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Plastic injection-moulded part with embedded component
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ABSTRACT

The invention relates to a method for production of a plastic injection-moulded part (2) having an insert (16, 40, 50) made of a material different from plastic material (60) and to a plastic component. An insert (16, 40,50) is introduced into a cavity (33) of an injection mould (30). The clamping force of the injection mould (30) is set, on a clamping mechanism (34), to a force predetermined by the material of the insert (16, 40, 50). The insert (16, 40, 50) is injected seamlessly, inside the injection mould (30), partially or completely into the plastic material (60) of the plastic injection-moulded part (2).

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Australian Patents Act 1990 – Regulation 3.2

**ORIGINAL COMPLETE SPECIFICATION
STANDARD PATENT**

Invention Title:

Plastic injection-moulded part with embedded component

The following statement is a full description of this invention, including the best method of performing it known to me:-

P/00/011

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Plastic injection-moulded part with embedded component

5 The invention relates to a method for production of a plastic injection-moulded part having a component made of ceramic or glass embedded in it, which plastic injection-moulded part can be a shell body of a rapid diagnosis appliance.

Prior art

10 In rapid diagnosis appliances, such as those used for determining blood sugar levels or for determining other blood values, it is often necessary to heat the reagent area inside the appliance housing of the rapid diagnosis appliance. Test strips wetted with human or animal blood, for example, are inserted into the evaluation area of a rapid diagnosis appliance. It is also possible to first introduce
15 the test-strip into the rapid diagnosis appliance and only thereafter apply the sample to the test strip. The test strips contain substances which react with the area of the test strip wetted with the blood of human or animal origin. To perform a measurement procedure yielding a meaningful measurement result, a defined temperature is needed during the evaluation procedure.

20 To generate an appropriate temperature level, metal or ceramic heating elements are therefore integrated in the interior of the housing body of the rapid diagnosis appliance. These heating elements are normally embedded in plastic components in the critical system environment. The heating elements made of metal or ceramic
25 materials are generally embedded by mechanical securing with springs or clip elements, or by adhesively bonding the heating element made of metal or ceramic into a depression provided for this purpose in the plastic material.

The disadvantages of mechanically securing the ceramic or metal heating element
30 inside a plastic component are that the spring elements or clip elements exerting spring forces on the heating element can induce stresses in a heating element made of ceramic for example, which can lead to its fracturing, with the result that the heating element integrated for example in the rapid diagnosis appliance is rendered unusable. Moreover, when the heating element is mounted mechanically in the
35 inside of the housing, the resulting seams, caused by production tolerances, may mean that if too much blood is applied to the test strip, blood can pass through the seams into the inside of the appliance and cause damage there to the evaluation electronics. The same applies to a cleaning agent with which the inside of the appliance is cleaned after several test strip evaluations in order to remove dried

5 blood plasma which, for example, has accumulated on the heating element made of metal or ceramic. The cleaning agents used are often very aggressive so as to be able to dissolve and remove the blood plasma which has accumulated mainly on the surface of the metal or ceramic heating element. If the cleaning agent, which often has an extreme dissolving action, passes into the inside of the appliance through the seams which arise in mechanical mounting of the metal or ceramic heating element, then the electronics may also be damaged by the cleaning agent.

10 The option of mechanically securing a ceramic or metal heating element inside a rapid diagnosis appliance additionally has the disadvantage of high costs of assembly, and the risk of incorrect assembly is not inconsiderable. If a heating element to be introduced at a later stage into a plastic component is incorrectly assembled, this can result in temperature control errors which may have the effect that the measurement results obtained from an evaluation of a test strip inserted
15 into the rapid diagnosis appliance are often rendered unusable.

20 Instead of the mechanical securing option, the heating element made of metal or ceramic material can also be adhesively bonded into a corresponding depression of a half shell in the inside of the rapid diagnosis appliance. By adhesively bonding a metal or ceramic heating element into a recess in the inside of the rapid diagnosis appliance, it is possible to largely avoid the seams which arise in the securing option discussed above, but the solvents admixed to the adhesive can affect the test strip inserted into the inside of the appliance. Moreover, it is not possible to avoid a situation where the cleaning agents, with which the heating element is cleaned in
25 order to remove dried blood plasma from time to time, dissolve the adhesive with which the heating element is bonded into a depression inside the housing interior. Moreover, all adhesives are subject to aging during the period of operation, particularly in the event of large temperature fluctuations, which means that this securing option is associated with risks concerning the reliability of a rapid
30 diagnosis appliance over the period of its use.

Moreover, in this type of securing, the high cost of assembly is a disadvantage if this option is used in large-scale production, for example as in the large-scale production of rapid diagnosis appliances. Here too, the production process is not
35 free from assembly errors which, in accordance with what has been stated above, can considerably compromise the meaningfulness of the evaluation result obtained.

A further option for securing a component, for example a heating element made of metal or ceramic material, inside a plastic injection-moulded part is to inject it

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directly as an insert in the injection-moulding of the plastic injection-moulded part. The problem with this method of production is that the pressure arising inside the injection mould is problematic for breakable materials, for example ceramics, since breakable materials like ceramic or glass cannot be randomly pressed.

5 In view of the disadvantages of the prior art as outlined above, the present invention seeks to work different materials, including breakable materials such as glass or ceramic, in the injection-moulding production process.

10 According to one aspect the present invention provides a method for production of a plastic injection-moulded part having an insert made of a material different from the plastic material, said method including the following method steps:

- 15 (a) introduction and positioning of the insert in a cavity of an injection mould, wherein the injection mould includes two halves and the insert, made of a breakable material, is pre-treated by application of a damping layer, wherein the insert is provided with the damping layer on at least one side facing towards one of the mould halves of the injection mould,
- (b) setting the clamping force of the injection mould, on a clamping mechanism, to a maximum force predetermined by the material of the insert, and
- 20 (c) partial or complete, seamless encapsulation of the insert with the plastic material of the plastic injection-moulded part inside the injection mould.

According to another aspect the present invention provides a rapid diagnosis appliance for evaluation of a test strip, having a housing body, wherein an insert acting as heating
25 element is seamlessly embedded in a system-critical area inside the housing body made of plastic material, the insert being pretreated by application of a damping layer, on at least one side thereof.

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According to yet another aspect the present invention provides an analysis chip, wherein an insert made of glass is injected into a border of plastic material, and a remaining, untreated exposed surface of the insert can be covered with reagents, said insert being pretreated by application of a damping layer on at least one side thereof.

The advantages of the method proposed according to the invention are principally that, within one operation in the injection-moulding process in multi-component injection moulding, it is now possible to work the plastic material or materials and at the same time also breakable materials such as ceramic or glass, because the injection mould in which the plastic injection-moulded part is encapsulated with an insert made of breakable material such as ceramic or glass, is equipped with a spring-actuated clamping mechanism.

It is thus possible, on the injection mould, to set the maximum pressing force to the maximum force that can be applied to the breakable component. This in turn opens up the possibility of also embedding, as inserts in plastic components, different breakable materials which can take up different forces. The maximum clamping force can thus in each case be adapted individually to the material used as insert.

The breakable component can optionally be coated with a damping layer. The damping layer used can, for example, be a lacquer which is applied across the entire surface either to the breakable components or to the steel parts of the injection mould which may come into contact with the insert of breakable material such as ceramic or glass, which contact would otherwise lead to fracturing of the breakable material. It is possible for the proposed damping layer, in the form of a lacquer layer, to be applied in such a way that the insert to be embedded in the plastic material is completely surrounded by this damping layer. On the other hand, it is possible for the damping layer to be applied as a frame around the breakable component to be embedded as insert in the plastic material, so that the contact between the steel parts of the injection mould and the insert of breakable material is damped only at certain places.

If, for example, analysis chips, in particular biochips, are produced as inserts in plastic material, in the manner of the injection-moulding method proposed according to the invention, they can be encapsulated by a plastic frame, so that, in the production of biochips, a damping layer is to be applied only partially and
5 other areas of the glass, which also represents a breakable material, could remain untreated. The untreated portions of the glass could be covered at a later stage with suitable reagents required for using the insert with a glass support as base material.

The production method proposed according to the invention and intended for
10 production of an insert of breakable material, such as ceramic or glass, integrated in a plastic component is characterized by a high degree of process reliability. Since the production process in question is mould-dependent, i.e. coupled to the injection mould, assembly costs are completely dispensed with, as is the associated risk of incorrect assembly. With the production method proposed according to the
15 invention for embedding an insert made of breakable material in a plastic injection-moulded part to be injection-moulded, seamless embedding of a heating element made of metal or ceramic material into a plastic shell of the plastic housing of a rapid diagnosis appliance is readily possible. By virtue of the seamless embedding of a heating element of ceramic or metal material into a
20 plastic injection-moulded part to be produced in one and the same operation, the insert is embedded in a liquid-tight and form-fitting manner in the plastic material.

Drawing

25 The invention is described in more detail below with reference to the drawing, in which:

- Figure 1 shows a perspective view of a rapid diagnosis and measurement
appliance,
30
- Figure 2 shows an exposed housing opening of a rapid diagnosis appliance,
- Figure 3 shows a detail of the housing body of a rapid diagnosis and
measurement appliance according to the view in Figure 1, with an
35 integrated heating element made of a breakable material, for example ceramic,
- Figure 4 shows a diagrammatic representation of an injection mould with
variable clamping force,

Figure 5 shows a glass body surrounded by a frame made of plastic material,

5 Figure 6 shows a ceramic body which is provided on its top face with a lacquer coating serving as a damping layer, and

Figure 7 shows an insert made of ceramic material, embedded seamlessly into a plastic material.

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Embodiments

The perspective view in Figure 1 is of a rapid diagnosis appliance whose housing body is a plastic injection-moulded part.

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A rapid diagnosis appliance 1 shown in Figure 1 comprises a housing body 2 made of a plastic material. Provided on a front face 6 of the housing body 2 there is a cover element 3 whose lower margin lies above an insertion opening 4. The insertion opening 4 comprises an insertion tongue 5 acting as a bearing surface for a test strip to be inserted into the inside of the housing body 2. The rear face of the housing body 2 of the rapid diagnosis appliance 1 is indicated by reference number 7. The rapid diagnosis appliance 1 is used for evaluation of test strips which are to be inserted into the housing body 2 and are wetted with blood of human or animal origin. The test strips have chemical substances which react with the applied quantity of blood, for example to permit blood sugar measurement. In order to perform the measurement on the test strip, the housing body 2 contains heating elements, electrical contact elements for the test strip to be inserted into the insertion opening 4, and also evaluation electronics, and an optical display.

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35 The view in Figure 2 shows the front face 6 of the housing body 2 of the rapid diagnosis appliance 1. Formed in the front face 6 of the housing body 2 there is a housing opening 10 which can have an oval and rounded appearance, as shown in Figure 2. The underside of the housing opening 10 is limited by the insertion tongue 5. On both sides of the insertion tongue 5 there are raised insertion rails 11 between which a test strip (not shown in Figure 2) to be introduced into the insertion opening 4 can be pushed into the inside 13 of the housing body 2. The test strip to be introduced into the insertion opening 4 is guided on the one hand by the two insertion rails 11 and on the other hand by the top face 14 of the insertion tongue 5.

Figure 3 shows a system-critical area in the inside of the housing body of a rapid diagnosis appliance for example.

- 5 Within a critical system area defined by reference number 15 inside the housing body 2, an insert 16 is integrated into a plastic component which has, for example, been injection-moulded as the lower shell of the housing. In the case of a rapid diagnosis appliance 1, the insert 16 embedded in the plastic material is a heating element which can be made of a breakable material such as ceramic or of metal.
- 10 When a test strip is pushed in, the insert 16 designed as heating element generates, inside the housing body 2, a temperature at which the reagent area on the inserted test strip is brought to a temperature permitting a meaningful measurement in a rapid diagnosis appliance.
- 15 In the view in Figure 3, the insert 16 is integrated with seamless embedding 17 in the lower shell of the housing body 2. The test strip (not shown in Figure 3) covers the top face of the insert 16 designed as heating element, and contact can be made with it via electrical contacts 19. A long side 20 of the insert 16 extends parallel to the measurement edge of a measurement strip, while the shorter transverse side 21
- 20 of the insert 16 extends perpendicular to the direction of insertion into the inside of the housing body 2.

The test strip, which covers the insert 16 when inserted into the housing body 2, is heated by the ceramic insert 16 designed as heating element and is brought to a

25 temperature required for a meaningful measurement result. This depends on the reagents provided in the test strip.

Figure 4 is a diagrammatic representation of an injection mould in whose cavity a plastic material and a breakable material can be injection-moulded at the same

30 time.

The view in Figure 4 shows an injection mould 30 comprising a first mould half 31 and a second mould half 32. The first mould half 31 can be displaced relative to the second mould half 32 in the direction of the double arrow, i.e. can be opened

35 and closed. The first mould half 31 and the second mould half 32 delimit a cavity 33. With the first mould half 31 and the second mould half 32 in the closed state, they are closed via a clamping mechanism. The contact pressure, which can be set via the adjustable contact pressure mechanism 34, is dependent on the force which can be withstood by the breakable material from which the insert 16 is made.

The first mould half 31 and the second mould half 32 are connected to one another via a hinge. In the first mould half 31, or in the second mould half 32, it is possible to provide sprue channels 36 through which the plastic material flows into the cavity 33 formed by the mould halves 31 and 32. The insert 16 is taken up and positioned by a press stamp 34a. When the mould halves 31, 32 are closed together, the insert 16 is pressed flat against the first mould half 31 and thus held in position. The recess for embedding of the insert 16 is produced by introducing the insert 16 into the cavity 33 and then encapsulating it.

The view in Figure 5 shows an insert 16 made of glass 40. The insert 16 made as a glass body 40 is surrounded on its peripheral surface by a plastic frame 42. On its long sides, the plastic frame 42 has projections 43, so that a not inconsiderable part of the top face and bottom face of the glass body 40 remains as an exposed surface 41. Arranging a plastic frame 42 around the glass body 40 is expedient particularly in the production of biochips whose top faces can be covered or coated at a later stage with suitable reagents needed for the use of biochips. By means of the plastic frame 42 surrounding the glass body 40, it is possible to avoid contact between the steel parts of the mould halves 31, 32 and the breakable glass body 40, since the steel parts of the first and second mould halves 31, 32 make contact only with the outside of the plastic frame 42 surrounding the glass body 40.

Figure 6 shows an insert 16 in the form of a ceramic body 50 on whose top face 51 a damping layer 53 in the form of a lacquer layer is applied across the entire surface. In the view in Figure 6, the bottom face 52 of the ceramic body 50 is untreated. In addition to a full-surface coating with a lacquer layer 53 as damping layer shown in Figure 6, it is also possible to coat only some areas of the ceramic body 50, both on its top face 51 and on its bottom face 52, with a damping layer in the form of a lacquer layer.

The view in Figure 7 shows that an insert, which for example can be made of a ceramic material or of a metal material, is embedded seamlessly in a plastic material 60. The insert 16, 50 shown in Figure 7 can be embedded seamlessly as a heating element in a housing body 2 of a rapid diagnosis appliance (compare the detail in Figure 3) and can be provided within the system-critical area 15. System-critical area 15 is to be understood as the area within a rapid diagnosis appliance 1 where excess blood from a test strip inserted into the inside of the rapid diagnosis appliance 1 may be present, or where aggressive cleaning agents, used to clean the inside of the housing of the rapid diagnosis appliance 1 from time to time, may be

present.

5 By virtue of the insert 16 being designed according to the invention as an integral component of a housing body 2 made of plastic material 60, the seams between the inserts 16, 50 and the plastic material 60, which arise when the insert 16, 50 is bonded or mechanically locked in place, are avoided by the solution proposed according to the invention. By virtue of the solution proposed according to the invention, the particular advantage achieved is that the top face of the insert 16, 50 forms a uniform plane with the top face of the plastic material 60, thus making it easier to insert a test strip at the insertion opening 4 into the inside of the housing body 2 of a rapid diagnosis appliance 1.

15 In the production method proposed according to the invention for production of a plastic component, with an insert made of breakable material embedded in the same operation, a simple mould-dependent production process can be provided which is characterized in particular by a high degree of process reliability. Incorrect assembly, which occurs in the assembly processes known in the prior art, can be ruled out. Within the system-critical area 15, which may be contaminated by aggressive cleaning media and by deposits of blood plasma, seamless embedding of an insert made of ceramic material, i.e. breakable material, into the insertion area of a test strip is possible, characterized by seamless embedding in the plastic material 60. By virtue of the fact that the method proposed according to the invention ensures that there are no seams permitting seepage of liquid, electronic components lying underneath the ceramic insert 16, 50 are effectively protected from these media. Fitting a heating element at a later stage into a rapid diagnosis appliance, at considerable cost, as is the case in the prior art, is now no longer necessary. The seamless embedding 17 of the insert 16, 50 of breakable material, for example metal or ceramic, also advantageously permits a liquid-tight and form-fit connection between the plastic material 60 of the housing body 2 and the insert 16, 50 made of breakable material which, along its long side 20 and along its transverse side 21 (cf. view according to Figure 3), is embedded seamlessly in the plastic material 60 between two guide rails for guiding the test strip to be inserted into the inside of the housing.

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Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as, an acknowledgement or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

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List of reference numbers

	1	rapid diagnosis appliance
5	2	housing body
	3	cover
	4	insertion opening
	5	insertion tongue
	6	front face
10	7	rear face
	10	housing opening
	11	insertion rail for test strip
	12	lower shell of housing
15	13	inside of housing
	14	top face of insertion tongue
	15	critical system area
	16	insert
	17	seamless embedding
20	18	test strip guide
	19	electrical contacts
	20	long side of insert
	21	transverse side of insert
25	30	injection mould
	31	first mould half
	32	second mould half
	33	cavity
	34	contact pressure mechanism
30	34a	press stamp
	36	sprue channel
	40	insert made of glass
35	41	exposed surface
	42	border made of plastic material
	43	projection
	50	insert made of ceramic

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	51	top face
	52	bottom face
	53	damping layer (lacquer)
5	60	plastic material

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The claims defining the invention are as follows:

1. Method for production of a plastic injection-moulded part having an insert made of a material different from the plastic material, said method including the following method steps:
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(a) introduction and positioning of the insert in a cavity of an injection mould, wherein the injection mould includes two halves and the insert, made of a breakable material, is pre-treated by application of a damping layer, wherein the insert is provided with the damping layer on at least one side facing towards
10 one of the mould halves of the injection mould,
(b) setting the clamping force of the injection mould, on a clamping mechanism, to a maximum force predetermined by the material of the insert, and
(c) partial or complete, seamless encapsulation of the insert with the plastic material of the plastic injection-moulded part inside the injection mould.
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2. Method according to Claim 1, wherein the insert is provided with a damping layer over its entire surface.
3. Method according to Claim 1, wherein the insert is provided with a damping layer
20 applied in only some areas.
4. Method according to Claim 1, wherein the damping layer is applied as a lacquer layer.
- 25 5. Method according to Claim 1, wherein the damping layer is applied in the form of a film or in the form of a lacquer.
6. Method according to Claim 1, wherein the insert inside the cavity of the injection mould is encapsulated seamlessly with a border of plastic material.
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7. Method according to Claim 6, wherein the border of the insert forms the limit of a recess for embedding the insert in a housing body.

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8. Method according to Claim 1, wherein the damping layer completely surrounds the insert.
9. Method according to Claim 1, wherein components made of ceramic material are used as insert.
5
10. Method according to Claim 1, wherein components made of glass are used as insert.
- 10 11. Rapid diagnosis appliance for evaluation of a test strip, having a housing body, wherein an insert acting as heating element is seamlessly embedded in a system-critical area inside the housing body made of plastic material, the insert being pretreated by application of a damping layer, on at least one side thereof.
- 15 12. Rapid diagnosis appliance according to Claim 11, wherein the insert functioning as heating element is an integral component of at least part of the housing body.
13. Rapid diagnosis appliance according to Claim 11, wherein the insert functioning as heating element is received with a form fit in part of the housing body.
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14. Rapid diagnosis appliance according to Claim 11, wherein the insert is made of ceramic or metal material.
15. Analysis chip, wherein an insert made of glass is injected into a border of plastic material, and a remaining, untreated exposed surface of the insert can be covered with reagents, said insert being pretreated by application of a damping layer on at least one side thereof.
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16. A method for production of plastic injection-molded parts, substantially as herein described.
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17. A rapid diagnosis appliance for evaluation of a test strip, substantially as herein described with reference to the accompanying drawings.
18. An analysis chip, substantially as herein described with reference to the
5 accompanying drawings.