustrated in Figure 3 or 4 of the accompanying drawings.

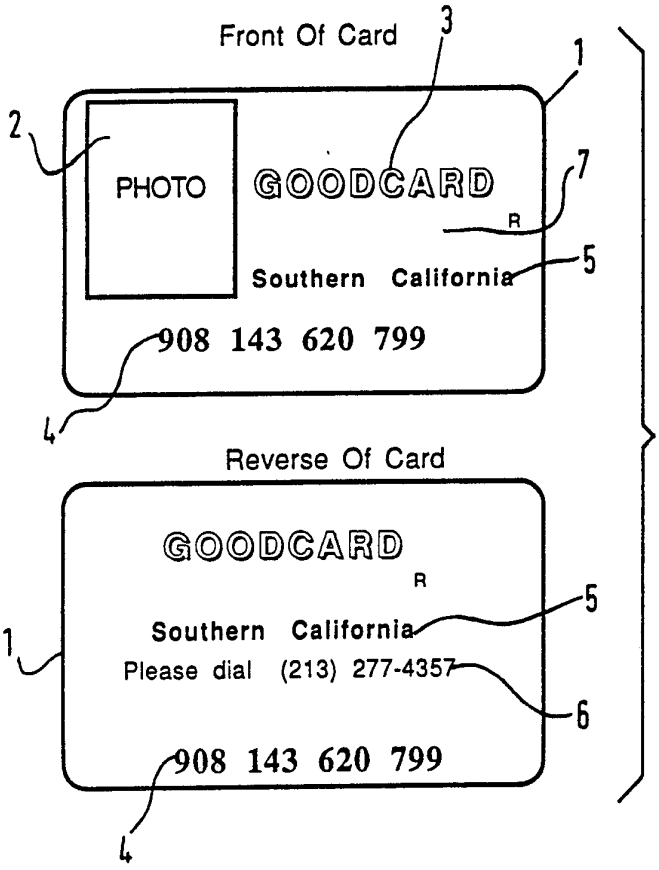
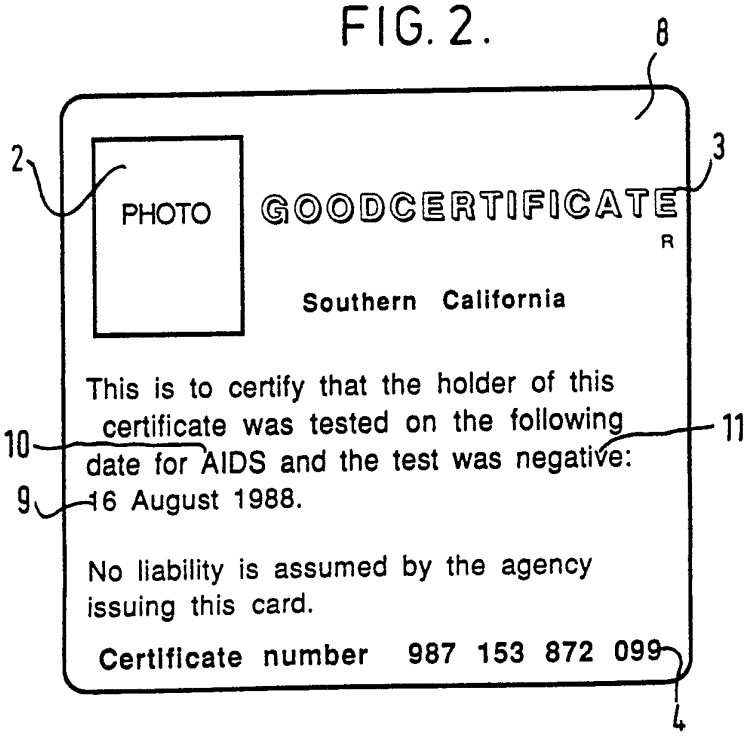

Front Of Card
3
1
2
PHOTO
GOODCARD
R
7
Southern California
5
908 143 620 799
4
Reverse Of Card
GOODCARD
R
5
1
Southern California
Please dial (213) 277-4357
6
908 143 620 799
4

FIG. 1.

FIG. 2.


8
2
PHOTO
GOODCERTIFICATE
R
3
Southern California
This is to certify that the holder of this
certificate was tested on the following
10
11
date for AIDS and the test was negative:
9
16 August 1988.
No liability is assumed by the agency
issuing this card.
Certificate number 987 153 872 099
4

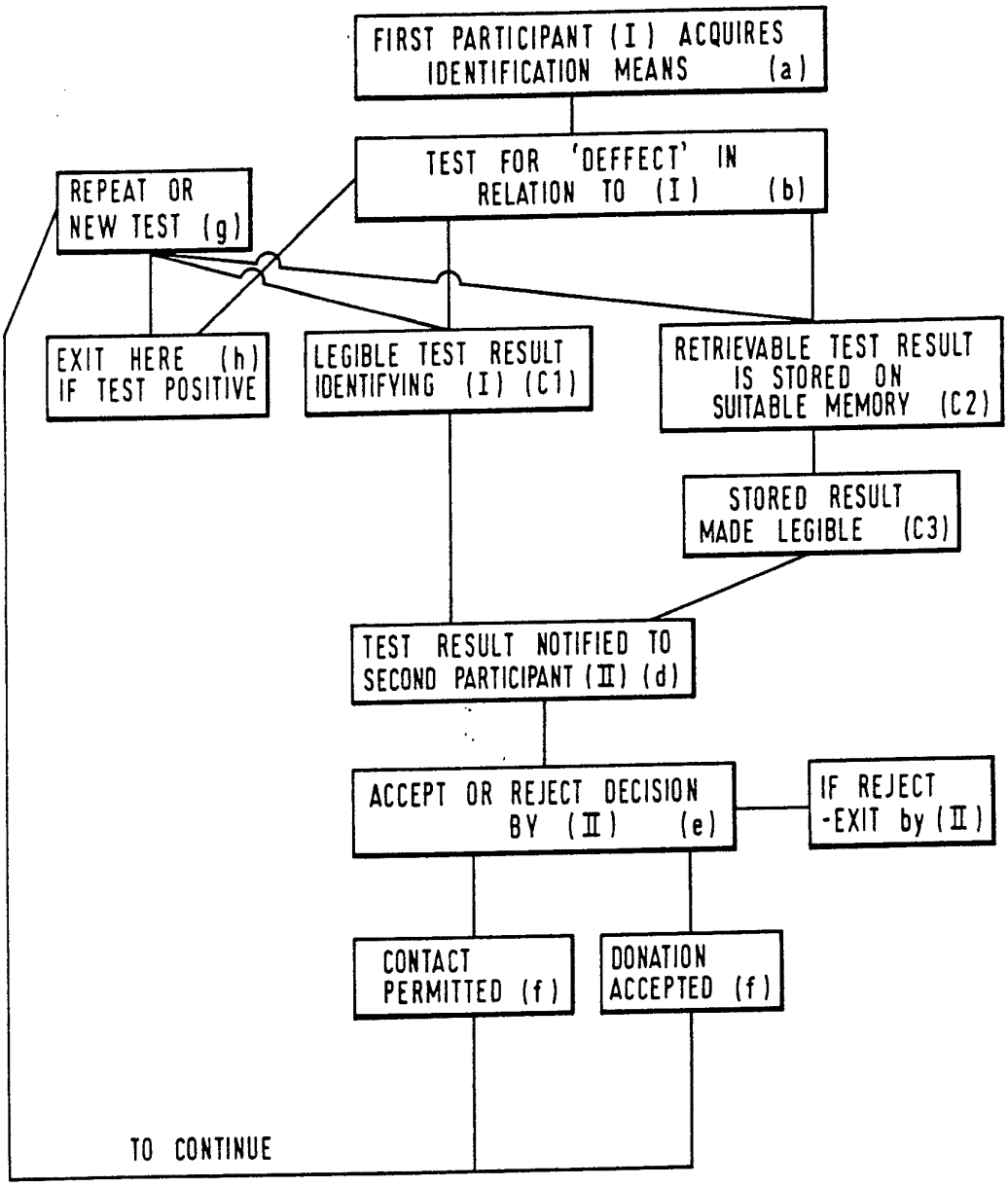

FIRST PARTICIPANT (I) ACQUIRES IDENTIFICATION MEANS (a)
TEST FOR 'DEFFECT' IN RELATION TO (I) (b)
REPEAT OR NEW TEST (g)
EXIT HERE (h) IF TEST POSITIVE
LEGIBLE TEST RESULT IDENTIFYING (I) (C1)
RETRIEVABLE TEST RESULT IS STORED ON SUITABLE MEMORY (C2)
STORED RESULT MADE LEGIBLE (C3)
TEST RESULT NOTIFIED TO SECOND PARTICIPANT (II) (d)
ACCEPT OR REJECT DECISION BY (II) (e)
IF REJECT -EXIT by (II)
CONTACT PERMITTED (f)
DONATION ACCEPTED (f)
TO CONTINUE

FIG. 3.

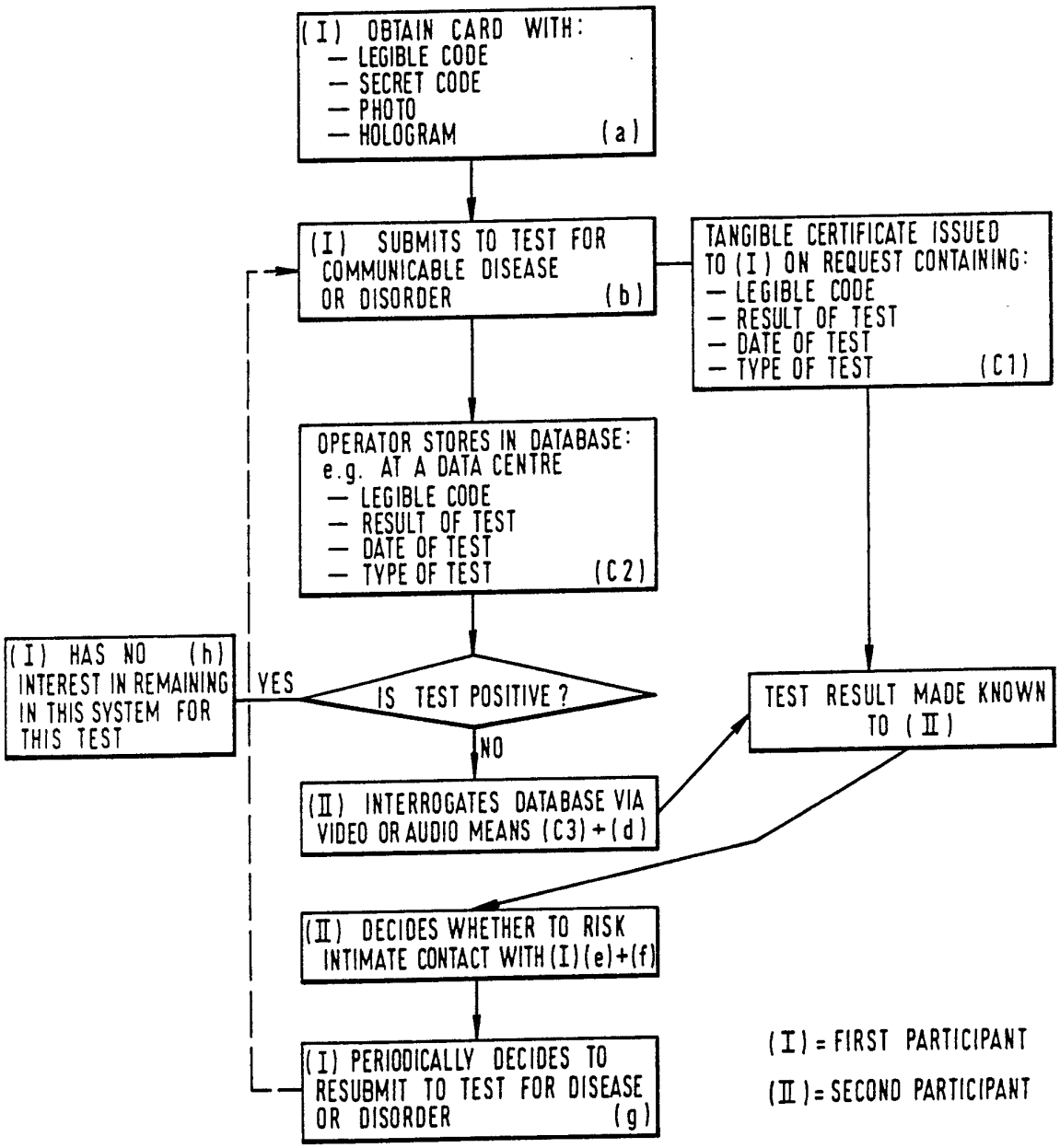

(I) OBTAIN CARD WITH:
— LEGIBLE CODE
— SECRET CODE
— PHOTO
— HOLOGRAM (a)
(I) SUBMITS TO TEST FOR COMMUNICABLE DISEASE OR DISORDER (b)
TANGIBLE CERTIFICATE ISSUED TO (I) ON REQUEST CONTAINING:
— LEGIBLE CODE
— RESULT OF TEST
— DATE OF TEST
— TYPE OF TEST (C1)
OPERATOR STORES IN DATABASE: e.g. AT A DATA CENTRE
— LEGIBLE CODE
— RESULT OF TEST
— DATE OF TEST
— TYPE OF TEST (C2)
(I) HAS NO (h) INTEREST IN REMAINING IN THIS SYSTEM FOR THIS TEST
YES
IS TEST POSITIVE ?
NO
TEST RESULT MADE KNOWN TO (II)
(II) INTERROGATES DATABASE VIA VIDEO OR AUDIO MEANS (C3)+(d)
(II) DECIDES WHETHER TO RISK INTIMATE CONTACT WITH (I) (e)+(f)
(I) PERIODICALLY DECIDES TO RESUBMIT TO TEST FOR DISEASE OR DISORDER (g)
(I) = FIRST PARTICIPANT
(II) = SECOND PARTICIPANT

FIG. 4.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00702

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: B 42 D 15/02

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	G 07 C; B 42 D; G 06 K; A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 3921318 (CALAVETTA) 25 November 1975, see abstract; column 3, line 38 - column 4, line 8; claims; figures	1,2
A	--	3-8,11,15
P,X	US, A, 4632428 (BROWN) 30 December 1986, see abstract; column 1, line 41 - column 2, line 33; column 3, line 16 - column 4, line 45; figures	1-7,11,12, 15
A	-- US, A, 4236332 (DOMO) 2 December 1980, see column 1, line 38 - column 2, line 19; claims; figures	1-6,8,11, 15
A	-- FR, A, 2229099 (ALLMANN SVENSKA) 6 December 1974, see page 2, line 33 - page 3, line 21; figures	1,15
A	-- GB, A, 2092952 (SILVER) 25 August 1982 see abstract; claims	1,4
	-- ./.	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
14th January 1988	19 FEB 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

International Application No. PCT/GB 87/00702

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 3502437 (MASS et al.) 24 March 1970 --	
A	US, A, 4259391 (BRECHT) 31 March 1981 --	
A	US, A, 4459015 (BRECHT) 10 July 1984 --	
A	FR, A, 2167252 (LABORATOIRES DE PHYSIQUE MEDICALE) 24 August 1973	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8700702 SA 18990

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 05/02/88
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3921318	25-11-75	None	
US-A- 4632428	30-12-86	None	
US-A- 4236332	02-12-80	None	
FR-A- 2229099	06-12-74	DE-A- 2421440	05-12-74
		CH-A- 575627	14-05-76
		GB-A- 1463903	09-02-77
		SE-B- 389413	01-11-76
GB-A- 2092952	25-08-82	None	
US-A- 3502437	24-03-70	None	
US-A- 4259391	31-03-81	None	
US-A- 4459015	10-07-84	None	
FR-A- 2167252	24-08-73	None	