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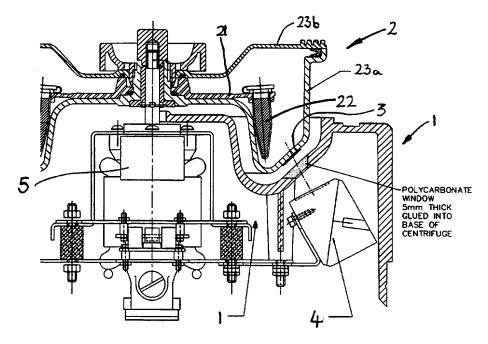
GB 2216259 A GB 2199407 A EP 0604912 A2 EP 0602587 A1 EP 0344443 A2 US 4622457 A US 4551715 A US 3680967 A

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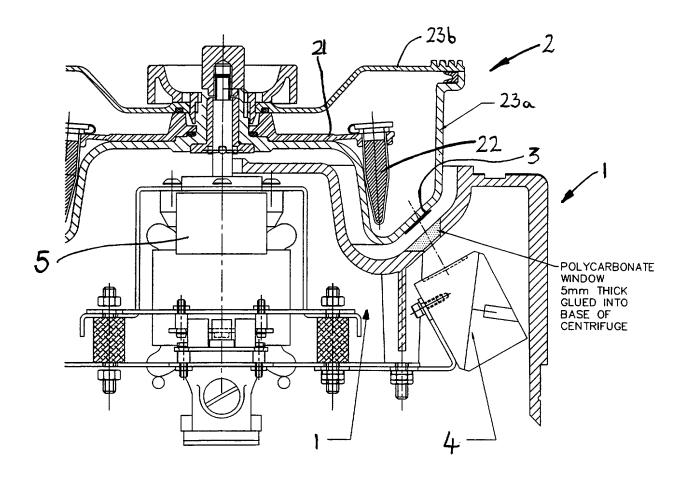
(54) Abstract Title

Medical and/or laboratory equipment

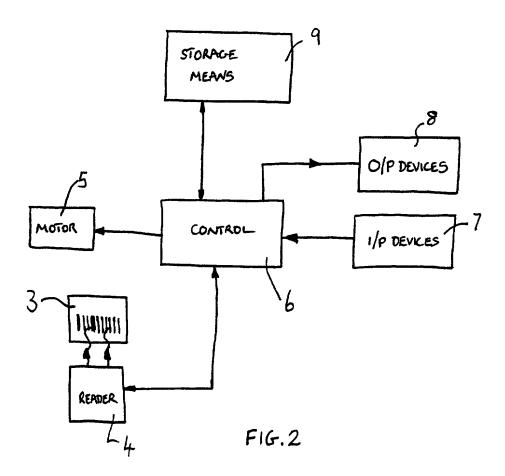
(57) A system for monitoring and controlling the use of medical and/or laboratory equipment and particularly centrifuge rotors. In the system, a barcode 3 is provided on each rotor 2 and an appropriate barcode reader 4 is provided in a centrifuge device 1. Thus, when a rotor 2 is inserted into the centrifuge device 1 the barcode 3 on the rotor 2 may be read such that the centrifuge device 1 can operate in a way appropriate for that particular rotor 2.



F16.1



F16.1



Medical and/or Laboratory Equipment

This invention relates to medical and/or laboratory equipment, in particular centrifuge rotors and centrifuge devices and more particularly still to systems in which any one of a plurality of different centrifuge rotors may be driven by a particular centrifuge device.

- Typically, a laboratory will have a limited number of centrifuge devices which are arranged to drive suitable centrifuge rotors. For practical reasons, although the number of centrifuge devices may be limited, it is useful to have a larger number of centrifuge rotors. This allows users to set up samples ready for centrifuging in a number of rotors whether or not a centrifuge device is available for use.
- 20 Traditionally the structural components of centrifuge rotors have been constructed from metallic materials such as aluminium. These have an extremely long working life but are expensive. Recently it has been realised that an alternative to the use of metallic materials is the use of suitable plastics for certain

parts of the rotor. In particular it has been found that rotors may be constructed using plastic housings made up of a bowl and a lid. These plastics components tend to have a shorter life than the metallic

5 equivalents but are significantly less expensive. Whatever type of rotors are used it is important for users to keep a record of the amount of usage to which each rotor has been subjected because all rotors have a limited life. However, such record keeping is 10 laborious and errors can occur.

As mentioned above, the provision of a large number of separate centrifuge rotors allows the setting up of samples to be carried out independently of the 15 centrifuging itself. However, the exact nature of centrifuging required will be sample dependent and if a different individual is to carry out the centrifuging then instructions need to be given as to what programme should be followed. Again this can lead to errors being made.

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Similar considerations apply in relation to other forms of medical and/or laboratory equipment in which one or more element has a limited life and a critical function. Examples are robotic assay devices making

use of disposable sample trays, e.g. 96 well microtitre plates and dialysis devices. In each case it is vital that various components are not mis-used or reused inappropriately. For example, disposable titre plates must not be re-used otherwise the results of the microbiological, biochemical, immunological assays will be essentially worthless.

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It is an object of the present invention to provide

10 systems which alleviate at least some of the problems
associated with the prior art.

According to a first aspect of the present invention there is provided a centrifuge rotor arranged to be received and driven in a centrifuge device, wherein the rotor comprises machine readable identifier means allowing identification of the rotor.

According to a second aspect of the present invention there is provided a centrifuge device arranged to receive and drive any one of a plurality of centrifuge rotors, the device being characterized by reading means arranged for reading identifier means provided on an inserted rotor to allow identification of the inserted rotor.

According to a third aspect of the present invention there is provided a centrifuge assembly comprising a centrifuge device and a centrifuge rotor arranged to be driven by the centrifuge device, wherein the rotor comprises identifier means and the centrifuge device comprises reading means for reading the identifier means whereby the rotor can be identified.

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According to a fourth aspect of the present invention
there is provided a method of monitoring and/or
controlling the usage of a plurality of centrifuge
rotors comprising the steps of providing each
centrifuge rotor with identifier means and using a
centrifuge device to read the identifier means on
rotors inserted in the centrifuge device.

The identifier means may comprise a bar code.

The identifier means may serve to identify the rotor as a rotor of a particular type and/or to identify the rotor as a specific rotor.

The rotor may comprise a sample holder and surrounding housing. One or more of the parts of the rotor, in particular the housing, may have a limited operational life. The identifier means may be provided on a part

having a limited operational life. This can allow the usage of the selected part to be monitored.

The centrifuge device may comprise logging means for keeping a record of the use made of a particular rotor. Preferably the logging means is arranged to record the aggregate time for which an inserted rotor has been operated.

- In a system where there are a plurality of rotors,
 each rotor may be associated with a memory module. The
 centrifuge device may be arranged to receive and read
 memory modules. The centrifuge device may be arranged
 to write log information to an inserted memory module.
- This can allow a record of the use of a rotor to be maintained even when that rotor is used with a number of different centrifuge devices.

Typically the memory module will be distinct from the identifier means provided on the rotor.

Preferably the memory module comprises a smart card.

The centrifuge device may comprise control means to

control driving operation of the device in dependence

on the established identity of an inserted rotor.

The control means may be arranged to prevent the operation of a rotor at a rotational speed in excess of that for which the rotor is intended.

Preferably, where the centrifuge device is arranged to monitor the aggregate time of operation of an inserted rotor, the control means is arranged to disable driving operation of the device when it is determined that the aggregate time for which an inserted rotor has been driven exceeds a predetermined threshold.

Both of the above features can improve safety.

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The control means may be arranged to subject an inserted rotor to a programme of operation which is determined by the rotor's established identity. This allows specific programs of operation to be pre-20 selected for different samples. For example the control means could be arranged so that a first rotor "X" is subjected to 20 minutes rotation at 8,000 RPM and a second rotor "Y" is subjected to 10 minutes at 6,000 RPM followed by 5 minutes at 10,000 RPM. This can facilitate a working system in which a first

person sets up the samples and provides them to a centrifuge operator to carry out the centrifuging without the need for detailed instructions.

5 The details of the program to which a rotor is to be subjected can be stored on a memory module, preferably a smart card, associated with the rotor. This further facilitates the separation of the tasks involved in setting up samples from the operation of the centrifuge itself whilst minimizing the risk that errors will occur.

According to another aspect of the present invention there is provided a medical and/or laboratory component arranged to be received and used in conjunction with an item of medical and/or laboratory equipment, wherein the component comprises machine readable identifier means allowing identification of the component.

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According to a further aspect of the present invention there is provided an item of medical and/or laboratory equipment arranged to receive and work in conjunction with any one of a plurality of medical and/or

25 laboratory components, the item of equipment being

characterized by reading means arranged for reading identifier means provided on an inserted component to allow identification of the inserted component.

invention there is provided a medical and/or laboratory equipment assembly comprising an item of medical and/or laboratory equipment and a medical and/or laboratory component arranged to be used in conjunction with the item of medical and/or laboratory equipment, wherein the medical and/or laboratory component comprises identifier means and the item of medical and/or laboratory component reading the identifier means whereby the component can be identified.

According to another aspect of the present invention there is provided a method of monitoring and/or controlling the usage of a plurality of medical and/or laboratory components comprising the steps of providing each component with identifier means and using an item of medical and/or laboratory equipment to read the identifier means on components inserted in the item of equipment.

Preferably the medical and/or laboratory component is one having a limited operational life. The component may be a one use article. The component may be such that use beyond its limited operational life is

5 prejudicial to safety and/or correct functioning of the associated item of medical and/or laboratory equipment. The component may, for example, comprise any one of a centrifuge rotor, a sample plate such as a 96 well micro-titre plate, and a component of a dialysis machine. The item of medical and/or laboratory equipment may, for example, comprise any one of a centrifuge device, an automatic/robotic assay device, and a dialysis machine.

- 15 Many of the subsidiary features described above in respect of the first to fourth aspects are also applicable to the above aspects changes in wording being made where necessary to retain consistency.
- An embodiment of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:-

Figure 1 is a schematic view of part of a centrifuge assembly comprising a centrifuge rotor inserted in a

centrifuge device; and

Figure 2 is a schematic view of the control circuitry of the centrifuge device shown in Figure 1.

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Figure 1 shows a centrifuge assembly which generally comprises a centrifuge device 1 and a centrifuge rotor 2. The centrifuge rotor 2 comprises a sample carrier 21 comprising a plurality of tubes 22 into which samples may be placed for centrifuging and a housing comprising a bowl 23a and a lid 23b which completely surround the sample carrier 21. The bowl 23a and lid 23b are made of a plastics material chosen to withstand the stress of high speed rotation.

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The centrifuge rotor 2 also comprises identifier means 3 disposed on an outer surface of the bowl 23a such that it can be read by a reader 4 provided in the centrifuge device 1. The identifier means 3 is typically a bar code which uniquely identifies the rotor 2. Correspondingly, the reading means 4 provided in the centrifuge device 1 is typically a bar code scanner. The bar code may be applied to the rotor 2 by using an ink jet printer.

The centrifuge rotor 2 is mounted in the centrifuge device 1 such that it can be driven at high rotational speeds by a motor 5 provided in the centrifuge device 1.

Figure 2 schematically shows control circuitry of the centrifuge device 1. The control circuitry comprises a central control means 6 which typically comprises a microprocessor. The central control means 6 is connected to the reading means 4, the motor 5, one or more input devices 7, one or more output devices 8 and storage means 9. The central control means 6 is arranged to receive and supply appropriate control signals and data to govern the overall operation of the centrifuge device 1.

The input devices 7 may, for example, comprise any one or any combination of a keypad, a disc drive and a smart card reader. The output devices may, for example, comprise any one of or any combination of, a visual display, a disc drive and a smart card writer. In the present embodiment it is assumed that the input devices 7 comprise a keypad and a smart card reader and that the output devices 8 comprise a visual display and a smart card writer.

In the operation of the present embodiment, one of a plurality of possible centrifuge rotors 2 is inserted into the centrifuge device 1 in preparation for centrifuging of samples contained in the respective tubes 22. When the operator places the rotor 2 into the centrifuge device 1 he also inserts a smart card into the centrifuge device 1 such that it can be read by the smart card reader 7. When the operator initiates operation of the device by pressing an appropriate button on the keypad 7, the rotor 2 is nudged around by the motor 5 to correctly position the bar code 3 provided on the inserted rotor 2. The bar code reader 4 reads the bar code 3 and supplies this information to the central control means 6. central control means 6 then compares the identity of the rotor 2 indicated by the bar code 3 with the identities included on the inserted smart card.

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Provided that the identity established by the bar code

reader 4 matches with an identity included on the

inserted smart card, further operation of the device
is enabled. If, on the other hand, there is no match,
the centrifuge device will output an appropriate
message via the display 8 and driving of the rotor 2

will be prevented.

Once a matching identity has been found, further checking and/or monitoring operations are carried out under the control of the central control means 6.

- In one mode of operation, the inserted smart card 5 includes a record of the usage of each associated rotor 2 and the control means 6 checks the information stored on the inserted smart card to ensure that the inserted rotor 2 has not been driven for an aggregate time in excess of a predetermined safe operating life. 10 In this mode of operation, only if it is established that the safe operating life has not been exceeded will driving operation of the centrifuge device 1 be enabled. Once driving operation has commenced, the time for which the motor is operated to drive the 15 inserted rotor is monitored and the information stored on the inserted smart card is updated to include this additional usage.
- 20 In another mode of operation, the information stored on the smart card includes a maximum operational rotational speed associated with the or each rotor 2. In such a case, during operation of the device 1, the control means 6 reads this maximum rotational speed for the inserted rotor 2 and prevents the centrifuge

device 1 from being operated at above this speed. The provision of such a facility can be useful where different types of rotors are used, and the different types are rated for usage at different rotational velocities.

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It is also possible to keep more detailed information concerning the usage of any particular rotor 2. For example, rather than merely recording the time for which the rotor is used, the information stored can include details of the total elapsed time for which the rotor has been used at specific rotational velocities.

15 In yet another mode of operation, details of a particular programme to which a rotor and its samples should be subjected may be included on the associated smart card. In such a case, a first person may load up the centrifuge rotor with the samples and at the 20 same time load details of the programme to be conducted onto a smart card. The rotor 2 and smart card may then be handed to another person to carry out the centrifuging operation. In this case, once the rotor 2 and smart card are inserted in the centrifuge device 1, the speed and duration of the centrifuging

process is automatically controlled by the centrifuge device 1 in accordance with the information on the smart card. A programme might, for example, consist of driving the inserted rotor 2 at 6,000 rpm for 10 minutes followed by 5 minutes at 10,000 rpm.

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Any of the above modes of operation may be used alone or in combination with one or more of the other modes.

In some alternatives the centrifuge device is provided with a lid or other means for preventing/monitoring removal of an inserted rotor 2 and the control means is arranged to repeat the scanning and checking operation with respect to an inserted rotor if removal or attempted removal of the rotor 2 is detected. Similarly the scanning and checking operations may be repeated if the power to the centrifuge device 1 is interrupted.

In alternatives, either using the centrifuge device 1
described above or a simplified device, a centrifuge
device can be arranged to store details relating to a
plurality of different rotors 2 within its own storage
means 9, which may comprise an EEPROM, rather than
making use of smart cards. In such a system, details

of the rotors which can be used with that device are entered into the storage means 9 using a suitable input device such as a keypad or a bar code scanner After this initial set up, each time a specific rotor is used in the centrifuge device 1, its usage can be monitored and/or controlled in a similar way to that described above. In a particular implementation, the bar code scanner 4 used to read bar codes 3 on the rotors 2 is also used, in the set-up operation, to 10 scan corresponding bar codes provided on cards supplied with each rotor. In such a case the bar codes can contain information which indicates whether the bar code is located on a rotor or a corresponding It will be appreciated that whilst this system 15 is simpler it does not give the same flexibility as the smart card based system described above.

Another alternative system could be based on a series of devices which are all connected to a common database or other storage means including details of all the relevant centrifuge rotors.

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In some embodiments, use of a rotor 2 beyond its safe operation life may be prevented by erasing the appropriate record of the associated rotor 2 from the

smart card and/or the storage device 9 such that the inserted rotor is no longer recognised. Further, a suitable entry may be made in a user non-erasable/non-re-writable memory indicating that the rotor concerned has already been used to prevent any reloading of the rotor's details.

The systems described in this application can significantly enhance safety as they can be used to prevent the use of a rotor and, in particular a housing, above its recommended operational speed and similarly can prevent the use of a rotor and, in particular a housing, beyond a safe operational lifetime. Whilst this invention is appropriate for rotors whatever their construction, it is particularly suited to systems where the rotor housings or bowls are constructed of plastics material because these generally have a shorter operational lifetime and the effects of failure are more problematic.

Whilst the preceding embodiments make use of a bar code 3 and bar code reader 4, it will be appreciated that any suitable form of identification means may be provided on the rotor provided that a corresponding reading means can be provided on the centrifuge

device.

Whilst a smart card is used in the embodiment described above and such cards are well known by those skilled in the art, it will be appreciated that any other similar portable machine readable media may be used in the place of a smart card without significantly affecting the operation of the system.

- In alternatives the centrifuge device comprises an interface allowing connection to a PC or other suitable computer means. Additional functionality may be provided in this way. Passwords or other suitable protection means may be provided and used to control
- 15 the ability to carry out certain "supervisor" operations. The following options, for example, may be provided:

Erasing of data in user non-erasable memory
Erasing of data in user erasable memory

20 Retrieval of data from any or all storage means provided in the device, exporting this to a PC where appropriate.

Similar systems for monitoring and controlling the use of critical components having limited life in other

medical and/or laboratory equipment can be implemented along similar lines to that described above in relation to centrifuge assemblies. One example is automatic/robotic assay equipment of the type used in biochemical, microbiological and immunological 5 research. Here so-called 96 well micro-titre plates are used for testing samples and re-use must be This can be achieved using the ideas above avoided. and applying identifying means to each plate and providing suitable reading means in the assay device. 10 In this way the identity of a plate may be established by the device before operation is commenced and operation can be prevented if the plate has been used previously. A programme of operations may also be associated with each plate in a similar way to that 15 described above in relation to the centrifuge assembly.

Similarly, components having limited life in a

dialysis machine may be provided with identifier means
and one or more reading means provided in the machine
to allow control and monitoring of operation in a
similar way to that described above in relation to
centrifuge assemblies.

In all such alternative systems it will be apparent that many of the features described above in relation to the centrifuge assembles, can be used, making the suitable modifications where necessary.

CLAIMS

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- 1. A medical and/or laboratory component arranged to be received and used in conjunction with an item of medical and/or laboratory equipment, wherein the component comprises machine readable identifier means allowing identification of the component.
- 2. A component according to Claim 1 wherein the 10 component is a centrifuge rotor arranged to be received and driven in a centrifuge device
 - 3. A component according to Claim 1 or Claim 2 wherein the identifier means is provided on a part having a limited operational life.
 - 4. A component according to Claim 2 in which the rotor comprises a sample holder and a surrounding housing and the identifier means is provided on the housing.
 - 5. An item of medical and/or laboratory equipment arranged to receive and work in conjunction with any one of a plurality of medical and/or laboratory components, the item of equipment being characterized

by reading means arranged for reading identifier means provided on an inserted component to allow identification of the inserted component.

- 6. An item of equipment according to Claim 5 which comprises logging means for keeping a record of the use made of a particular component.
- 7. An item of equipment according to Claim 6 in
 10 which the logging means is arranged to record the
 aggregate time for which an inserted component has
 been operated.
- 8. An item of equipment according to any one of
 15 Claims 5 to 7 which is arranged to receive and read
 memory modules.
 - 9. An item of equipment according to Claim 8 when dependent on Claim 6 or 7 which is arranged to write log information to an inserted memory module.

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10. An item of equipment according to any one of Claims 5 to 9 which comprises control means to control operation of the device in dependence on the established identity of an inserted component.

11. An item of equipment according to any one of Claims 5 to 10 which is a centrifuge device arranged to receive and drive any one of a plurality of centrifuge rotors.

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- 12. An item of equipment according to Claim 11 when dependent on Claim 10 in which the control means is arranged for preventing the operation of an inserted rotor at a rotational speed in excess of that for which the rotor is intended.
- 13. An item of equipment according to Claim 12 or Claim 11 when dependent on Claim 10 in which the centrifuge device is arranged to monitor the aggregate time of operation of an inserted rotor, and the control means is arranged to disable driving operation of the device when it is determined that the aggregate time for which an inserted rotor has been driven exceeds a predetermined threshold.

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14. An item of equipment according to Claim 10 in which the control means is arranged to subject an inserted component to a programme of operation which is determined by the components established identity.

15. An item of equipment according to Claim 12 or Claim 13, or Claim 11 when dependent on Claim 10, in which the control means is arranged to subject an inserted rotor to a programme of operation which is determined by the rotor's established identity.

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- 16. An item of equipment according to Claim 14 or Claim 16 in which the details of the program to which a rotor is to be subjected are readable from a memory module, preferably a smart card, associated with the rotor.
- 17. A component or an item according to any preceding claim in which the identifier means comprises a bar code.
 - 18. A component or an item according to any preceding claim in which the identifier means serves to identify the component as a component of a particular type and/or to identify the component as a specific component.
 - 19. A method of monitoring and/or controlling the usage of a plurality of medical and/or laboratory components comprising the steps of providing each

component with identifier means and using an item of medical and/or laboratory equipment to read the identifier means on components inserted in the item of equipment.

- 20. A method according to Claim 19 in which the components consist of centrifuge rotors and the equipment comprises a centrifuge device.
- 21. A medical and/or laboratory equipment assembly comprising an item of medical and/or laboratory equipment and a medical and/or laboratory component arranged to be used in conjunction with the item of medical and/or laboratory equipment, wherein the

 15 medical and/or laboratory component comprises identifier means and the item of medical and/or laboratory equipment comprises reading means for reading the identifier means whereby the component can be identified.







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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): G4H (HJ), B2P (P2)

Int Cl (Ed.7): B04B

Other:

Documents considered to be relevant:

Category	Identity of docume	nt and relevant passage	Relevant to claims
X	GB 2216259 A	(MICROVOL)	1,5,19,21 at least
X	GB 2199407 A	(GENETIC SYSTEMS)	11
X	EP 0604912 A2	(KUBOTA SEISAKUSHO)	н
X	EP 0602587 A1	(E.I. DU PONT DE NEMOURS)	и
X	EP 0344443 A2	(MASCHINENFABRIK)	11
X	US 4622457	(BRADLEY ET AL)	11
X	US 4551715	(DURBIN)	. 11
X	US 3680967	(ENGELHARDT)	11

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- A Document indicating technological background and/or state of the art.
- P Document published on or after the declared priority date but before the filing date of this invention.
- E Patent document published on or after, but with priority date earlier than, the filing date of this application.

X Document indicating lack of novelty or inventive step

Y Document indicating lack of inventive step if combined with one or more other documents of same category.