

Exhibit M



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(54) **SYRINGE DEVICE WITH A DOSE LIMITING MECHANISM AND AN ADDITIONAL SAFETY MECHANISM**

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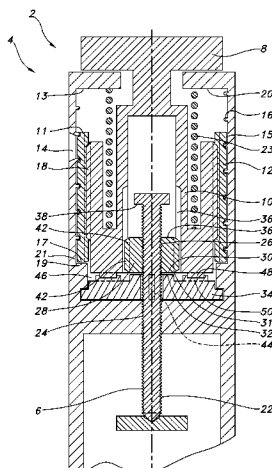
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(57) **ABSTRACT**

A syringe device for ejecting a dose of a medicament, the syringe device comprising: a dose limiting mechanism arranged to interact with a dose ejecting mechanism to prevent ejection of a dose exceeding a set dose, and a safety mechanism, which is arranged such with respect to the dose ejecting mechanism that, if the dose limiting mechanism fails, the safety mechanism prevents ejection of a dose exceeding the set dose.

8 Claims, 1 Drawing Sheet



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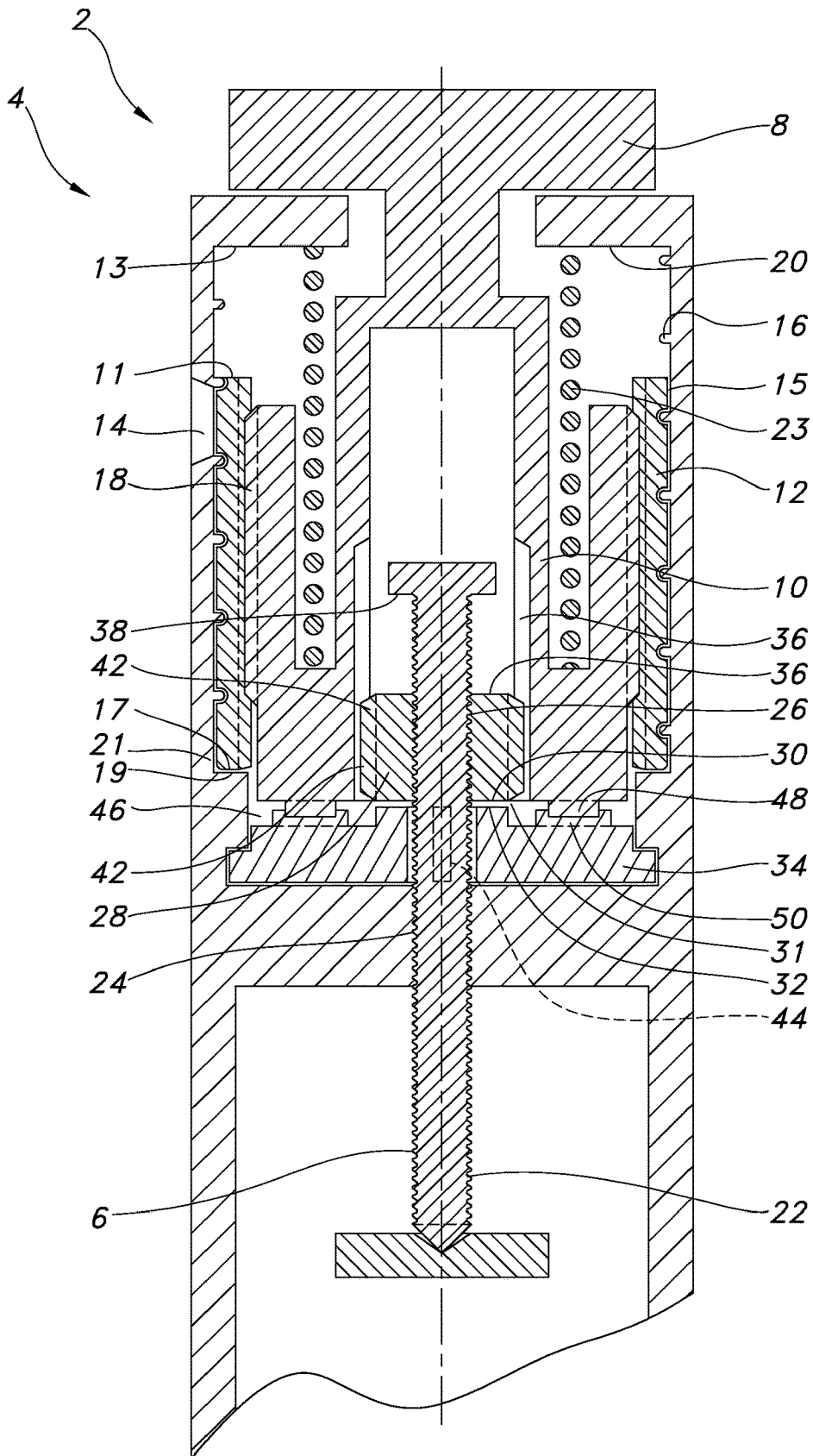
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**SYRINGE DEVICE WITH A DOSE LIMITING
MECHANISM AND AN ADDITIONAL
SAFETY MECHANISM**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a 35 U.S.C. § 371 national stage application of International Patent Application PCT/EP2006/007006 (published as WO 2007/017053), filed Jul. 17, 2006, which claimed priority of European Patent Application 05016286.6, filed Jul. 27, 2005; this application further claims priority under 35 U.S.C. § 119 of U.S. Provisional Application 60/708,211, filed Aug. 15, 2005.

FIELD OF THE INVENTION

The present invention relates to a syringe device comprising a mechanism for preventing ejection of a dose exceeding a set dose. In particular the present invention relates to a syringe device comprising two independent mechanisms for preventing ejection of a dose exceeding a set dose.

BACKGROUND OF THE INVENTION

When drugs are to be injected into the human body, it may have serious or even lethal consequences if the injected dose exceeds the set dose. Accordingly, it is important that the syringe devices comprises means for limiting ejection to the set dose.

It is an object of the present invention to provide a syringe device comprising means for prevention ejection of a dose exceeding the set dose. Furthermore, as such means may fail, it is an object of the present invention to provide a syringe device comprising a safety mechanism adapted to prevent ejection of a dose exceeding the set dose if the means for preventing fails.

SUMMARY OF THE INVENTION

The present invention relates to a syringe device for ejecting a dose of a medicament, the syringe device comprising:

- a housing,
- a dose ejecting mechanism comprising:
 - a dose setting member being rotatable in relation to the housing so as to set a dose to be ejected,
 - a piston rod arranged with respect to the housing such that translational movement of the piston rod in a distal direction causes the dose to be ejected,
 - means for transforming translational movement of the dose setting member into translational movement of the piston rod,
- a dose limiting mechanism arranged to interact with the dose ejecting mechanism to prevent ejection of a dose exceeding the set dose, and
- a safety mechanism, which is arranged such with respect to the dose ejecting mechanism that, if the dose limiting mechanism fails, the safety mechanism prevents ejection of a dose exceeding the set dose.

An advantage of the present invention is that if a dose limiting mechanism fails to limit the ejected dose, the

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In one embodiment the dose limiting mechanism and the safety mechanism are two independent mechanisms working independently from each other.

In one embodiment the two mechanisms are adapted to simultaneously prevent ejection of a dose exceeding the set dose. In another embodiment the safety mechanism is only activated if the dose limiting mechanism fails to prevent ejection of a dose exceeding the set dose. In one embodiment the two mechanisms are arranged such that even if the dose limiting mechanism fails, the safety mechanism is activated instantaneously such that the ejected dose does not exceed the set dose. In another embodiment the ejected dose is insignificantly larger than the set dose, if the dose limiting mechanism fails and the safety mechanism is activated. By insignificantly larger is meant that the change in dose is too small to have serious or fatal consequences.

The housing may define a passage for the piston rod, the passage may have a threaded inner surface for engagement with a threaded outer surface of the piston rod, the piston rod may be arranged with respect to the housing such that rotation of the piston rod relative to the housing causes the piston rod to be displaced translationally relative to the housing.

In one embodiment at least one of the dose limiting mechanism and the safety mechanism is adapted to limit relative rotational movement between the piston rod and the housing, to a rotation corresponding to ejection of the set dose. This may be the case, when the piston rod comprises a threaded outer surface adapted to engage a threaded inner surface of the housing. Accordingly, rotational locking of the piston rod (relative to the housing) results in a translational locking of the piston rod relative to the housing.

The dose limiting mechanism may comprise at least one first stopping surface adapted to engage at least one corresponding second stopping surface of the housing. Furthermore, rotation of the dose setting member during dose setting may cause the first stopping surface to move away from the second stopping surface and rotation during dose ejection may cause the first and the second surface(s) to move towards each other. Furthermore, ejection of a dose may be prevented when the first stopping surface abut the second stopping surface. The dose setting member may comprise the at least one first stopping surface. Alternatively, or as a supplement, the dose setting member may be coupled to a cylinder comprising a first stopping surface, and said cylinder may be adapted to indicate the set dose. The first and second stopping surfaces may be substantially plane surfaces which may extend in a direction parallel with the axial direction of the syringe device. Alternatively, the stopping surfaces may extend in a plane transverse to the axial direction, such as a plane orthogonal to the axial direction.

In one embodiment the safety mechanism comprises: a limiter defining a passage for the piston rod, the passage of the limiter defining a threaded inner surface for engagement with the threaded outer surface of the piston rod, and a driver defining a passage for the limiter, the driver being rotationally retained in relation to the limiter, the driver being coupled to the dose setting member such that rotation of the dose setting member during dose setting causes the driver to rotate, wherein relative rotation between the driver and the piston rod during dose setting causes the limiter to move away from a stopping position wherein the limiter prevents ejection of a dose.

In one embodiment the syringe device is adapted to

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