Elekta

White Paper

Recommendations for commissioning of the Geneva applicator

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Introduction

The Geneva applicator, a new brachytherapy applicator for treatment of gynecological malignancies, was released in 2020.[1-2] This novel applicator replaces the Utrecht applicator and several other applicators, and aims at offering a versatile option that complements the Venezia applicator in the spectrum of gynecological applications.

Before clinical introduction of a new applicator, the responsible medical physicist should perform a set of commissioning measurements aimed at verifying proper functioning of the device. Most importantly, accurate dose delivery is verified. Next, measurements can reveal possible manufacturing defects in the applicator, and it helps the physicist familiarize themselves with the equipment. The results of the commissioning measurements should be appropriately documented in a quality system, meeting hospital and local regulations and guidelines, e.g., the EU Medical Device Regulations.[3]

Several reports have been published describing specific measurements for brachytherapy equipment, notably ESTRO booklet no. 8[4] and, more recently, report 30 of the Netherlands Commission on Radiation Dosimetry.[5] Nevertheless, in practice, the adoption of various commissioning measurements varies greatly between centers.[6] Potential reasons for this variation are differences in clinical practice and in resources for doing commissioning measurements.

The aim of this white paper is to offer a guideline for commissioning that enables users worldwide to introduce the Geneva applicator into clinical practice swiftly, yet with high and reproducible quality that is independent of the operator and resources of the hospital. This guideline might save Geneva users time in devising, describing and executing commissioning methods for the applicator.

Scope

This white paper provides users of the Geneva applicator with a detailed but practical set of instructions for performing commissioning measurements of the applicator. We have defined a set of measurements for the following three relevant parameters, either relevant for accurate dose delivery or durability, that we describe in more detail in this document:

- The distance from the tip to the most distal dwell position. This parameter, used during reconstruction, determines where sources are projected on the anatomy during treatment planning. A mismatch between the value used in treatment planning, and the actual value, results in an error in dose delivery.
- Intrauterine tube wall thickness. This parameter can vary between applicators due to variations in the manufacturing process and is relevant to the durability of the applicator.
- General inspection. Check whether the length, size and angle of tubes and ovoids correspond to the nominal values; check whether needle holes are accessible.

This paper does not discuss other parameters relevant to accurate delivery during brachytherapy that are not directly related to the Geneva applicator, e.g., CT/MR image quality, interstitial needle offset, dose calculation in the TPS, transfer tube length, afterloader timer accuracy, and source strength. For commissioning measurements of these parameters, the reader is referred to the previously mentioned reports.

This white paper is applicable for commissioning of the Geneva applicator in combination with Flexitron® and microSelectron® afterloaders when using Applicator Modeling or manual catheter reconstruction in Oncentra Brachy.

In Oncentra Brachy, the Geneva applicator model uses the central path (lumen axis) as the source path, as opposed to the Venezia applicator model, for which a measured source path is provided by Elekta.[7] This is because the ovoids of the Geneva applicator are less curved compared to the Venezia lunar-shaped ovoids. It is, however, necessary to check at least the first two clinically used source positions in the ovoid tubes during commissioning. It is assumed that, when moving through intrauterine and ovoid tubes, the source does not significantly deviate from the center of the tube.

All described measurements use tooling and software that is either generally available in a radiotherapy department, or can be acquired at no cost (e.g., open-source software). For reproducible setup of the applicator items, 3D printed holders have been designed and developed in this work that can optionally be used in the measurements. These holders can be prepared using a 3D printer, if available. So-called STL-files (Standard Triangle Language) describing the holders have been made available online (see Appendix).

Commissioning

Overview

In Table 1, the various items of the Geneva applicator are listed together with the recommended commissioning measurements. The commissioning measurements are described in the following sections.

	Commissioning measurement			
Geneva applicator item	Distal dwell position	Wall thickness	General inspection	
			External dimensions	Needle accessibility
Intrauterine tubes 30–80 mm	√	√	√	
Intrauterine tube 0 mm	√			
Interstitial tube				√
Ovoid tubes	√			
Interstitial ovoid tubes 13 mm	√		√	√
Interstitial ovoids 15–40 mm			√	√

Table 1. Overview of the different applicator items and the recommended commissioning measurement.

Distal dwell position

The measurement of the distance from the outer tip of the tube to the most distal dwell position is performed by irradiating a film. To simplify this procedure, a 3D printed holder was developed for the different intrauterine tubes as well as for the standard ovoid tubes. If a 3D printer is not available, the individual tubes should be attached to the film using tape.

Applicator reconstruction in Oncentra Brachy can be done either using Applicator Modeling or manual catheter reconstruction. The distance from the outer tip to the most distal dwell position for each catheter, shown in Figure 1, is fixed and incorporated in the Oncentra Brachy applicator library model. In case of manual reconstruction, when the outer catheter tip is used as the distal catheter reconstruction point, the user should enter the distance from the tip (1) to the distal dwell position (3) per catheter as an offset. Similarly, if the lumen end is used as the distal catheter reconstruction point, the distance between the points 2 and 3 shall be used as the offset. Of course, it is also possible to use the distal marker inside each catheter as the distal reconstruction point, in which case the offset value shall remain 0 mm (assuming that the distal marker position corresponds to the most distal dwell position). All three mentioned points (1–3) are represented in the applicator library files as so-called anchor points, available during applicator placement, to be applied on the images.

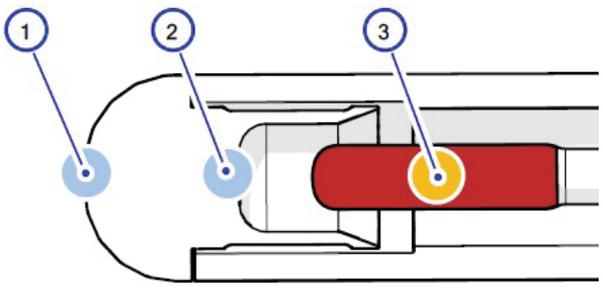


Figure 1.
Drawing of the tip of the applicator.[8]

Materials

- Afterloader
- Intrauterine and ovoid tubes
- Corresponding transfer tubes
- 3D printed holders or tape
- Radiosensitive film (EBT3 or XRQA2)
- Permanent marker pen
- Scanner suitable for film dosimetry
- ImageJ version 1.53e
- Microsoft Excel

Preparation

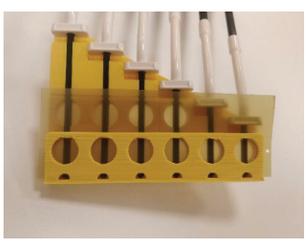
The setup for the measurements is a bit different depending on the tubes to be measured and the availability of the 3D printed holder.

a. Intrauterine tubes 30–80 mm and ovoid tubes using 3D printed holders or tape

First, prepare the 3D printed holder as described in the Appendix. Before the measurements, test if the applicator tubes can be inserted into the holder and use a dummy film to test whether it can be inserted completely.

Two measurements will be done for each item. Therefore, cut two pieces of film of minimally 5 cm long and as wide as the width of the 3D printed holder (12 cm for the intrauterine tubes and 4 cm for the ovoid tubes holder).

Place the film and the applicator tubes in the 3D printed holder as shown in Figure 2. For positioning the intrauterine tubes, the design provides separate channels for all available intrauterine tube lengths. We strongly recommend using the proper channels for the corresponding tube lengths. Make sure that both the tip of the applicator and the edge of the film are inserted completely toward the end of the holder.



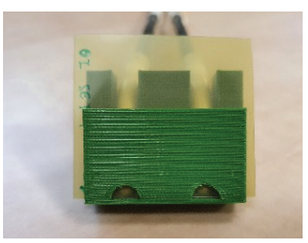
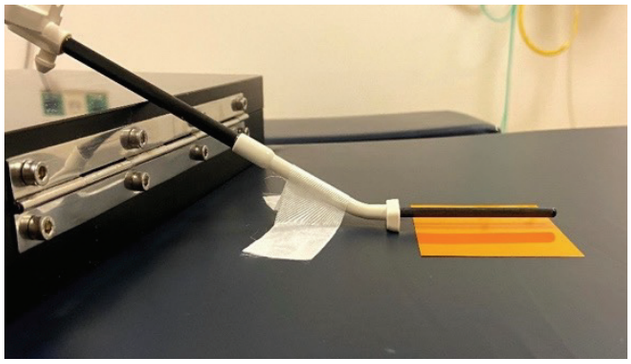


Figure 2.
Positioning of the intrauterine and ovoid tubes with film in the 3D printed holders.

If the 3D printed holders are not available, this setup can be performed by fixing the tubes to the treatment table using tape. First, the tubes are placed parallel to the table and fixed to the table with tape, leaving the distal part of the tube free of tape. Then a film is placed horizontally on the table, below the tube. In this case, the edge of the film must be aligned manually with the tip of the tubes (Figure 3).



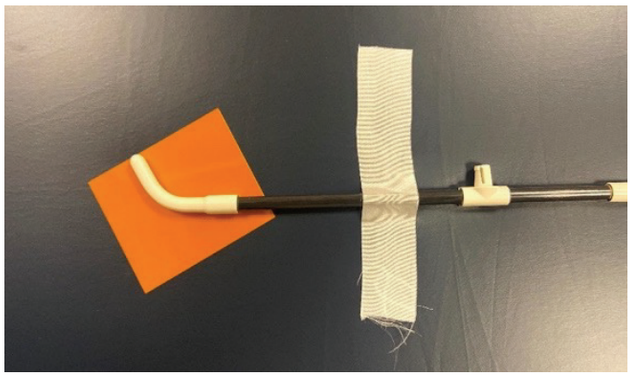


Figure 3.
Positioning of the intrauterine and ovoid tubes with film on the treatment table using tape.

b. Intrauterine tube 0 mm and interstitial ovoid tubes 13 mm using tape

Since no 3D printed holder was prepared for these items yet, the best way to set up the tubes for commissioning is with tape. Tightly fix the tubes to the table, with the film placed on the table below the applicator, parallel to the source path. An example of the setup for the interstitial ovoid tubes 13 mm is shown in Figure 4. The edge of the film should be aligned manually with the tip of the tubes as shown.

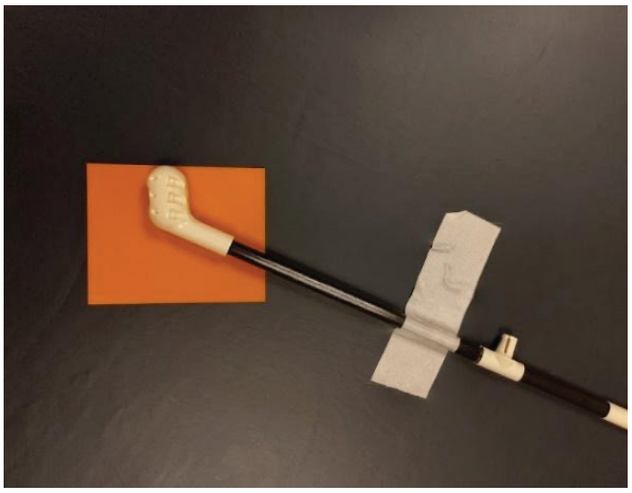


Figure 4.
Setup for the interstitial ovoid tube 13 mm using tape.

Irradiation

Two QA plans should be prepared on the Flexitron or microSelectron, the first with one channel for the intrauterine tubes and the second with two channels for the ovoid tubes. These plans should have two dwell positions per channel separated 15 mm from each other.

- Flexitron dwell positions 300 and 285 mm
- microSelectron dwell positions 1500 and 1485 mm

The recommended dwell time per position for an Ir-192 HDR source is 20 seconds for a source strength of between 2 and 4.5 cGy h^{-1} m^2. This can be changed depending on the source strength or type of film. Irradiate the film with the applicator tubes in the holder. Repeat the measurement with a second film to increase the accuracy of the measurement and to check reproducibility. When removing the film, write down with a marker pen which set of irradiation spots corresponds to which applicator tube, as indicated in Figure 5.

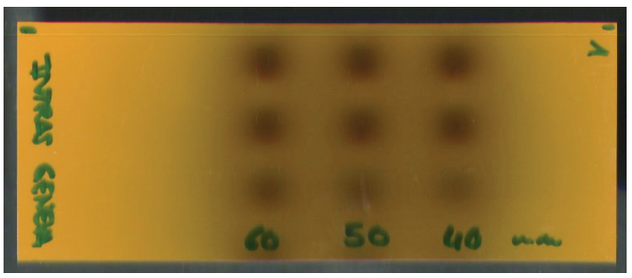


Figure 5.
Irradiated film with marks and name of intrauterine tubes.

Analysis

1. Before scanning the film, use a marker to draw two dots on the film 15 mm apart from each other (Figure 7).
2. Scan the film in TIFF format. Pay attention to the resolution of the scanner. The recommended resolution is 150 dpi.
3. Open the scan in ImageJ. It is possible to drag the image from the folder in Windows Explorer to the ImageJ bar.
4. Set the scale/pixel size of the image in pixels/mm in **Analyze > Set Scale** (the pixel size depends on the scanner settings). Check the **Global** box. The pixel size can be checked by measuring the distance between the two dots (Figure 7). Note: depending on the image settings, this might be done automatically.

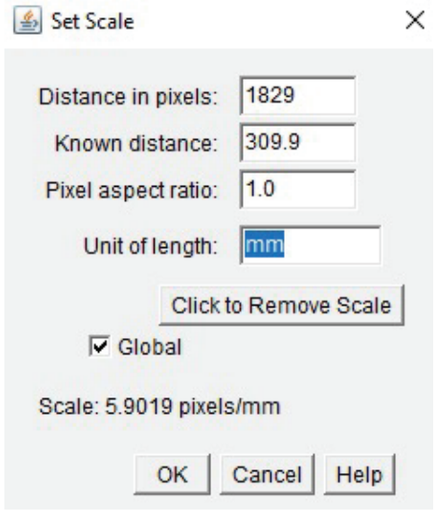


Figure 6.
ImageJ scale settings.

5. With the **Straight** tool, draw a line through the centers of the irradiation spots, starting from the outside of the film.

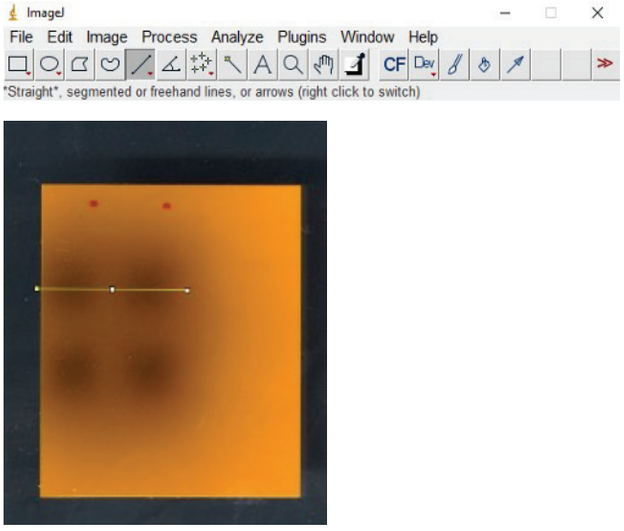


Figure 7.
ImageJ line drawing for profile plot.

6. Make a profile plot by pressing **Analyze > Plot profile** (Ctrl + K).

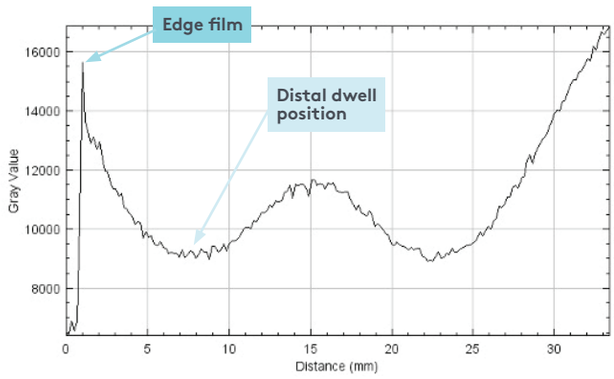


Figure 8.
ImageJ profile measurement.

7. Measure the distance between the edge of the film and the first minimum (valley) of the profile, which is the distal dwell position, or the center of the first irradiation spot.
8. Measure the second film irradiated and use the average value of both measurements as the final result.

Tolerance

The distance from the outer tip of the tube to the most distal dwell position should be within 1 mm from the values reported in the Geneva user manual,[8] which are also incorporated in the Geneva applicator model of Oncentra Brachy (if applicable). If manual reconstruction in Oncentra Brachy is used, apply the measured value as an offset if you start manual catheter reconstruction from the outer tip.

Wall thickness

The wall thickness of the tip of the intrauterine tube can be measured to assess the robustness of the tip and to gauge intrauterine tube concentricity. This can be done by acquiring a CT scan of the intrauterine tubes. By using open-source software ImageJ, it is possible to fit the outer diameter (3.85 mm) and the lumen diameter (2.55 mm) with a circle. The shift between the center of both circles is directly related to the wall thickness (Figure 9).

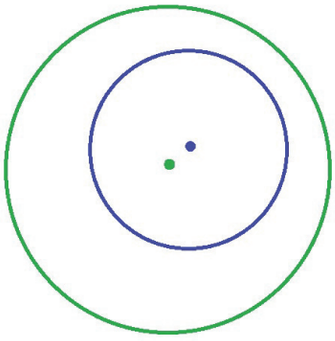


Figure 9.
Schematic of wall thickness measurement.

Materials

- CT scanner
- Intrauterine tubes 30–80 mm
- 3D printed holder or tape
- ImageJ version 1.53e
- Microsoft Excel

Preparation

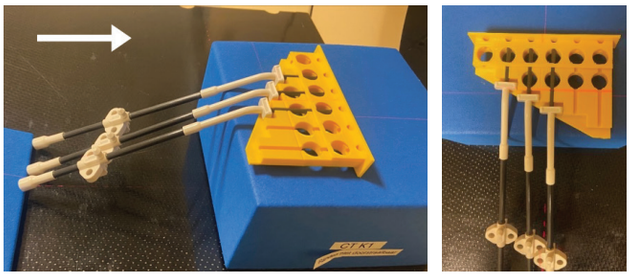


Figure 10.
Positioning of the 3D printed holder with the intrauterine tubes on the CT table. The arrows indicate the scan direction.

A CT scan of the black tip of the intrauterine tubes should be acquired. Place the intrauterine tubes in the corresponding 3D printed holder. Align the holder so that the intrauterine tubes are perpendicular to the scanning plane as shown in Figure 10. Use the alignment marks on the holder to center and align it with the laser. Limit the FOV and scan length to the size of the holder and use thin slices, e.g., 1 mm slice thickness.

Analysis

1. Open the CT scan as a sequence in ImageJ (**File > Import > Image sequence**).
2. First, scroll through the dataset to visually check asymmetry along the entire length of the scanned tips.
3. Scroll to the slice where the thickness should be measured. It is recommended to use a slice at the level of the holes in the holder, so the black tip is surrounded by air and image quality of the tip is least affected by the surrounding holder material. Note: for larger tip lengths, the holder is designed with two holes.
4. Once the slice is chosen, close the image sequence and open only the selected slice to make the procedure more efficient.

Figure 11.
CT slice of three intrauterine tips within the 3D printed holder.

5. Set the unit length to mm (using **Image > Properties > Pixel width** [units]). Note: depending on the image settings, this might be done automatically.

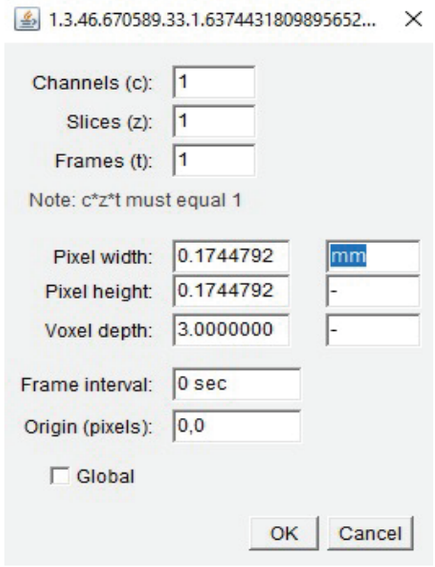


Figure 12.
ImageJ pixel width settings.

6. Use the Window Level tool to properly visualize the tip of the intrauterine tubes (**Image > Adjust > Window Level**). Levels 50/1200 are usually suitable.
7. For the next step, it is necessary to increase the number of pixels of the image in ImageJ by interpolation (**Adjust > Size**). It is recommended to increase it until the pixel width and height are equal to 0.02 mm (this can be checked after changing the number of pixels using **Image > Properties**) (Figure 12).
8. Select the **Oval** function.
9. Make a circle of 3.85 mm in diameter. Keep **Shift** pressed to draw a circular shape. The size of the circle is shown in the menu bar of ImageJ while drawing.
10. Drag the circular shape until it corresponds to the external contour of the intrauterine tip as shown in Figure 13. The **Window Level** tool can be used to facilitate this.

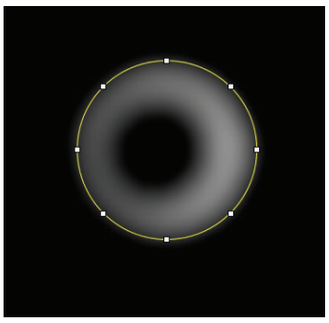


Figure 13.
ImageJ outer surface detection of intrauterine tip.

11. Write down the coordinates of the circle. They can be found in **Image > Show Info**, then scroll to the bottom of the window. Note: these coordinates correspond to the vertex of the square around this circle (further explanation in step 12).
12. Repeat steps 8 to 11 for the lumen with a circle of 2.55 mm in diameter (see Figure 14).

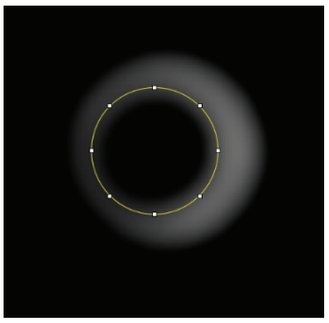


Figure 14.
ImageJ lumen detection of intrauterine tip.

13. Calculate the coordinates of the center of the circle. The coordinates obtained from ImageJ correspond to the vertex of the square around the circles (x_1, y_1) (see Figure 15).

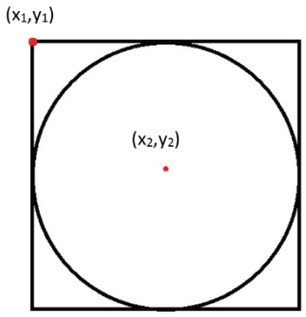


Figure 15.
ImageJ definition of circle position.

Therefore, the coordinates of the center of the circle (x_2, y_2) for the external surface can be calculated as:

$$x_{2_{out}} = x_{1_{out}} + 1.925$$

$$y_{2_{out}} = y_{1_{out}} + 1.925$$

And the coordinates of the center of the circle (x_2, y_2) for the lumen can be calculated as:

$$x_{2_{in}} = x_{1_{in}} + 1.275$$

$$y_{2_{in}} = y_{1_{in}} + 1.275$$

14. Calculate the shift between the two coordinates using Pythagoras' Theorem.

$$dx = x_{2_{out}} - x_{2_{in}}$$

$$dy = y_{2_{out}} - y_{2_{in}}$$

$$dD = \sqrt{(dx)^2 + (dy)^2}$$

15. Calculate the minimum wall thickness in mm.

$$D_{min} = 0.65 - dD$$

N.B. The nominal wall thickness is 0.65 mm, corresponding to the difference between the outer radius (1.925 mm) and the lumen radius (1.275 mm). This is the case when the lumen is drilled exactly in the center of the tip.

Tolerance

The thickness along the whole perimeter should be more than 0.47 mm, which is the minimum wall thickness required in manufacturing by Elekta.

General inspection

A general inspection of all applicator items is necessary to avoid unexpected problems during clinical use. The items should be checked visually to reveal possible cracks. Furthermore, the external dimensions, like the nominal length of the tip of the intrauterine tubes and the different ovoid sizes, should be checked using a caliper.

The angle of the intrauterine tube as a whole, as well as the tip of the intrauterine tube in the cervical stopper, have an allowed angle deviation which differs per tip length. The absolute angle tolerance parameter is the maximum allowed deviation with respect to the nominal tip angle. This can be checked by fitting the applicator model on a CT scan of the tubes. If applicator modeling is not available, angles can be checked in two orthogonal planes using the measure tool of Oncentra Brachy (Figure 16).

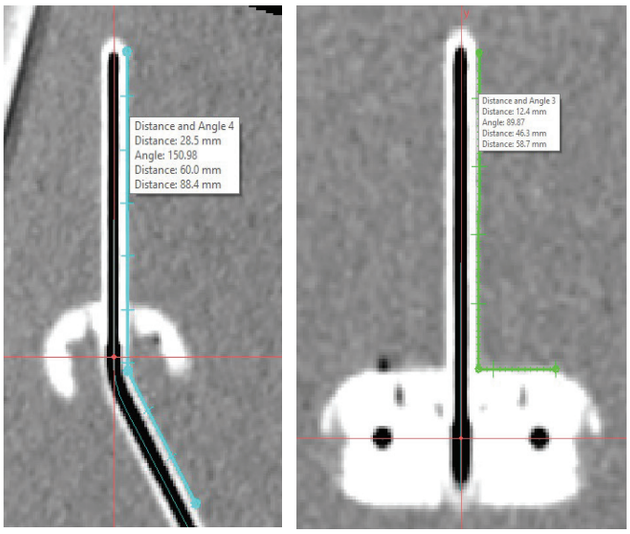


Figure 16.
Oncentra Brachy measure tool to measure the tip angle deviation in two directions. A 30-degree intrauterine tube with a tip length of 50 mm is shown here.

The accessibility of the different interstitial items (interstitial tube, interstitial ovoid tube and interstitial ovoids) should be checked using a guiding tube and a 6F Proguide needle to reveal possible obstructions. Finally, assembly of all items should be performed before clinical use to ensure the mechanical integrity of the entire applicator.

Tolerance

The tip length of the intrauterine tubes has an allowed margin of ±1 mm. The maximum allowed deviation from the nominal tip angle differs per tip length and can be found in the Geneva user manual.[8]

Summary

Commissioning measurement		Materials	Analysis software	Tolerance	Frequency
Distal dwell position		Afterloader, 3D printed holder or tape, film, marker pen, scanner	ImageJ v1.53e, Microsoft Excel	±1 mm	Annually
Wall thickness		CT scanner, 3D printed holder or tape	ImageJ v1.53e, Microsoft Excel	0.47 mm (lower limit)	Before first use
General inspection	External dimensions	Caliper	–	tip length ±1 mm, tip angle deviation[8]	Before first use
	Needle accessibility	Guiding tube, 6F Proguide Needle	–	–	Before first use
	Assembling	Applicator items	–	–	Before first use

Table 2.
Summary of the recommended commissioning measurements.

Declaration

This work was performed by the Departments of Radiation Oncology of Leiden University Medical Center and Radboud University Medical Center, supported by a sponsorship of Elekta AB.

References

[1] Press release: https://www.elekta.com/pressreleases/elekta-launches-geneva-brachytherapy

[2] Product brochure: https://www.elekta.com/Geneva-applicator

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, http://data.europa.eu/eli/reg/2017/745/2020-04-24

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[7] Berger et al. Direct reconstruction of the Vienna applicator on MR images. Radiother Oncol. 2009;93:347–51. 93 (2009) 347–51, https://doi.org/10.1016/j.radonc.2009.07.002

[8] Geneva Instructions for Use: Document ID 77700610MAN-00 Publication date 2020–02

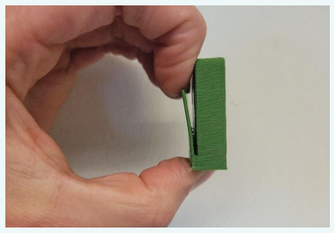
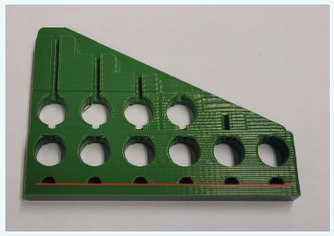
Appendix: 3D printed holders

For reproducible setup of the applicator tubes, 3D printed holders have been designed and developed in this work that can optionally be used in the measurements. These holders can be printed by users using a common FDM (fused deposition modeling) 3D printer that uses PLA (polylactic acid) filament.

As part of this work, no 3D printed holders were developed yet for the intrauterine tube 0 mm and 13 mm ovoid tubes. A creative reader of this paper is invited to model these and make them available along with the others on Thingiverse.

Table I describes where necessary files can be downloaded and gives some advice regarding printing of the holders.

Table I.
Details regarding the 3D printed holders.

Download location	STL-files that can be processed by a slicing program such as Slic3r or Cura is provided on Thingiverse: https://www.thingiverse.com/thing:4821285 The original Freecad design is provided via the same location for further modification (FCStd-file) if necessary.
Printer type	Any FDM (fused deposition modeling) printer using PLA (polylactic acid) filament. Minimum printing size should be 12x1x9 cm (wxdxh). FDM printers are generally available at hospitals, or at commercial 3D printing services.
Printer settings	Example settings are provided at the download location. Note: when the tip channels are too narrow or wide for the tube tips, change the following setting in your slicing software before printing to make the channels slightly wider or narrower. • Cura: horizontal expansion • Slic3r: XY Size Compensation • Simplify3D: horizontal size compensation Please consult the manual of your slicing software for further explanation of these settings.
Further preparation steps	• Between the main part of the holder and the film clamp, there are a number of grips designed to hold the film once inserted. After printing, these can be slightly attached to the main part, preventing the film from being inserted in the holder completely. After printing, carefully pull the film clamp as shown at right to detach the grips from the main part.  • During the film measurements, both the tips and the film need to be inserted completely toward the end of the holder (the stopper). Due to temperature inhomogeneities of the printer platform, the stopper can be slightly curved, decreasing the accuracy of measurements. Make sure, directly after printing, that the stopper is completely straight (see red line in figure at right) by carefully observing the print, or inserting a thin object with a straight edge, e.g., a dummy film or a sheet of paper. If the stopper is indeed curved, the result can be improved by making a new print with the holder positioned at a different position on the platform. 

As a leader in precision radiation therapy, Elekta is committed to ensuring every patient has access to the best cancer care possible. We openly collaborate with customers to advance sustainable, outcome-driven and cost-efficient solutions to meet evolving patient needs, improve lives and bring hope to everyone dealing with cancer. To us, it's personal, and our global team of 4,700 employees combine passion, science, and imagination to profoundly change cancer care.

We don't just build technology, we build hope.

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