Test magazine and method for processing the same

Description

The invention concerns a test magazine comprising two spoolable foil tapes that are joined together in a sandwich-like manner and between which holding cells for test elements are kept free, and a plurality of test elements which each comprise a lancing unit for piercing body tissue and a test unit to which body fluid can be applied. The invention also concerns a method for processing such a magazine.

Such test systems are intended for use especially by diabetics for blood sugar self-monitoring that is carried out several times daily. Recent concepts envisage a microneedle in conjunction with a test field as a single-use system (disposable) in order to generate a skin puncture, to utilize capillary forces to remove a small amount of blood therefrom and to analyse this blood sample. Such an integrated system should also enable laymen to carry out the required steps in a simple and rapid manner in a substantially automated measuring process. An important aspect is miniaturization also with regard to a high integration of disposables in a small space in a portable device. In this connection blister packs for test elements integrated into a firm package have already been proposed which, however, due to a rigid framework with well-shaped mouldings have disadvantages for the manufacture as well as in use.

On this basis the object of the invention is to avoid the disadvantages that occur in the prior art and to make improvements which also enable a high integration density and hygienic handling.

The combinations of features stated in the independent patent claims are proposed to achieve this object. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

The idea behind the invention is to ensure a high integration density and handling safety for test elements in two-dimensional cell-shaped regions of a foil pack. Accordingly a first aspect of the invention is that the lancing units and test units are arranged separately from one another in separate holding cells. The cells can be simply provided by the intermediate region between the foil tapes that are not further formed out. The separation is also advantageous with regard to the fact that the lancing elements can be independently pretreated and in particular sterilized and hydrophilized without damaging the test chemistry and there is no risk during the lancing process that test chemicals enter the body. Moreover, this solution is characterized by the possibility of a simple manufacture in particular by roll-to-roll manufacture which enables a particularly flat, spoolable construction.

The lancing units and test units are advantageously arranged alternately in the tape direction or adjacent to one another in pairs at right angles to the tape direction in assigned holding cells.

A particularly preferred embodiment provides that the lancing units in the assigned holding cells are sterilized by irradiation preferably through a mask in order to screen the test units.

The manufacture can also be simplified by means of the fact that the foil tapes are joined to a test tape over their length and that the test tape is exposed cell by cell through perforations in the foil tape to form the test units.

With regard to a long shelf-life it is also advantageous when a desiccant is stored in the holding cells for the test units.

Another aspect of the invention is that at least the lancing units can be removed by transport means from their respective holding cell and can be moved into a working position which is completely separate from the foil tapes. This enables a completely automated processing sequence that is unimpeded by the storage in magazines which also allows the hygienic disposal of used units in a simple manner.

In order to simply and successively expose individual units, it is advantageous when the transport means comprises a tape tensioning device to pull apart the foil tapes in different directions. This can be achieved by the tape tensioning device having two deflecting cylinders that can rotate in opposite directions or are stationary and are arranged laterally spaced apart from one another at a dispensing site, and having tape-up spools for the foil tapes downstream of the deflecting cylinders.

In order that the body fluid to be analysed after the collection process can be further processed in a simple manner, it is advantageous when the transport means are in operative connection with a test unit and/or disposal site located on the foil tape in order to return a lancing unit.

Another improvement is achieved by the transport means having a handling device to pick up and position a lancing unit that has been exposed by pulling apart the foil tape at a dispensing position. In this connection it is advantageous when at least one of the foil tapes has positioning holes especially in the region of the holding cells for the test units to enable the handling device to engage.

The individual removal and handling is also suitable for integrated test elements in which the lancing units are physically joined to the test units.

A particularly preferred embodiment of the invention provides that at least one of the foil tapes is provided with a withdrawal structure for the preferably adhesive or clamping fixation of used lancing elements. This enables a particularly simple disposal of contaminated units.

In order to increase the integration density it is advantageous when the lancing units are arranged flat between the foil tapes as flat material components. In this case the foil tapes should have a planar design and rest laminarly against the lancing units free of blisters or three-dimensional mouldings.

Another advantageous embodiment provides that the lancing units exposed at a dispensing site can be redispensed at a return position on one of the foil tapes that is distant thereto. This additionally avoids limitations in the individual handling of lancing units and test elements that may be joined thereto.

The lancing units advantageously have a capillary structure that is preferably formed by a semi-open channel to collect body fluids. Another improvement provides that the lancing units are formed on the test units in order to transfer collected body fluid.

For the manufacture of the cell structure it is advantageous when the holding cells are delimited by linear foil connections, preferably welded or adhesive seams between the foil tapes. Another improvement is achieved in that the holding cells are sealed against one another and against the environment in a material-tight manner by the foil connections.

In order to make it easy to tear open the foil pack, it is advantageous when the linear foil connections extend obliquely to the tape longitudinal direction of the foil tapes.

The lancing units are advantageously immobilized in a fixed position in their assigned holding cell by form-locking bordering foil connections or foil connections that engage in recesses.

It is also advantageous when at least one of the foil tapes has or forms a transparent measuring window for an optical measurement of the test units to enable a contact-free scanning through the tape.

A high packaging density can also be achieved in that the foil tapes with the test elements located therein are held ready as a folded package in a zigzag folding.

The foil tapes with test elements located therein are advantageously accommodated in a cassette. The test units can be specially designed as detection fields coated with reagents to detect an analyte in the body fluid and in particular glucose.

The invention also concerns a test device for processing a said test magazine.

With regard to the process the object stated above is achieved in that the lancing units optionally in conjunction with integrated test units are individually exposed by pulling apart the foil tapes, are then moved into a working position that is distant from the associated holding cell and are subsequently stored again on one of the foil tapes. In this connection it is particularly advantageous when body fluid is collected in the working position by means of the lancing units and is subsequently transferred onto the test units.

The invention is elucidated in more detail in the following on the basis of the embodiment examples shown schematically in the drawing.

Fig. 1 shows a foil magazine for blood glucose tests in a sectional top-view.

Fig. 2 shows another foil or test magazine in a sectional top-view.

Fig. 3 shows the individual constructional elements of the foil magazine of fig. 2 in an exploded view.

Fig. 4 and 5 show further embodiments of foil magazines in a sectional top-view.

Fig. 6 shows an embodiment with a bellows as a store for test elements in a diagrammatic view.

Fig. 7 shows a test magazine in a magazine housing in a broken-open perspective view; and

Fig. 8 shows a portable device for processing a test magazine according to fig. 7.

The test magazines shown in the drawing comprise as a foil package 10, two foil tapes 12, 14 which are joined together in a sandwich-like manner and between which holding regions or cells 16 are kept free in which test elements 18, 20 are made available for successive processing.

As shown in fig. 1 lancing units 18 and test units 20 arranged in pairs are provided as test elements which are arranged separately from one another in separate holding cells 16. In the embodiment examples shown the lancing units 18 and test units 20 are arranged alternately in the direction of the tape. They may also conceivably be arranged at the side of one another across the tape direction or obliquely displaced or be present as integrated combinations of test elements in which the lancing units 18 are physically joined to the test units 20.

The lancing units 18 are formed from a thin sheet of high-grade steel as flat formed parts and have a distal lancing member 22 in the form of a microneedle to puncture for example the finger of a test person for blood collection. The lancing member 22 is connected via a semi-open groove-shaped capillary channel 24 to a holding region 26 to collect and transfer blood. For this purpose the respective lancing unit 18 is connected after the collection process with an associated test unit 20 in such a manner that the collected blood is applied to this test unit in order to detect an analyte (glucose) located therein in a single measurement. It can be detected in a known manner by means of a colour reaction of the strip-shaped test units 20 and a photometric measurement. For this purpose at least one of the foil tapes 12, 14 can be composed of a transparent material as an optical window.

The holding cells 16 are kept free as essentially two-dimensional expanded intermediate regions between the flat foil tapes 12, 14 in order to receive the test elements 18, 20 in a flat manner. The foil tapes 12, 14 thus rest in a planar manner against the flat test elements free of blisters or of well-shaped mouldings thus enabling a compact winding or space-saving folding. For example the lancing units 18 can have a square measure of 5 x 10 mm so that even with about 100 units the spool diameter is still acceptable for use in a portable device.

In order to insulate and optionally fix the test elements the holding cells 16 are delimited by linear connections 28 between the foil tapes 12, 14. In fig. 1 a ladder-shaped structure of welded or adhesive seams is provided for this purpose which ensure a material-tight sealing of the holding cells 16 from one another and from the environment.

The separate arrangement enables the packaged lancing units 18 to be sterilized by irradiation independently of the test units 20 without damaging the sensitive test chemicals of the test units. This can be carried out by a screening mask that is not shown which allows an energy-rich radiation (X-ray or electron rays) only to pass

through to the lancing units 18. In addition the separation enables the lancing units 18 to be hydrophilized by a surface treatment for an effective uptake of liquid without having to make allowances for the test chemistry. Another advantage is that the chemicals used for the detection cannot enter the body of the person being examined during the lancing process.

Figures 2 and 3 result in an expedient assembly of a tape package 10 with alternating lancing and test units 18, 20. The prefabricated lancing units 18 are enclosed in a flat manner between the tapes 12, 14 whereby the adhesive lines 18 arranged on the inner side of the tape 12 delimit the holding cells 16. A continuous test strip 30 is fixed by means of an adhesive tape 32 to the outside of the tape 14. The test strip 30 is exposed in each second holding cell 16 by perforations 34 in the carrier tape 14 for applying body fluid or blood such that the separate test units 20 are thus formed. The described multifoil structure simplifies mass production at a high throughput from roll to roll.

Desiccants 36 which are optionally also in the form of tape sections can be contained in the cell regions of the test units 20. Positioning holes 38 are also punched into the tape 14 in these regions in order that the lancing unit 18 can be accurately positioned after the collection process as is elucidated in more detail below. It is particularly advantageous when in particular line-shaped or point-shaped adhesive structures 40 on one of the foil tapes 14 allow a simple restorage of used lancing units 18 or integrated test elements into the magazine. It is also possible that additional locking points 42 are provided in the cells of the lancing units 18 in order to hold them in a detachable manner.

The embodiments according to figs. 4 and 5 show similar foil packages 10 in which the same components are provided with the same reference numerals as described above. In this case the connecting structure 28 between the tapes 12. 14 whose broad sides rest against one another are characterized by additional functions. On

the one hand an immobilization of the lancing units 18 is ensured by an engagement in recesses 44 of the lancing units and an abutment of the edge against supporting sites 46. On the other hand, joining seams 28′ extending obliquely to the longitudinal direction of the tape enable the tapes 12, 14 to be torn apart to expose the lancing units 18 without peak forces and without jerking.

Fig. 6 illustrates in a very simplified schematic manner the provision of individual test elements or lancing units 18 from the foil magazine 10. In the embodiment shown the foil tapes 12, 14 with the test elements located therein are stored in a zigzag shape as a folded package 48. In order to successively release the lancing units 18, a tape tensioning device 50 is provided in a housing (not shown) which comprises two winding spools 52, 54 for the foil tapes 12, 14 and, in front of them, deflection rollers 58 arranged laterally spaced apart at a dispensing site 56. The lancing units 18 are released for further processing by tearing apart the tapes 12, 14 in the region of the deflection rollers 58. The rotation of the winding spools 52, 54 is synchronized in order to always keep the tapes 12, 14 tensioned. Such an arrangement as a dispenser can also be designed to dispense individual units 18 which are then for example inserted manually in a separate measuring instrument.

Fig. 7 shows a preferred arrangement in a magazine housing 60 which is shown in a partially broken open view. The foil package 10 is arranged there on a storage roller 62 from which the tapes 12, 14 connected to each other are pulled over the deflection rollers 58 and are thus torn apart to release the test elements. After use the test elements are returned to the inner side of the tape 12 at a return position 63 which is optionally at a distance from the dispensing position 56 where adhesive strips 40 effect the retention. In this manner the used test elements 18 can be wound onto the spool 52 and thus be simply disposed of.

The test cassette 64 described above can be used in a portable device 66 as a disposable article as shown in a simplified form in fig. 8. Such a device 66

comprises all equipment required to carry out a glucose measurement such as an energy supply 68, measurement and display electronics 70 and actuatorics 72 for handling individual lancing units 18 dispensed from the tape magazine 10 and measuring optics 76. In the embodiment shown a handling device 74 is provided as part of the actuatorics 72 in order to receive the elements 18 at the dispensing site 56, to move them into a transversely positioned lancing position at a distance from the tapes 12, 14, to carry out the lancing movement through an opening in the housing and to return them onto the tape 12 after blood collection. At this position a contact-free optical measurement is carried out by the measuring unit 76 in order to subsequently be able to display the determined results to the user. In this manner it is possible for laymen to carry out self examinations in a completely automated measuring process whereby the storage magazine allows a large number of tests to be carried out. The used cassettes 64 can be removed as a complete unit from the device 66 without having to individually dispose of the components that are contaminated with blood.

Claims

1. Test magazine comprising two spoolable foil tapes (12, 14) joined together in a sandwich-like manner and between which holding cells (16) are kept free for test elements (18, 20), and a plurality of test elements (18, 20) arranged in the holding cells (16) which each comprise a lancing unit (18) for puncturing body tissue and a test unit (20) to which body fluid can be applied, **characterized in that** at least the lancing units (18) can be removed by transport means (50, 74) from their respective holding cell and can be moved into a working position which is separate from the foil tapes (12, 14).

2. Test magazine according to claim 1, **characterized in that** the transport means (50, 74) comprises a tape tensioning device (50) to pull apart the foil tapes (12, 14) in different directions.

3. Test magazine according to claim 2, **characterized in that** the tape tensioning device (50) has two deflecting cylinders (58) that can rotate in opposite directions or are stationary and are arranged laterally spaced apart from one another at a dispensing site (56) and has take-up spools (52, 54) for the foil tapes (12, 14) downstream of the deflecting cylinders (58).

4. Test magazine according to one of the claims 1 to 3, **characterized in that** the transport means (50, 74) are in operative connection with a test unit (20) and/or disposal site located on the foil tapes (12, 14) in order to return a lancing unit (18).

5. Test magazine according to one of the claims 1 to 4, **characterized in that** the transport means (50, 74) comprise a handling device (74) to pick up and

position a lancing unit (18) that has been exposed by pulling apart the foil tapes (12, 14) at a dispensing position (56).

6. Test magazine according to claim 5, **characterized in that** at least one of the foil tapes (12, 14) has positioning holes (38) especially in the region of the holding cells (16) for the test units (20) to enable the handling device (74) to engage.

7. Test magazine according to one of the claims 1 to 6, **characterized in that** the lancing units (18) are physically joined to the test units (20) as integrated test elements (18, 20).

8. Test magazine according to one of the previous claims, **characterized in that** at least one of the foil tapes (12, 14) is provided with a withdrawal structure (40) for the preferably adhesive or clamping fixation of used lancing elements (18).

9. Test magazine according to one of the claims 1 to 8, **characterized in that** the lancing units (18) are arranged flat between the foil tapes (12, 14) as flat material components.

10. Test magazine according to one of the claims 1 to 9, **characterized in that** the foil tapes (12, 14) have a planar design and rest laminarly against the lancing units (18) free of blisters.

11. Test magazine according to one of the claims 1 to 10, **characterized in that** the lancing units (18) exposed at a dispensing site (56) can be redispensed at a return position on one of the foil tapes (12, 14).

12. Test magazine according to one of the claims 1 to 11, **characterized in that** the lancing units (18) have a capillary structure (24) that is preferably formed by a semi-open channel to collect body fluid.

13. Test magazine according to one of the claims 1 to 12, **characterized in that** the lancing units (18) are formed in order to transfer collected body fluid to the test units (20).

14. Test magazine according to one of the claims 1 to 13, **characterized in that** the holding cells (16) are delimited by linear foil connections (28), preferably welded or adhesive seams between the foil tapes (12, 14).

15. Test magazine according to claim 14, **characterized in that** the holding cells (16) are sealed against one another and against the environment in a material-tight manner by the foil connections (28).

16. Test magazine according to claim 14 or 15, **characterized in that** the linear foil connections (28′) extend obliquely to the tape longitudinal direction of the foil tapes (12, 14).

17. Test magazine according to one of the claims 1 to 16, **characterized in that** the lancing units (18) are immobilized in a fixed position in their assigned holding cell (16) by complementarily engaging bordering foil connections or foil connections (28) that engage in recesses (44).

18. Test magazine according to one of the claims 1 to 17, **characterized in that** at least one of the foil tapes (12, 14) has or forms a transparent measuring window for an optical measurement of the test units (20).

19. Test magazine according to one of the claims 1 to 18, **characterized in that** the foil tapes (12, 14) with the test elements (18, 20) located therein are held ready as a folded package (48) in a zigzag folding.

20. Test magazine according to one of the claims 1 to 19, **characterized** by a cassette (64) that receives the foil tapes (12, 14) with the test elements (18, 20) located therein.

21. Test magazine according to claim 20, **characterized in that** the cassette (64) is designed as a dispenser for test elements (18, 20) such that the individually dispensed test elements can be used in a separate test device.

22. Test magazine according to one of the claims 1 to 21, **characterized in that** the test units (20) are designed to detect an analyte in the body fluid.

23. Process for processing a test magazine (10) according to one of the claims 1 to 20 in which the lancing units (18) optionally in conjunction with integrated test units (20) are individually exposed by pulling apart the foil tapes (12, 14), are then moved into a working position that is distant from the associated holding cell (16) and are subsequently stored again on one of the foil tapes (12, 14).

24. Process according to claim 23, **characterized in that** body fluid is collected in the working position by means of the lancing units (18) and is subsequently transferred onto the test units (20).